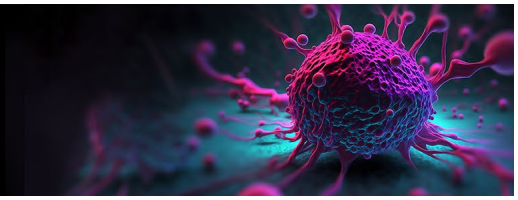
Oncologist's Corner:
Conversations with Cancer Experts About Novel Delivery Options with Immune Checkpoint Inhibitors



Editor's Note: This is a transcript of an online course released in July 2025. It has been edited for clarity. To obtain credit for participation, CLICK HERE.

Module 1
Background of ICI & Highlights in Oncology

Lucio Gordan, MD: Hi, my name is Dr. Lucio Gordan. I am a medical oncologist/hematologist at Florida Cancer Specialists and Research Institute (FCS). I practice in Gainesville, Florida. I also serve as the managing partner and president for FCS. Today, we have the pleasure of having a conversation with Dr. Saby George who represents academic/hospital-based medical oncologists and I am representing community oncology for the purpose of this conversation.

Saby George, MD: Thank you, Dr. Gordan, I am excited to be here with you to have this conversation. I am Saby George. I am a genitourinary (GU) medical oncologist practicing at Roswell Park. We have an academic oncology practice and I treat kidney, bladder and prostate cancer, and it is a clinical trial-based practice. I treat a lot of patients on trials. Once again, I am excited to be here.

Lucio Gordan, MD: Thank you, Dr. George, we look forward to learning from our experience today. First question for you, Dr. George, we have seen multiple advancements in novel therapies in oncology over the last couple of decades, including immune checkpoint inhibitors (ICIs). What has been the impact of ICIs for patients with cancer in the last 10 years, in your opinion?

Saby George, MD: That is a very important question because, in the past decade, things have changed a lot in the field within the direction of a number of novel ICIs. Multiple program death-1/program death-ligand 1 (PD-1/PD-L1) targeting inhibitors have been approved since 2011 when ipilimumab was approved originally. And that has led to impressive survival advantages for patients with lung cancer, non-small-cell lung cancer and small-cell lung cancer, colorectal cancer, melanoma, renal cell carcinoma and head and neck cancer. ICIs are utilized as monotherapy or in combination with chemotherapy or other immune therapy or even tyrosine kinase inhibitors (TKIs) like cabozantinib and are groundbreaking and transformative for patient care in terms of its impact. However, not all patients respond to ICIs. Some patients have tumors which are responsive to ICIs and some do not, and some patients have resistance to ICIs, such as immunoresistance, or they form adaptive resistance or acquired resistance to ICIs. Acquired resistance is having initial response followed by eventual disease progression, often due to impeding T-cell activation and T-cell exhaustion, another potential tumor mutation preventing binding of T-cell activity at the tumor site. These may be rendered ineffective in some patients, and so we have some biomarkers, like PD-L1 expression level in some cancers or microsatellite instability-high (MSI-high) status or tumor mutation burden (TMB) in some cancers, but we do need to develop robust biomarkers for selecting patients to have optimal responses.

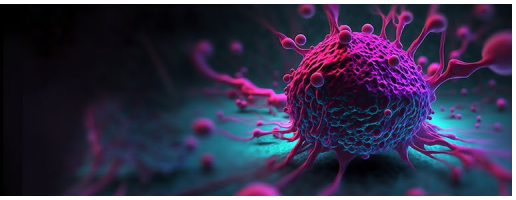
Dr. Gordan, I just mentioned a few ICI agents being approved and available and their benefits. What ICIs are currently approved for use by the FDA and what are some examples of cancer disease states for which they are utilized?

Lucio Gordan, MD: I remember well when the first ICI was approved, it was such an incredible change in how we practiced medicine in oncology. The anti-PD-L1 agents that we have available today include cemiplimab, dostarlimab, nivolumab, pembrolizumab and retifanlimab. The anti-PD-L1 agents that we have available include atezolizumab, avelumab, and durvalumab. The ICIs represent an enormous breakthrough in the field of cancer over the last decade-plus and are used in virtually all disease spaces in some capacity, and the benefit happens regardless of the PD-L1 status, but response may be increased in patients with higher PD-L1 status or expression. We need more biomarkers to really understand who the best patients are to respond to therapy.

We use PD-1 and PD-L1 agents to treat lung cancer, colorectal, melanoma, kidney, head and neck cancer, endometrial, and even some tumor agnostic indications with dostarlimab and pembrolizumab for patients with either microsatellite instability high or high tumor mutational burden.

Patient Burden from IV Therapies

Lucio Gordan, MD: From a patient perspective, with the current IV ICI therapies available, what key burdens do you see and challenges that may be experienced by patients treated with an ICI administered via standard IV infusion?



Saby George, MD: That is a good question because even though these drugs have improved the benefits in terms of overall survival and progression-free survival, for these patients, there are some challenges and burdens with IV ICIs experienced by the patient. For example, adverse events. Adverse events are seen with any type of ICI use. Infusion-related reactions are unique for IV ICIs, and patients are likely to experience immune-related adverse events also with ICIs, and the treatment burden, that is another issue. Patients, for them to receive IV ICIs, they need to have an access line or port placement and an appointment at an infusion center. And then have a chair time burden from 30 to 60 minutes for single agent ICI infusion. If they are getting an ICI along with chemotherapy, the time varies, actually. It may be even more infusion time. Time also may be increased with the compounding requirements and all those involved in IV administration of ICIs.

Let me ask you a question, Dr. Gordan. Now, all of the ICI agents we have discussed are available as IV therapies, initially. A few of them have recently become available as subcutaneous (SC) injections, which we will be discussing throughout our time here. What are the advantages and disadvantages of SC therapies in oncology compared to IV therapies and how do these advantages and disadvantages impact patients and the healthcare systems or healthcare teams?

Lucio Gordan, MD: Some advantages of SC administration may include patient convenience. It may be a 5- to 10-minute or a 3-minute injection time vs a 30- to 60-minute infusion time which may be longer if a patient gets IV access, especially if it's a difficult venipuncture. Operational efficiencies can be optimized, faster infusion times, and less chair time. We all run very tight and busy infusion centers, so having a shorter chair time is a good outcome for all parties involved. And this may allow us to treat more patients per unit of time as there is limitation on how many chairs, we may have available during working hours. It is possible that there may be cost improvement due to reduced economic burdens on the health system related to less infusion reactions and management of other toxicities since there is mostly skin injection-related toxicity, which is usually mild. The SC formulation with hyaluronidase products allow for larger volume to be administered in the SC space without really impacting patient comfort, which has been a significant advancement.

As far as disadvantages are concerned, there may be increased injection site reactions, generally mild. Nursing resources and time required for SC administration can be additional. Sometimes, the nurse will have to sit from 3 to 10 minutes, depending upon which product, other than starting an IV and moving on to another patient. There may be some disadvantage there. On the other hand, I hear the nurses and patients sometimes do appreciate the extended opportunity of chatting while the SC administration is being given by the nurse who is at the bedside. And another disadvantage, potentially, is that the products may have different SC administration times, so standardization and workflows may be somewhat compromised. I think these are all issues that can be overcome with relative ease.

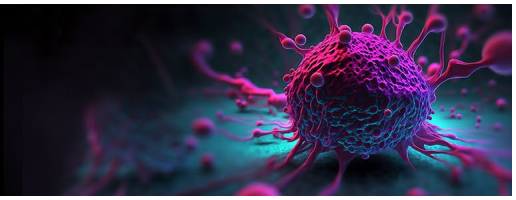
Manual SC administration for shorter injection times is probably better than the longer SC infusion times for patients and the nurses who are giving it. There is a potential for medical error if an IV formulation is given via the SC route. We cannot give the total dose that is necessary to have the immune event or efficacy because the volume would be much higher. This is all overcome through workflows being properly implemented leading to good outcomes. I think this is a minor concern.

Module 2
Treatment Strategies with ICIs (Efficacy and Safety Data for SC Products)

Lucio Gordan, MD: With the 2 currently FDA-approved SC formulations, atezolizumab and nivolumab—and pembrolizumab currently undergoing clinical trial investigation for SC administration—what are the safety and efficacy data of SC atezolizumab that we have available at this time? Can you discuss some of them?

Saby George, MD: Of course! It is very important data to be discussed because people may have questions about is it going to work as well as the IV? Atezolizumab SC product was FDA approved in September 2024 based on the IMscin001 trial. This trial was conducted in 2 parts. Part 1 was a phase 1b and part 2 was a phase 3 trial. SC atezolizumab is available as a 15 mL, 1875 mg dose, administered once every 3 weeks over approximately 7-minutes as a slow injection.

That being said, Dr. Gordan, what are the safety and efficacy of the second drug available as SC, nivolumab, that we have available at this time?



Lucio Gordan, MD: Nivolumab was FDA approved as the SC formulation towards the very end of 2024, based on the CheckMate-8KX and CheckMate-67T clinical trials.

The CheckMate-67T phase 3 trial in patients with metastatic clear cell renal cell carcinoma randomized to SC nivolumab at 1200 mg every 4 weeks vs nivolumab 3mg/kg IV every 2 weeks. And the weight-based dosing of IV nivolumab was based on the FDA guidance from the previous study done, CheckMate 025, which was performed in renal cell carcinoma as well.

Nivolumab SC is approved at various doses depending upon indication. For instance, 600 mg every 2 weeks or 1200 mg every 4 weeks for the majority of indications; 900 mg every 3 weeks with patients receiving 4 cycles of adjuvant/neoadjuvant therapy for non-small-cell lung cancer, urothelial carcinoma in combination with gemcitabine/cisplatin every 3 weeks, which is your area, Dr. George, gastric/gastroesophageal (GE) junction adenocarcinoma every 3 weeks in combination with chemotherapy. Nivolumab SC is available in a 600 mg in 5 mL vial and is administered over a period of 3 to 5 minutes. What do we know so far regarding the safety and efficacy of SC pembrolizumab?

Saby George, MD: That is very important to acknowledge because pembrolizumab has more indications as a single drug than any other checkpoint inhibitor. Pembrolizumab has been evaluated in 2 trials: KEYNOTE-555, which is a phase 1 trial and D77 trial which is a phase 3 trial. This SC formulation of pembrolizumab is coformulated with berahyaluronidase, which is a hyaluronidase variant. Hyaluronidase, is a reversible degrader of SC connective tissue and so that allows for larger volumes of injections to be administered in the SC space.

The second trial, the MK-3475A-D77 trial, which is a phase 3 trial, tested SC pembrolizumab vs IV pembrolizumab in combination with chemotherapy in non-small-cell lung cancer patients. This is an ongoing confirmatory trial.

Dr. Gordan, with these SC ICI products becoming approved and available, how do the safety profiles of IV and SC ICI options compare?

Lucio Gordan, MD: In summary, the overall safety of the SC ICI products compares really well and similarly to the IV formulations. There is no evidence of concern that they may have exacerbated changes in the toxicity profile, and tolerability is comparable overall. There is more skin site reaction, but generally it is mild. Overall, really well tolerated.

Dr. George, we always try and thrive by practicing under guidelines. How have the national guidelines, for instance National Comprehensive Cancer Network (NCCN), incorporated the SC formulations of ICIs into their recommendations?

Saby George, MD: It is very important to notice that the approval of this atezolizumab and nivolumab were based on 1 trial, but the FDA approvals for SC are applicable in pretty much all of the indications where these drugs are used. Where SC formulations of ICIs are approved, NCCN guidelines have footnote statements allowing their utilization and recommend that the SC formulation can be substituted for the IV formulation at provider/patient discretion. A reminder in NCCN highlights the differing dosing between the formulations. This is important to treat these products separately as an IV dose/vial cannot be interchanged for SC administration because the SC drug is coformulated with hyaluronidase, and that is different from the IV formulation. They come in different forms, different doses in the vials. The key distinction in renal cell carcinoma, nivolumab SC injection is not approved in combination with ipilimumab, but may be used in the maintenance phase of the regimen because of the dosing in that regimen.

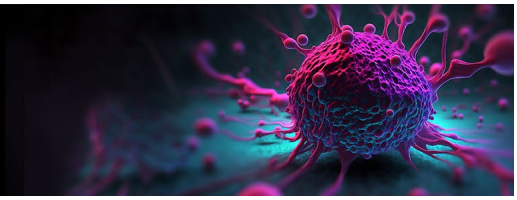
Module 3
Interprofessional, Multidisciplinary Collaboration Strategies for Novel Immune-Checkpoint Inhibitor Delivery Systems

Christopher Flores, MD: I'm Chris Flores and I'm in family medicine at Eisenhower Medical Center in Rancho Mirage, California.

LaTosha Mollette, DNP: I'm LaTosha Molette. I'm a family nurse practitioner at Louisiana Family Medicine Clinic in Jonesboro, Louisiana.

Mike Smith, PharmD: I'm Michael Smith. I'm a clinical pharmacist specialist in pain and palliative care at the University of Michigan in Ann Arbor, Michigan.

Christopher Flores, MD: We have an interprofessional team here to talk about interprofessional education and collaboration. In medical school, I was taught that the



patient-doctor relationship was the most critical and important dynamic in healthcare. But after 30-plus years in clinical care, I can attest that healthcare is a team sport and we deliver care in teams of individuals with different training, different skills, different talents. And we teach each other, we learn from each other, we brainstorm and problem solve to meet the needs of the patient.

I want to make a point that interprofessional refers to the mix of people like nurses and doctors and social workers, nutritionists, pharmacists, etc. Interdisciplinary refers to groups of physicians of different specialties that are problem solving for a patient. LaTosha, do you want to talk about interprofessional collaboration?

LaTosha Mollette, DNP: When you talk about interprofessional collaboration, the World Health Organization defines that as collaborative practice that occurs when multiple healthcare workers from various backgrounds work together with patients, families, and communities to provide the best healthcare possible. This is exactly what teamwork should look like, but it is important to remember that healthcare teams can vary from patient to patient.

I work in a rural setting, working together with various healthcare professionals helps to improve access to needed healthcare services, which helps to prevent unnecessary delays in care and treatment. Ultimately, working together as a team, it helps to meet the needs of others to improve health outcomes, patient care and safety.

Christopher Flores, MD: Right. I think all of us in healthcare are trying to figure out how to do things better, make life easier for ourselves and make everybody happier, patients, our staff and ourselves, to make things more sustainable. Interprofessional education and collaboration can accomplish this. There's a growing body of literature that shows that interprofessional collaboration can improve patient outcomes. It can decrease costs, improve efficiency, reduce disparities, improve health equity, and make things more sustainable for providers.

There's a couple of core competencies or basic foundational building blocks for this. Michael, do you want to talk a little bit about the roles and responsibilities?

Mike Smith, PharmD: Certainly, it's one of these things that we don't often think about, but it's important for 2 reasons. One, understanding our own responsibility and roles that we have within our team and what our teammates can expect from us in terms of what we can deliver to them and deliver to patients. The other is understanding what your team can do for you as well, so that you understand their educational background and you can help them practice at the top of their license by utilizing their skillset to the fullest extent.

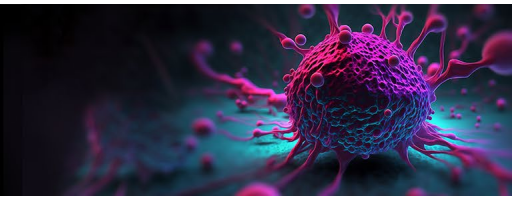
Just as a quick example, there are various differences in training a pharmacist. We all now come out with the PharmD, but some of us have done 2 years of residency training or postdoc fellowships. So, getting to know your teammates and what you can expect from them and what they can expect from you can really help your team function at a high level.

Christopher Flores, MD: We talk about values and ethics as well. In medicine, we're constantly required to make very difficult and complicated treatment decisions for our patients. We really are missing a great opportunity if we don't involve the opinions of all the members of our team. What does the nurse think about this plan or what does the social worker who's talked to the family members think about this plan? Or what does the physical therapist think who's been working with the patient for the last 3 days? LaTosha, what do you think about communication?

LaTosha Mollette, DNP: Communication is very essential in everything that we do, and it's how we're able to effectively achieve goals as well as improve relationships and interactions with others. The healthcare system is often described as being fragmented with little communication and collaboration, but when healthcare professionals communicate responsibly and respectfully, this allows them to overcome differences, working together to accomplish a shared goal, including learning from each other to better improve patient outcomes and safety.

Christopher Flores, MD: We're talking a lot about teamwork and teams. Michael, do you have any other points you want to make about teamwork?

Mike Smith, PharmD: There's lots of teams that we sit on, on a daily basis. Think about the team members that you work with every day to take care of patients, but also think about a team from a networking standpoint. Do you have a



network of like colleagues? As an example, other pharmacists in our healthcare system may reach out to me to help a patient that has pain, whether or not I'm actually seeing them. We can make our team small, we can make them big, but we should be making our teams in ways that everybody's functioning at a high level and putting the patient into the center of those teams.

Christopher Flores, MD: Michael, we talk about the fragmented healthcare system and how interprofessional collaboration can help with that. Do you have any examples from your experience?

Mike Smith, PharmD: Think about the patient's experience through our healthcare system. Even if a patient has all of their healthcare taken within 1 system, they have to travel to many different places just to get care. From a primary care clinic to a hospital, to a specialty clinic, to a pharmacy. They have to travel to many different places, and they're 1 person. But where we're able to fill these gaps is by using our interprofessional framework, our education, and allowing our collaborative practice teammates to step in and fill that.

There are lots of teammates that can help. And ultimately, we're strengthening the healthcare system and improving patient outcomes.

Christopher Flores, MD: In conclusion, I just want to summarize that medicine is a team sport and that there is a growing body of evidence in the literature. You can hardly pick up a medical journal or go to a medical conference where we're *not* talking about interprofessional collaboration. LaTosha or Michael, do you have any final thoughts?

LaTosha Mollette, DNP: I think just being willing to change. I think sometimes we have become complacent in previous practices, but our healthcare system is ever evolving. So, learning how to be that team player always benefits everybody involved.

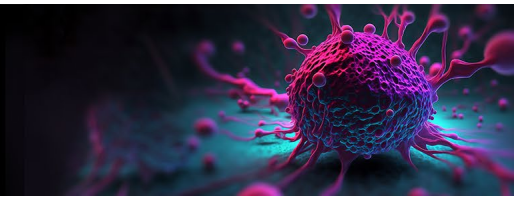
Mike Smith, PharmD: I've learned a great deal from my interprofessional colleagues, and I hope that I've helped them learn, as well, with the ultimate goal of really improving patient care.

Lucio Gordan, MD: We will discuss interprofessional, multidisciplinary collaboration strategies for novel ICI delivery systems and they include, SC products offer convenient and safe options for patients that may be preferred by patients and conversations, shared decision-making should be utilized. Training is required for providers and staff related to operational consideration of SC products. Administration for nursing staff will be more intensive, requiring more hands-on time for administration of the SC product. Lastly, consider financial challenges, such as no unique J-code for newly-approved products.

Saby George, MD: Dr. Gordan, it is important to involve patients and caregivers in shared decision-making, especially related to novel delivery systems and changes from standard IV therapies. With that in mind, what key information about SC formulations of ICIs should be shared with patients during treatment selection?

Lucio Gordan, MD: It always boils down to the trust, explanation, and good communication to ensure good outcomes and compliance with treatment. It is really important to have a discussion about efficacy with the patients and highlighting the efficacy of the SC being similar to the IV formulation. That is very reassuring, based on the data that we have today. We always have to discuss safety, so similarities and differences, there is SC injection site reaction, generally mild, but in terms of total safety, the drugs are equivalent and so that is important. A convenience discussion, patient preferences and desires, this is where we may spend more time with the patient. A patient with poor IV access or somebody who is afraid of needles may prefer a short injection vs a 30- to 60-minute infusion. We will likely find some variability. I presume that a significant proportion of patients will end up choosing SC in the future, but there will be some patients who prefer IV, but that remains to be determined. It all boils down to shared decision-making, early discussion with the patients, showing the data, speaking with the caregivers to make sure that everybody is well-informed.

Dr. George, I have a question for you. Involvement and collaboration with the interprofessional and multidisciplinary teams is vital for patient care, what strategy can the interprofessional, multidisciplinary care team employ to address safety and tolerability limitations associated with SC formulations of the ICIs?



Saby George, MD: ICIs, whether given IV or SC, have adverse events, and particularly of interest are the immune-related adverse events (IRAEs). These IRAEs need to be identified and treated in a timely fashion. Early recognition, early detection and treatment of these adverse events before they get to grade 3 or grade 4 is paramount because some of them could be fatal. If a high-grade toxicity is unrecognized, it could be toxic. So, that boils down to the importance of treating these patients on a constant basis to assess for their toxicities, particularly IRAEs, if they have any of those. Early detection of barriers or safety issues is important. Communication among physicians, nursing, and pharmacy teams is also very important because safety is totally dependent on timely communication. Operational needs and workflows need to be straightened out because when you talk about switching from IV to SC, it is not that simple. It is not that you can just have the drug and inject it. There are a lot of issues with accessing the drug, having the J-code, getting reimbursed, for SC, that is different from that of IV. We cannot use an IV formulation for SC injection. It is important to have a dedicated working group for a transition from IV to SC and determination of how to implement and maintain SC ICIs in addition to plans for future advancements of delivery methods of ICIs and other therapies. Now, we have a choice. In the future, we may or may not have a choice of what to use for a particular disease state, and effective education and ongoing discussion with patients will help streamline the processes for integration of SC products into practice. We have started using it, particularly in nivolumab, which was recently approved in our clinic, where that is indicated in GU malignancy. In terms of documentation, we have to have documentation that we had the discussion with the patient, patient agreed to switch to nivolumab SC, and then the order set is different, to create a new order set in the electronic health record (EHR). There are a lot of steps involved in this.

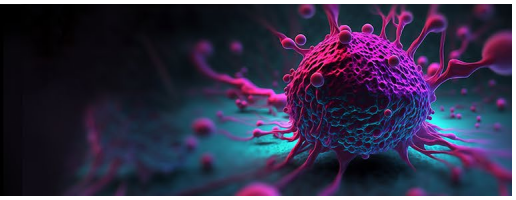
Knowing that not just physicians will play a key part in integrating SC ICIs into practice, what strategies can the nursing and pharmacy members of the care team employ to address operational and financial challenges associated with SC formulations of ICIs?

Lucio Gordan, MD: The nurses, the pharmacists, the revenue cycle billing teams, they tend to run the show and spend a lot of time making this happen. Nurse training is of paramount importance to understand that this is a 3-minute, 5-minute, 7-minute, 10-minute SC injection vs IV, how to separate the IV from the SC formulation to make sure no errors are made. The nursing team has to also set the appropriate expectations. We, with the nursing staff and nursing staff with the patient as well. The way the clinic is scheduled has to be also adapted to a faster turnaround time as we use shorter chair time with such patients, which is good. This all leads to the need for increased communication and collaboration with the nursing teams and pharmacists to determine operational efficiencies and workflow, to make sure that everything is done appropriately. Are we going to use an infusion room, a dedicated shot room, who is going to be supervising? These are all details that matter. It is not necessarily just easy to switch from an IV to SC formulation, but once the workflow gets set properly, it goes smoothly.

We have to be able to address, proactively, patient and caregiver questions, to make sure that they have enough education, not only verbally but with potential educational materials. From an economic, financial, revenue cycle standpoint, atezolizumab does have a unique J-code which helps. Nivolumab SC is under the miscellaneous code at this time. And some practices have concerns about the potential financial burden as it relates to any mishaps with drug reimbursement. It usually works well, even with miscellaneous code, but given the cost of the drugs in oncology in general, it does generate some anxiety. So, having a J-code that's unique and established is a big help and this will happen to every other drug that gets approved. It is just a matter of time.

Practices approaching the conversion to SC, they have to work proactively in mitigating barriers. I usually encourage a practice to speak with others who may have done this before. Not everybody needs to reinvent the wheel at all times. One needs to know how to do the proper storage and differentiation between IV and SC products to avoid medical errors, which is critical. Education, staff awareness, EHR updates, all these things are important to avoid any confusion as to what is being given to the patient and why. There are many lessons to be learned, but, in oncology and in medicine, we are keen on adapting to new challenges all the time, so I am sure we will thrive and scale this up in the next several months.

As practices begin to evaluate SC ICI products and consider adding into their formulary in oncology treatment paradigms, what are some key best practices for workflow optimization for treating patients with SC ICIs?



Saby George, MD: That is a question that I am very happy to answer because we just went through this process at our center. Effective communication among the interprofessional, multidisciplinary team and patients/caregivers is crucial to success and streamlining this process. What we did was, I had a meeting for rollout for SC nivolumab as soon as it got approved and so I had gathered team members from the senior leadership, administrative leadership, nursing leadership, pharmacy leadership, and practitioners in the field who are relevant, because not every subspecialty uses these drugs. We had all those groups in one room and shared the data and talked about approval and what is unique about their efficacy, safety, pharmacokinetics (PK), and the benefit of hyaluronidase in coformulation, which allows for SC injection. We talked about financial implications. We had the financial analysts talk about how this was potentially going to cut into the clinic revenue stream and then talked about J-code. Now, J-code is available, then we had this strategy planning meeting early and then we started using it a couple of weeks ago.

Before using the drug, you have to add it to your formulary at the hospital, go to the Pharmacy & Therapeutics (P&T) committee and get the approval by showing the data, and ensure FDA approval. Once that is in the formulary, you have to have your EHR team add it or create a new order set for SC nivolumab or atezolizumab or pembrolizumab, so that it is available for all the people to safely order the drug accurately. Then development of subcommittees, champions within each department if you have a huge operation, so that you can effectively implement SC ICIs. If you just decide to go from IV to SC, patients may not receive it correctly. Without proper planning, there may be a chance of making mistakes, so, I would recommend planning it out clearly with proactive engagement and collaboration with all these members from various teams. This is very important because, without the help of these teams, it is not possible to succeed because it is a heavy lift for transitioning from one drug to another. Then appropriate integration and optimization in the EHR so that the transition can occur safely and also, we need regular evaluation, follow-up and adjustments, as needed. It is really important and I am glad that we were able to do this, and I am involved with helping a lot of centers with this as well.

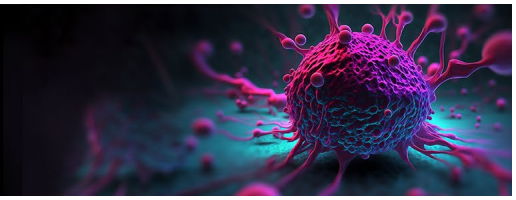
SC products are not new and others have been formulated in oncology, such as daratumumab, rituximab, and trastuzumab/pertuzumab combination. What strategies and insights can be learned from other oncology SC products that have been approved and available for some time now?

Lucio Gordan, MD: The conversion from IV to SC has precedence with daratumumab, rituximab, trastuzumab/pertuzumab. For daratumumab and rituximab, it was easier to convert to SC just because the time of infusion, specifically of daratumumab, in the beginning was 4 to 8 hours, then we needed 3 hours and now, with SC, it is much shorter. Rituximab, the same, and trastuzumab a little bit less infusion time. That is a touch different from IV infusion of ICIs which are administered as 30- to 60-minute infusions, but, if you can minimize chair time, it is always good for the patients and the system.

Key factors include educating the patient, understanding patient's preferences, and the caregiver, making sure they understand the data, the safety profile and why SC vs IV is desired or vice versa. We did learn quite a bit from the previous agents which were a harder conversion than ICIs. We learned a lot from the key barriers. We need a multidisciplinary team to tackle every operational and financial area because if those are not addressed, then a conversion to SC treatment may fail, which I do not think will be the case here. Being proactive in identifying barriers, learning from the past, adapting and addressing concerns of the nursing staff and patients, this is what will make us successful. Integration of an adoption for SC ICI will be routine in 12 months or so, especially once J-codes are established for the products and once we start doing this in a higher scale.

Module 4
Summary of Key Concepts

Saby George, MD: Dr. Gordan, this was a great discussion so far and, in addition to what we have shared from the trials and good clinical practice of rolling out SC, there are a couple of things that I would like to mention also on top of what we have seen, particularly about the time that will be given back to patients by switching from IV to SC. The IV administration takes roughly 30 to 60 minutes for any of these agents if it's a single agent infusion. If these are given once every 3 weeks or 4 weeks, and over the course of the year, when you consider the infusion time, compounding time, all the additional time at the infusion center, we may be giving back at least 1 to 1.5 hours every visit which may translate into 20 to 26 hours over the course of a year per patient. This is particularly relevant for a patient who, with terminal cancer,



may have only weeks or months or years to live. This is a terminal illness and the most important thing I consider that the patients benefit from transition to SC is time given back to them which they can spend with their family instead of spending it at the hospital or traveling to an infusion center, making an appointment, and wait time .

These SC drugs are pretty similar to IV drugs, so outcomes and safety are probably the same, but the benefit is a lot more for the patients in my opinion. So, Dr. Gordan, do you have anything to add to that?

Lucio Gordan, MD: I definitely agree with your points and comments, Dr. George. Our set-up here is very large. We have almost 100 clinics and we see about 100,000 new patients a year, so if you multiply this by the number of patients treated and the number of hours and days saved back to the patients, it can be incredible. It is a very good point that you raised. The other thing I was thinking is related to caregivers. Sometimes waiting there 5 to 10 minutes is much easier for them, as well, if they are dropping off the patient, they do not have to come back and unnecessarily upset their routine and work schedule. It could be a much more beneficial situation for the whole family and healthcare providers. A good number of patients do not like to come to the clinic and stay too long in the clinic just because sometimes they associate that with their disease process and they may be upset. A quicker visit in general makes much more sense.

Saby George, MD: Thank you so much and to summarize, ICIs have helped greatly improve patient outcomes across multiple tumor types in early stage and late-stage and various stages of cancer, in single agent also as in combinations. Historically, ICI products have been administered as IV therapies over 30 to 60 minutes. IV therapies have operational burden, as well as patient burdens, that can create challenges. IV-line access is required or port placement is required. Chair time is increased. You book a chair and sometimes wait time for a chair is long at some centers with chairs not being readily available for patients. Medication compounding and preparation time has increased and materials' costs have increased. A lot more utilization is required for delivering IV drug to patients. Adverse events, such as infusion-related reactions, are seen with IV drugs which will not be seen with SC drugs, but SC drugs may cause a local site reaction which is largely self-limited and does not require any additional intervention. Finally, the SC route of administration may offer several benefits clinically and operationally for patients and organizations which is important. It may reduce the wait time for patients to get to a chair. For example, at a large center, if the wait time for a chair is 2 weeks, by the time switching IV ICI patients to SC ICI, you may be able to open up more chairs and treat more patients at the same time while you give a SC product in clinic and it is faster and opens up a lot of chairs. Those are the main advantages that I see from this transition to SC ICIs.

Lucio Gordan, MD: Yes, thank you, Dr. George. My key points are as follows: We have 2 SC ICI products currently FDA approved, atezolizumab and nivolumab, and a third, pembrolizumab, currently undergoing clinical trial evaluation and hopefully it will be approved by the end of 2025. Atezolizumab SC is administered over 7 minutes and nivolumab SC is administered over 3 to 5 minutes, so there is a difference there. It is important that all of us have a shared decision-making process with patients that we integrate all the interprofessional and multidisciplinary teams that run our clinics to make sure that integration of SC ICIs into practice is successful. We addressed some concerns that both of us had in terms of financial barriers as it relates to absence of final J-code for some of the drugs and concerns with reimbursement, but this will be mitigated and fixed over time and the level of concern will be overcome soon.

In summary, having novel delivery systems for ICIs, such as SC administration, may become a preferred route of administration for patients and for organizations due to saved chair time and other considerations, such as IV access and reduced burden to the patient and the caregiver and to the clinic administration and nursing staff.

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