CELL & GENE THERAPY INSIGHTS

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INTERVIEW

Expect the unexpected: maintaining and optimizing a cell collection network during COVID-19

AMY HINES, RN, BSN, is the Director of Collection Services for the NMDP/Be The Match. She works with senior leadership to develop the strategy for the growth of the NMDP/Be The Match-owned network of apheresis facilities and is responsible for the implementation of that strategy. Hines was an instrumental member of the NMDP/Be The Match team that planned and launched the Be The Match Seattle Collection Center, which opened in January 2020.

She joined NMDP/Be The Match in 2013 managing the NMDP/Be The Match Apheresis and Collection Center Network of more than 90 apheresis center and 80 collection center partners. She then became the Director of Collection Network Management for Be The Match BioTherapies. In this role, Hines oversaw the performance of apheresis centers and cell therapy labs in the Collection Network, and ensured their ongoing compliance with FDA and international standards and criteria, industry best practices, and appropriate regulatory and accrediting entities.

Hines has spoken about the challenges apheresis centers are facing and then need for standardization during multiple conferences and webinars, including Cell and Gene Therapy World U.S. 2018, the Adoptive T-Cell Therapy: Development track of the Immuno-Oncology Summit 2018, Phacilitate: Leaders World 2019 and World Advanced Therapies & Regenerative Medicine Congress 2019.

She has nearly 20 years of experience in the cellular therapy field, starting her career as a stem cell transplant nurse. She received her Bachelor of Science in Nursing from Grand Valley State University in Allendale, Mich.

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Q We last spoke to you in 2018, before the COVID-19 pandemic began, about optimizing the cell collection network to support commercialization of cell and gene therapy. What has changed over the past few years, and what do you think still needs to be achieved?

AH: Since 2018, the industry has become increasingly aware of the challenges that come with managing consistency and standards across a wide variety of cell collection facilities, and also the value and benefits of working together to overcome these challenges.

A few years ago there was a lot of talk about the need for consistency and standards, but there was no real agreement on how to move forward, and no real cooperation as to who was going to take the lead and push these things through. One major change over the past year has been the continued growth of collaborative efforts towards standardization across the whole industry.

It has also been great to see the industry working together with apheresis centers, accrediting bodies, and other key stakeholders, towards identifying opportunities to develop common standards and expectations, with the realization that when we are all on the same page, we all benefit.

These efforts are incredibly important, and we have definitely come a long way since 2018. But there is so much yet to be done so that developers of new therapies can take these standards and incorporate them into their development process early on.

Q Do you feel Be The Match has cemented itself as one of the key voices in driving that initiative?

AH: I do, and in addition, I think Be The Match has played an instrumental role in kicking off that cooperation.

We are very specialized within this industry. We have been doing a lot of these processes that are similar to the cell and gene therapy industry needs for a long time, but we have done it in a unique way, through our cell collection network and through overseeing activities at multiple facilities.

One of the things we have brought to the table over the course of the past few years is in helping to pull together the right stakeholders to collaborate and talk about standards and consistency. I would like to take a little bit of credit for our organization in drumming up some of that excitement to participate amongst the apheresis centers. It is key to have those hands-on experts helping to drive what is feasible and what is not when it comes to developing standards.

Q The impact of COVID-19 on cell therapy supply chains is impossible to ignore. Could you go a little deeper into how Be The Match has been able to successfully navigate this incredibly challenging period?

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AH: There were three key components. One was an unwavering dedication to donors and patients. Two was the ability to leverage the longstanding relationships our organization has built over the past 30+ years. Third was some amazingly innovative thinking.

Our operational management model allowed us the success that we have had during the pandemic. While the depth and duration of this long year of dealing with COVID may have been a surprise, at Be The Match that is part of our role. We are constantly at the ready for unexpected events.

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Perhaps we hadn't expected the pandemic, but we were well suited to handle these events. Whether it is due to weather, power outages, political events, airline strikes, or anything else, our organization is 100% dedicated to mitigating whatever challenges arise in order to ensure that patients can receive the therapy that they need.

I will comment too on our large, geographically dispersed, and highly capable network of collection centers, and our diverse donor pool. This allowed us to focus collections close to where donors are located, helping to minimize donor travel, which was obviously extremely complicated and continues to be somewhat challenging. It also meant we were able to maximize our ability to be flexible to collect, whether because of COVID hotspots or weather events – we have just had Winter Storm Yuri in the southwest, and that caused a lot of issues. We are able to mitigate these challenges because of the model that we have developed. Our managed logistics model helps to provide flexibility in moving cell product shipments when flights get cancelled and things get challenging.

We have a great emergency preparedness team, and their relationships are really critical to help us work across the world with partners to ensure we can still have couriers moving across borders. If and when donors do travel, and travel is impacted, they are able to get really creative to get a donor from his or her home to one of our network collection centers.

Additionally, the capability and willingness of our network partners to cryopreserve products has been absolutely critical to ensure that before a patient starts prep, the cells are where they need to be, and they are ready with zero delay when the patient is ready to receive them.

Q Looking to the future, what would you say are the key lessons or benefits that the COVID-19 experience has brought to Be The Match's cell collection operations and network management?

AH: In the interests of full transparency, I will say that the pandemic has put our organization to the test. We have successfully navigated this past year, but we have learned quite a bit about our capabilities, and also our opportunities.

A key lesson was that it is critically important to be prepared for the unexpected in order to ensure business continuity, especially when the business at hand has such direct impact on patient lives. But no matter what innovative and creative pathways we can forge to continue donor collection activities despite these unexpected events, what cannot change is the focus on compliance and product quality.

For example, back in 2018 I spoke about the complicated process of coordinating donor availability with apheresis collection availability, and ultimately with manufacturing availability. What we realized through our experience over this past year is that something like cryopreservation of the collected product really helps permit some flexibility in that core patient, and that sometimes helps to mitigate a complex challenge.

As I mentioned, a few weeks ago we had Winter Storm Yuri, which was in and of itself challenging, but also had widespread effects – for example, in terms of moving Filgrastim from the pharmacy to the donor. These types of challenges are not going away.

While we as an organization have been, and always are, prepared for these types of events, going through the COVID experience has made us more proactive in identifying opportunities to successfully continue our business throughout whatever events might happen. Cryopreservation has played a huge part in that. Being able to collect early means that despite whatever challenges there may be in getting product from a collection center to a patient or manufacturing facility, the product is collected, and we face instead a logistical challenge of getting it from point A to point B, with no detrimental effects to the product.

Going into COVID we had been addressing these challenges for years successfully, but we have realized some new opportunities that we can keep in our toolkit for both anticipated and unanticipated events in the future.

Q What are the main opportunities to mitigate the variabilities between collection centers in particular?

AH: In my view, the best way is starting with a challenge to help uncover what opportunities there might be. The biggest challenges in mitigating the variabilities between collection centers lies in the fact that no two centers are fundamentally organizationally alike. This is something we have known for years, and in some ways it is just the nature of the game.

Certainly, there are commonalities between blood center-based collection centers and even somewhat amongst hospital-based collection programs. But the ability to standardize detailed policies and complicated procedures is not necessarily feasible. Things like the laboratory, the staffing, and all sorts of other components go into the collection process, and they likely impact not just the collection center team but also other departments within that center's organization. The opportunities to mitigate these variabilities can come from identifying the commonalities, coupled with what aspects of the process necessitate consistency in order to establish industry acceptable standards.

Good work towards developing proposed standards has been done, and continues to be done, for things like labelling, site training, and site qualification, and this will undoubtedly decrease variability and promote consistency across the collection center network.

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Q What is the current state of play in terms of the drive for standardization around cell collection? What are the chief areas of focus to drive both efficiencies at cell collection sites, and increased quality and consistency?

AH: As I mentioned before, it is very exciting to see so many experts coming together and driving efforts for standardization, as opposed to everyone trying to do it on their own.

There are representatives from all aspects of this work, from cell and gene therapy companies, to accrediting bodies, to collection centers administrators, to apheresis clinicians, and everyone is actively working together to develop standards around the cell collection process.

For example, standardization around collection center qualification has had lots of attention in the past couple of years. Most of industry is aware of the term "audit burden". When we last spoke in 2018, I shared that some collection centers report up to 30, or maybe even more, audits a year, and many of them are almost cookie cutter repeats of previous audits.

So while we still have a way to go, there has been some progress towards an acceptable standard for the onboarding and qualifying of new collection center sites, which increases collection center satisfaction by freeing up their resources and time to actually do the work we are asking them to do. It also brings a realization that we can leverage each other's qualifications of a center, if we come together and determine what those standards for onboarding and qualification should look like.

Probably the biggest success so far in standardization has been around labelling. The use of the ISBT 128 labeling platform has provided some much needed consistency, and is a great example to show there are areas in which standardization is possible, and can be successful.

Q How is the industry's increasing focus on allogeneic cell therapy products, particularly in the cellular immunotherapy space, impacting Be The Match, and how are you preparing for continued growth in this area?

AH: It has been an exciting few years as this industry has really blossomed. Because of our vast network of amazing and diverse donors, our organization is really well suited for this increased focus on allogeneic cell sourcing.

When available, most transplant centers will select younger donors for their transplant patients, which is completely understandable, but leaves those of us upwards of 35 wondering how we can help. We are on the registry, we are signed up to be able to help someone, but we probably are not going to be the first selection for a patient for transplant.

Because not all allogeneic donor source protocols in cell and gene therapy require a certain donor age, we are able to offer altruistic volunteer members of our registry to help to save a life, or to continue a mission, by participating in some of the cell and gene therapy protocols requiring cellular starting materials.

We are continuing to invest in the biotherapies side of the business, to ensure that we have scalability once emerging cell therapies enter the commercial scale environment. This is something that we are very familiar with, and we are readily prepared to be at the forefront of assisting and helping to source allogeneic cell products at that time. And of course, we continue to work with clients to bring our expertise and work to influence standardization, and to help clients get therapies to patients faster.

Q What other key future trends do you anticipate relating to cell collections for cell therapy R&D and commercial applications?

AH: There are a couple of areas I think we might anticipate seeing more attention. One is more research into what aspects of the actual collection process and product truly influence therapy efficacy. If we are going to look at standardization, we have to ask what aspects of the product itself are most appropriate for standardization. What areas of the collection process are product-specific, and will truly impact the end therapy efficacy?

Identifying those areas is going to greatly advance standardization efforts, and is going to improve overall protocol compliance, and decrease the pressures and challenges apheresis centers face with current collection protocol expectations.

Secondly, as I mentioned above, we realized throughout the pandemic that cryopreservation certainly permits flexibility in scheduling. It allows collections to occur when the donor is ready and available, and allows the receiving entity, whether it is a transplant center or a manufacturing facility, to accept the cellular therapy product when they are ready. Ultimately, it enables the patient to receive his or her lifesaving therapy when timing is optimal for a successful outcome.

An increase in research on how cryopreservation affects the end therapy, as well as other cryopreservation techniques and comparisons to fresh products, will help to provide flexibility in the supply chain. This seems like an area that definitely needs some further development, and there are some great opportunities there.

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