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Operational Considerations for Bispecific T-Cell Engager Therapies

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You're listening to ReachMD. This medical industry feature, titled "Operational Considerations for Bispecific T-Cell Engager Therapies," is sponsored by Amgen. Here's your host, Dr. Jennifer Caudle.

Dr Caudle:
In recent years, bispecific T-cell engager therapies have emerged as an innovative approach for treating cancer by directing the patient's own T cells to target tumor-associated antigens on cancer cells.[1] However, the implementation of bispecific T-cell engager therapies into clinical practice comes with some operational challenges.[2] So, what are some operational considerations, and how can they be addressed to facilitate patient access? This is ReachMD, and I'm your host Dr Jennifer Caudle.

And joining me in this discussion is Dr David M. Waterhouse, who's a Medical Oncologist and Chief Innovation Officer at Oncology Hematology Care in Cincinnati. Dr Waterhouse, welcome to the program!

Dr Waterhouse:
Thank you, Dr Caudle. I'm excited to be here!

Dr Caudle:
Well, we're excited you're here as well, and let's just go ahead and dive right in. What are the key operational considerations for implementing bispecific T-cell engager therapies into clinical practice, and how might they be addressed?

Dr Waterhouse:
Well the key operational considerations for implementing bispecific T-cell engager therapies in clinical practice include such things like

- Collaboration and communication among the multidisciplinary team[2]
- Comprehensive staff education and training[2]
- Transition of care coordination[2]
- And patient and caregiver education[2]

Ways to address these operational considerations include

- Having an established multidisciplinary team and clinical champions[2]
- Standardizing staff training and implementation of institutional policies and protocols for administering bispecific T-cell engager therapies and for monitoring of the potential side effects[3]
- Establishing a transition of care plan, including a communication plans[2]
- And providing patient and caregiver education and support throughout the treatment journey[3]

Dr Caudle:
So then let's take an in-depth look at each of the elements you just mentioned, starting with the multidisciplinary team. Can you tell us more about this?

Dr Waterhouse:

Absolutely. So, one of the key elements in operationalizing bispecific T-cell engager therapies is to consider establishing a multidisciplinary team of oncologists, hospitalists, nurses, pharmacists, nurse navigators, administrative staff support, and other care team members.[3,4] Each member of the team has a distinct and important role. For example, the oncologist typically evaluates the patient's eligibility for bispecific T-cell engager therapy and collaborates with other members of the multidisciplinary team for treatment planning, administration, and adverse event monitoring. They may also educate patients and caregivers on how the therapy works and what to expect during the treatment journey.[2] Pharmacists may lead operational efforts by drafting treatment protocols and EMR order sets, managing drug handling, and educating the multidisciplinary team on dosing, storage, and managing adverse events. Pharmacists often bring new therapies to the hospital Pharmacy and Therapeutics committee for formulary approval and ensure medications needed to manage adverse events are on hand.[2] Nurses are also key, as they may be involved in the administering of the therapy, monitoring for adverse events, of course educating patients and caregivers about those adverse events, including when to seek medical attention.[2] I also think it's important to assign nurse navigators to patients as early as possible in the treatment journey so the navigator can help coordinate care by scheduling appointments and supporting patients and their caregivers. This may include ensuring that the patients have received planned education and connecting them to financial, social, or transportation resources.[2,3] And as I mentioned earlier, institutions and practices may also consider assigning a clinical or an institutional champion.[2]

Dr Caudle:
Now with that being said, what exactly is an institutional champion?

Dr Waterhouse:
The institutional champion is really someone who has the time and the capacity to spearhead the integration and the operationalization of the bispecific T-cell engager therapies in practice.[2,3] So, this can be someone who has administered such a therapy before and is monitored for potential adverse events, someone who has prior experience developing institutional rotocols and workflows, someone with an established network of experienced professionals whom they can rely on to overcome challenges, and/or someone who can assemble and lead a multidisciplinary team to address the challenges as they arise.[2,3] Now, the institutional champion may be a physician, advanced practice provider, pharmacist, nurse, or any other healthcare professional who is able and willing to invest their time and energy in not only implementing the program, but also handling any necessary updates and being available as a resource for the multidisciplinary team.[3] But ultimately, an institutional champion should be willing to learn and share those findings with the team because not everyone may have experience operationalizing bispecific T-cell engager therapies.[2]

Dr Caudle:
And if we focus on establishing institutional protocols, can you tell us what that might look like in relation to bispecific T-cell engager therapies?

Dr Waterhouse:
Of course. So, establishing institutional protocols may entail several aspects. To begin, patient identification tools within the EMR are helpful to identify eligible patients for bispecific T-cell engager therapies.[2] To achieve this, treating physicians should identify eligible patients by confirming that the patient meets the approved indication for the therapy, has no contraindications, has appropriate functional status, and has sufficient caregiver support. Integrating tracker systems within the EMR can also identify patients who may be eligible.[2,3] At my institution, for instance, if we're considering a bispecific T-cell engager therapy, we will identify the appropriate patients using ICD-10 codes, so we can proactively prepare should the patient be deemed eligible for treatment. Other protocols that can be integrated into the EMR include order sets that outline the dosing schedule as well as order sets that help with the identification and management of adverse events common to many bispecific T-cell engager therapies, like cytokine release syndrome, or CRS, and immune effector cell–associated neurotoxicity syndrome, also known as ICANS.[2] And lastly, integrating flags within the EMR can also help emergency department staff quickly identify patients on bispecific T-cell engager therapies to more quickly understand that their symptoms may be related to the bispecific T-cell engager therapy side effect.[2]

D Caudle:
Now, Dr Waterhouse, another key element you alluded to earlier was comprehensive staff education and training. Why is this important?

Dr Waterhouse:
Well, comprehensive staff education and training may be an important consideration in not only integrating bispecific T-cell engager therapies into clinical practice at an institution, but also to maintain the program over time.[3,4] And so, institutions should consider standardizing education and training across the multidisciplinary team, including hospitalists, nurses, and nurse navigators.[3] Education may be tailored to each team member's role and cover relevant aspects

like dosing, preparation, administration,[2,3] how to identify and manage adverse events,[3] and insurance considerations like obtaining prior authorization.[2] For example, since many bispecific T-cell engager therapies are associated with the risk of CRS and ICANS, identifying and managing these events is an important topic for nurses, hospitalists, emergency department staff, and ICU staff.[2,3]

Topics within this training may include how to identify these adverse events early and performing a comprehensive workup including physical exams and labs for a differential.[3] Training may also include the different criteria that may be used to grade these adverse events, and protocols for how to manage them, whether that includes supportive care, dose modifications or interruptions, or escalation of care. Grading criteria may include the American Society for Transplantation and Cellular Therapy, or ASTCT, criteria, or the Common Terminology Criteria for Adverse Events, or CTCAE. [1,3,5] It's important to note that each bispecific T-cell engager therapy has a unique safety profile so it's important to review the corresponding Prescribing Information and have resources for staff for identifying and managing relevant adverse events.[3,6] The training itself can include a variety of concise formats, like learning modules, videos, or live presentations, so that the information is easy to grasp and remember.[3]

And when it comes to keeping the staff up to date, I recommend having regular refreshers on the training and developing a plan for the staff turnover so that any new care team members are fully educated on bispecific T-cell engager therapies to prevent delays in care.[4] At OHC, we introduced the idea topic of bispecific T-cell engager therapies at office town halls so that everybody knew these therapies were coming. We then provided these groups with a slide deck explaining bispecific T-cell engager therapy in an easily understood fashion. Key stakeholders and members of the multidisciplinary team received more comprehensive training which included more detailed slide decks as well as in-person education. Everyone was made aware as questions arise, they could come to the institutional champion of the project for answers. By giving these individuals slide decks, they also had the ability to go back and look at the information when desired or could review the content on their own timeframe. Later, we shared some of our early experiences together, including patient cases and toxicity management. We wanted our staff to feel ownership of the process and to take pride in the work.

Dr Caudle:
And if we switch gears to another very important aspect of operationalizing bispecific T-cell engager therapies, what are some key considerations regarding transitions of care?

Dr Waterhouse:
Well, once a patient is identified as an appropriate candidate for bispecific T-cell engager therapy, consider mapping out a comprehensive treatment plan that outlines the potential sites of care for administration and monitoring.[2,3] Because billing and reimbursement for bispecific T-cell engager therapies may differ across sites, it may be important to think about coverage and reimbursement considerations early on to avoid delays in patient care. This may include checking for, and completing, and submitting any required prior authorization requests and submitting an appeal if it's denied.[2] And of course, patient preferences and ability to get to sites of care are important considerations when mapping out this treatment plan.[7] Along with that, consider whether the identified sites of care are operationally ready to administer bispecific T-cell therapy, have bed availability, and monitoring capacities as needed.[3] Also keep in mind the sites' operating hours and how that may impact the scheduling.[3]

So then once these initial considerations are addressed, proactive communication between the different sites of care during the treatment journey is incredibly important.[2] Documentation is one way to help ensure that the care team is informed about patients across the continuum of care. I recommend integrating a progress note template within the EMR that tracks patient care details, like treatment doses received and any adverse events experienced.[2] Lastly, keep in mind that nurse navigators can be a great resource throughout the entire transition period as they can help coordinate and schedule inpatient and outpatient visits.[3] At OHC, our nurse navigators help schedule appointments for the patient and the nurse practitioner helps with the transition of care from the inpatient to outpatient team. This is done through both verbal communication and email. At all times, the patient is kept aware of the plan.

Dr Caudle:
Thanks for breaking all of that down for us, Dr Waterhouse. Now, we've talked a lot about how institutions can get operationally ready to administer bispecific T-cell engager therapies in their practice. But patients and their caregivers also play an important role in the implementation of these programs.[3] So how can we help educate them?

Dr Waterhouse:
I'm really glad that you brought this up because you know the patients and their caregivers are integral partners in the care team, and it's important to educate them on each step of their journey.[3] For instance, before starting and during treatment, consider providing an

overview of the therapy, including how it will help treat their cancer, dosing, pre- and postdosing medications, and potential side effects.[1,3] It can also help to discuss the tentative treatment schedule, how many infusions will be necessary, where these infusions will take place, and contact information for key stakeholders involved in their care.[3] Personally, I've found a lot of success in providing the patient with useful resources that outline key components of their treatment. Then, if they have a problem as an outpatient, they are capable of giving the oncall or triage team information that can help direct their care. More importantly it establishes confidence in the patient and their caregiver that we are overseeing their potential toxicity and we have a plan. At discharge, it may be important to educate the patients and their caregiver on how to monitor, assess, and seek treatment for adverse events.[3] And then finally, I always ensure that my patients and their caregivers are informed about the follow-up and the laboratory testing schedules so that we can better monitor their own progress, and assess treatment efficacy, and manage any delayed adverse events.[2,3] So those are my key recommendations for educating patients and their caregivers, but once again, nurse navigators can be a great resource to help execute some of these items as they support patients and caregivers right from the beginning of the treatment journey.[3]

Dr Caudle:
Well, we've certainly covered a lot today, Dr Waterhouse, but before we close, can you share your key operational recommendations for implementation of bispecific T-cell engager therapies into clinical practice?

Dr Waterhouse:
Sure! To help ensure an institution is operationally ready to administer bispecific Tcell engager therapies, I think it's important to consider forming a multidisciplinary team,[2] and integrating institutional policies and protocols for administration and monitoring,[3] and implementing comprehensive staff education and training.[3] Then, once those elements are all in place and a patient is identified as an eligible candidate for bispecific T-cell engager therapy, consider mapping out a
comprehensive treatment plan across the sites of care so that patients can seamlessly transition and not experience any delays in their care.[2] And speaking of the patients, consider educating them and their caregivers on the treatment and follow-up schedule, how to monitor adverse events, and importantly who to contact if needed.[3] And finally, consider collaborating and communicating with your multidisciplinary team members and ask for help when needed![2]

Dr Caudle:
And that brings us to the end of today's program, and I'd like to thank my guest, Dr David Waterhouse, for joining me to share these operational considerations associated with the implementation of bispecific T-cell engager therapies. Dr
Waterhouse, it was great speaking with you today!

Dr Waterhouse:
Thank you for having me here, Dr Caudle, it was really a pleasure being here.

ReachMD Announcer:
This program was sponsored by Amgen. If you missed any part of this discussion, visit Industry Features on ReachMD.com, where you can Be Part of the Knowledge.

CRS, cytokine release syndrome; EMR, electronic medical record; ICANS, immune effector cell–associated neurotoxicity syndrome; ICD-10, International Classification of Diseases, Tenth Revision; ICU, intensive care unit; OHC, Oncology Hematology Care.

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