

Expert perspective: IVAN BORRELLO, MD

Expanding cell and gene therapy access: a community hospital perspective

After 25 years at Johns Hopkins, Ivan Borrello, MD, joined Tampa General Hospital (TGH) in 2022 with a mission: build a program that could provide patients with the same cutting-edge cell therapies that are more readily available at large academic medical centers.

Borrello, a translational investigator in multiple myeloma, bone marrow transplant and cell therapies, had the right background to take on this project. He has been involved with cancer



immunology and immunotherapy since its infancy in the 1990s and is recognized as a leader in the field.

The challenges Borrello and TGH faced in this effort were multifaceted, from establishing treatment guidelines, bringing on staff with the right training and expertise, to building relationships with payers to enable coverage approvals. But the benefits—expanding patients to access to these therapies closer to home—greatly exceed the barriers.

“These people have to be in the hospital and their families need to take time off from work to take care of them. All of these things need to be factored in,” Borrello said.

Building from the Ground Up

At Johns Hopkins, infrastructure and processes for CGTs were long established, but TGH was starting at square one. That meant Borrello needed to build everything from scratch: creating procedures and guidelines, educating staff about basics like the urgency of treating neutropenic fevers, building an outpatient transplant unit, and developing the accompanying systems to deliver these therapies.

Borrello said he was fortunate to have the support of TGH’s CEO, who understood the long-term benefit, not just for oncology patients, but also in areas like rheumatology and neurology in the future. “It’s not just hiring a physician to build a BMT cell therapy program. You need a hospital-wide infrastructure to do this, and it requires a significant commitment,” Borrello said.

The process of building the internal expertise has taken time. Borrello has committed himself to teaching emergency room physicians and ICU staff about managing the serious side effects that can occur with CAR T-cell therapies.

“As we talk about expanding cell therapy into the community, this is something that cannot be underestimated,” he said. “There have to be standard operating procedures. People need



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— Ivan Borrello, MD

Medical Director of the Myeloma, Bone Marrow Transplant (BMT) and Cell Therapies program, TGH Cancer Institute

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That work has paid off. TGH is going through the process of FACT accreditation, an independent designation that would help sway insurers to sign off on more patients receiving cell therapies at the hospital.

“A lot of payers won't approve cell therapies for us because we're not a FACT-accredited institution,” he said. “I think it is going to give us a level of confirmation in the community to go forward.”

A Hybrid Model Emerges

TGH's position as a community hospital has created what Borrello describes as a unique “hybrid model” that combines elements of both community and academic medical centers. While larger cancer centers are referring patients who have already been diagnosed, community hospitals like TGH may be the first stop for patients who are experiencing symptoms but have no diagnosis.

This hybrid approach has allowed TGH to be “innovative and also potentially quicker” in implementing changes, while building toward academic-level specialization with dedicated specialists for different cancers, he said.

These efforts include building a manufacturing facility to make cell therapies nearby. While requiring a significant financial investment, the capabilities will position TGH to expand access to these therapies as they are developed for conditions beyond cancer, such as autoimmune disease.

The Hub-and-Spoke Solution

Borrello sees a path forward to expanding CGTs into community settings through a “hub and spoke model,” where major centers develop best practices and guidelines for administering new therapies that they can share with smaller community hospitals and clinics, along with support and education.

Under this model, established centers like TGH would audit community hospitals using a checklist similar to FACT accreditation requirements, provide education through seminars, and maintain close oversight through daily rounds when patients are hospitalized.

“It's going to be one of these things that sort of gradually expands out, but it needs to be done with close monitoring by the ‘mothership,’ until that level of expertise has been achieved in these smaller hospitals,” he said.

Education as Foundation

Central to making the hub-and-spoke model work is comprehensive education across multiple departments. When expanding into community settings, Borrello suggests knowledge sharing with other providers on topics as diverse as setting up financing systems, inpatient procedures, checklists for emergency rooms, and post-treatment monitoring standards.

The need for specialized expertise extends beyond clinical staff. When TGH first started offering CAR T, the staff didn't have much experience routing CGTs through insurance companies for approval and were facing frequent roadblocks. Building relationships with the right people at payer organizations helped change things.

“Knowledge is power. You ask the right questions, you give the right information,” Borrello said. “You develop a relationship, and you develop credibility. It streamlines the process.”

Strict Standards, Careful Expansion

While Borrello strongly supports expanding access to cell and gene therapies, he said not every hospital can or should offer these treatments. Success requires deep institutional commitment, significant investment, and experienced leadership willing to maintain strict standards.

“I think the key thing is to have a framework, to have SOPs, and to have someone who has the power to say, ‘this is what we can do and this is what we can't do’...no matter what the external pressures are.” ●



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