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Elevation Through Innovation: An Updated Advanced Practice Provider-Led Approach to Outpatient CAR T-Cell Monitoring

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Abstract

Immune effector cell (IEC) therapies have introduced a new era of treating aggressive hematologic malignancies in patients who may have previously had limited therapy options. While undoubtedly impactful, IEC therapy brings forth significant challenges, including high health-care resource utilization, limiting cost barriers, life-threatening toxicities, and logistical obstacles for the health-care team. In 2019, Vanderbilt University Medical Center developed an outpatient cellular therapy program driven by advanced practice providers (APPs) to address these barriers. Since its development, this cellular therapy program has found ways to alleviate some of the financial burden associated with IEC therapy and therefore directly contributed to increased accessibility and sustainability of these treatments. As the program has expanded, some critical modifications have been made in the initial workflow to accommodate growing volumes, including the implementation of continuous, at-home remote monitoring. This article provides an overview of the updated 2026 CAR T-cell outpatient program. Additionally, this article highlights the vital role that APPs serve in fostering the expansion of safe, patient-centered and cost-effective CAR T-cell therapy through outpatient monitoring and telemedicine practices.

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Chimeric antigen receptor (CAR) T-cell therapies have expanded the hematologic malignancy landscape for patients with multiple myeloma, B-cell malignancies, mantle cell lymphoma, and follicular lymphoma (Alexander et al., 2021). While transformative, the side effect profile of CAR T-cell therapies is significant enough to require intensive monitoring by a health-care professional who is familiar with the side effect profile, which can be both costly and resource intensive. In response, Vanderbilt University Medical Center in Nashville, Tennessee, implemented an advanced practice provider (APP)-driven outpatient monitoring program to address these barriers.

The transition to outpatient monitoring has been noted in the literature to significantly reduce costs by cutting overall expenses incurred in the inpatient setting (LeBar et al., 2020). Advanced practice provider–driven outpatient monitoring maintains patient safety through prompt detection of toxicities, minimizes unnecessary hospitalizations, and allows care to be delivered in a flexible, patient-centered manner. As CAR T-cell treatments expand into other disease processes, more centers may be looking to implement a workflow that allows for outpatient administration of CAR T-cell therapies, and our institution's process serves as a possible blueprint for other centers.

IMPLEMENTATION OF A NOVEL OUTPATIENT MONITORING PROGRAM

In 2017, Vanderbilt University Medical Center became an authorized treatment center for CAR T-cell therapy, the only center in a seven-state region of the Southeast (Vanderbilt Health News, 2017). At that time, the program was exclusively inpatient and required a 14-day hospitalization for cell infusion and toxicity monitoring, which proved to be both costly and resource intensive. Therefore, the financial feasibility of the new program was questioned at an institutional level. In response, the program was transitioned to an outpatient model with around-the-clock provider monitoring driven by APPs. The goal of this new model was to decrease the financial burden of CAR T-cell therapy while ensuring safe and close monitoring for life-threatening toxicities such as cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS). Members of the APP team at the time published their outpatient monitoring workflow as a prototype for other cancer centers (LeBar et al., 2020). This initial iteration required patients to have a dedicated caregiver and secure local accommodations within 30 miles of the hospital for 30 days following cell infusion. Additionally, it included twice daily clinic visits with an attending physician and an APP, manual vital sign tracking at home by the caregiver every 4 hours, nightly telehealth visits at 2200, and a phone call at 0600 with an APP to review the evening's events. In addition to the multiple point-of-care checkpoints, APPs were available 24/7 via a dedicated team cell phone for patient and caregiver support (LeBar et al., 2020). If admission was warranted, the APPs served as the catalyst for prompt admission and inpatient management of acute toxicities. This former workflow is outlined in the model in Figure 1.

Growth of the CAR T-Cell Treatment Landscape

Since the publishing of the 2020 article mentioned previously, there have been many exciting changes in the CAR T-cell therapy landscape. In April 2022, the US Food and Drug Administration (FDA) approved axicabtagene ciloleucel (Yescarta) as a second-line therapy for adults with large B-cell lymphoma (LBCL), which vastly increased the number of patients eligible for treatment (Dholaria et al., 2022). Additionally, allogeneic CAR T-cell products from healthy donors are now being researched to provide an "off-the-shelf" option to offset barriers such as production time, manufacturing delays, and cost (Lamprecht & Dansereau, 2019). Lastly, trials to expand CAR T-cell therapies into other disease processes such as solid tumor malignancies, including ovarian cancer, lung adenocarcinoma and breast cancer, systemic lupus erythematosus, myasthenia gravis, and other autoimmune processes are under way (Patel et al., 2022; Wu et al., 2025). The growing list of indications for CAR T-cell therapy is naturally expected to increase the volume of patients eligible for this treatment. This shift has already forced elite centers to rethink workflows for program sustainability (Hansen et al., 2023). Our institution has seen this growth firsthand. In 2024, 69 patients were treated under the outpatient CAR T-cell model at our facility, a notable increase from

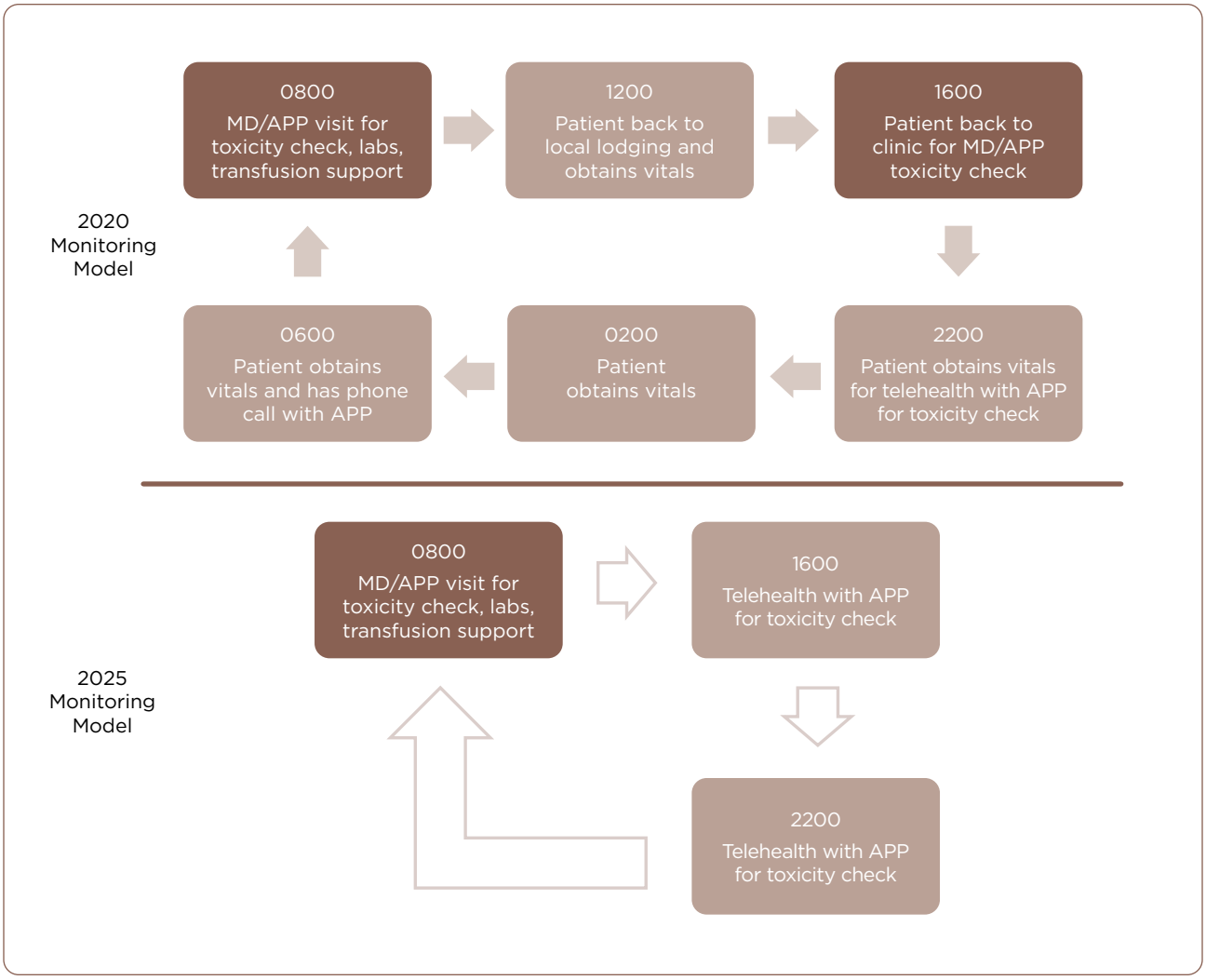


Figure 1. Improvements made to outpatient CAR T-cell monitoring program from 2020 to 2025. Dark brown: outpatient clinic. Light brown: at local lodging. White arrow: Continuous remote vital sign monitoring.

the 13 patients treated from January 2020 to January 2022. The APP team has continued to adapt the outpatient monitoring program to address the increase in demand.

Institutional Response to Changing CAR T-Cell Landscape

There have been several changes to the CAR T-cell therapy program since its development in 2019 to personalize patient care and address efficiency, safety, and satisfaction. The standard of care for patients receiving CAR T-cell therapy now includes clinic administration of the cells on day 0, followed by 14 days of vigilant outpatient monitoring through a combination of in-person clinic visits, remote telehealth visits, and automated vital sign tracking using a Bluetooth-enabled wearable device. This adapted model is outlined in Figure 1, in direct comparison to the outpatient program's workflow at the time of creation.

Manual Vitals Replaced by Remote Monitoring

In early outpatient implementation of the program, patients and caregivers were trained to obtain manual vital signs every 4 hours, including overnight. This system led to patient and caregiver fatigue, interrupted rest and recovery, and was

subject to error, which could lead to unnecessary hospitalization. The program has since transitioned to an automatic remote monitoring system via Bluetooth, which provides 24-hour vital sign data through a wearable device. The APP is able to set individualized parameters to detect earlier signs of toxicity. Specifically for CRS monitoring, parameters are set to alarm for temperatures greater than or equal to 100.4°F, hypoxia for oxygen saturation levels less than 90%, and hypotension defined as less than 20% from the patient's baseline blood pressure. This ultimately results in faster toxicity identification and management, as the APP is alerted of vital changes in real time and thus can contact the patient for immediate triaging. Real-time monitoring eliminates the need for patients and caregivers to wake up overnight to obtain vital signs, reducing patient and caregiver fatigue (Banerjee et al., 2021).

Removal of 0600 Phone Call

Historically, caregivers and patients were tasked with obtaining manual vitals at 0200 and 0600, which were reported to the inpatient APP during the morning telephone visit. With the implementation of continuous remote vital sign tracking, this telephone visit was eliminated, thus further removing responsibilities from the patient and caregiver.

Afternoon Clinic Visit Transitioned to Telehealth Appointment

The addition of remote vital sign monitoring has also eliminated the need for patients to report back in the afternoon for an additional clinic visit. Instead, the APP conducts a telehealth appointment to complete toxicity and vital sign checks at 1600. This method has improved the APP workflow to accommodate higher patient volumes.

STAT Bed

The myelosuppression unit at the institution has further improved workflow barriers by creating a "STAT" room, which is an allocated patient room that is reserved specifically for certain blood and bone marrow transplant patients, including all CAR T-cell recipients. This resource allows patients to be directly admitted in the setting of CRS, ICANS, or other toxicities. By bypassing the

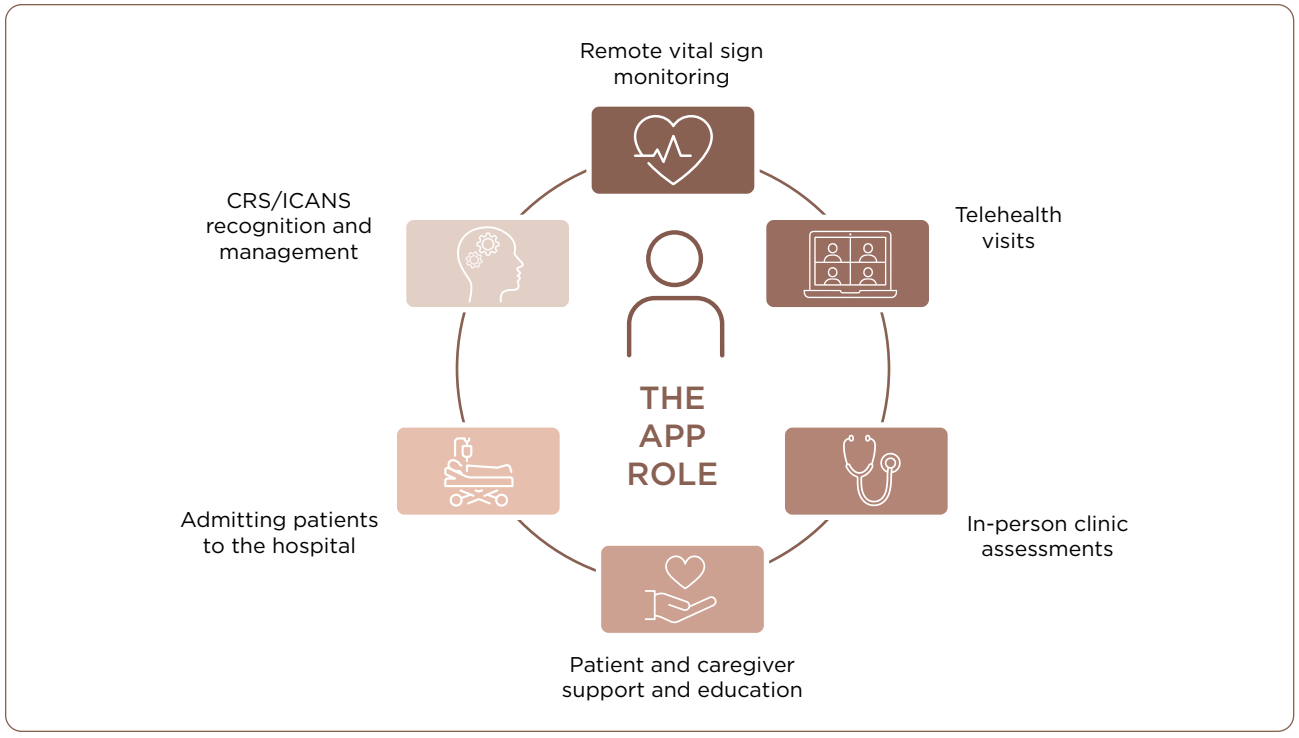


Figure 2. Role of the advanced practice provider (APP) in the outpatient CAR T-cell monitoring program.

emergency room, the patient can avoid potential sick contacts and have expedited access to treatment and to an APP who is knowledgeable and trained on the specific CAR T-cell product.

DISCUSSION

APPs as Continued Drivers

Advanced practice providers play an integral part in the care of CAR T-cell patients by assisting in making the program more efficient and cost effective. One of the largest benefits of this updated outpatient program is the financial implications. Drug acquisition of the CAR T-cell product alone costs on average $373,000 (Lyman et al., 2020). After drug cost, hospital admissions are the second highest expenditure for patients. A recent cost analysis found that administering CAR T-cell therapy in an outpatient setting within a nonacademic oncology network resulted in a reduction in total costs by over 40% (Lyman et al., 2020).

In 2024, 69 patients underwent CAR T-cell therapy at our institution. Using the average length of stay of 15 days and number of patients, it can be estimated that utilization of outpatient monitoring saved roughly 1,035 inpatient bed days. It is important to recognize that the outpatient cellular therapy program would not be sustainable without the 24-hour care provided by APPs as evidenced by Figure 2. For patients to be safely managed in the outpatient setting while undergoing these therapies, a provider must be available around the clock to detect and manage any toxicities that arise. Through the utilization of both outpatient and inpatient APPs, a sustainable solution was implemented at the institution using preexisting roles. Key responsibilities of the APP include monitoring vital sign data, performing telehealth visits, providing patient and caregiver support, coordinating admission, and treating CRS or ICANS as indicated.

Future Opportunities

The promising outcomes seen with current FDA-approved CAR T-cell therapies have spurred interest in expansion of this targeted treatment approach into other cancers, specifically solid tumor malignancies (Patel et al., 2022). As research explores the applications of this exciting therapy in new disease processes, more challenges will likely arise. While cost is already a barrier for some institutions and patients, it is possible these therapies could become even more expensive with the growing amount of novel CAR T-cell products (Choi et al., 2022). Additional resources may be needed to accommodate this growing population, and new care team models may need to be explored. For instance, some health-care entities have already instituted clinics dedicated to immune effector cellular therapies (Gatwood et al., 2022). This type of model and other novel workflows may become more commonplace with time.

CONCLUSION

Our institution's outpatient CAR T-cell monitoring program has proven to be a safe, efficient, and cost-effective alternative to traditional inpatient care (Dholaria et al., 2022). By leveraging technology and multidisciplinary collaboration, this model not only reduces the financial and logistical burden on the health-care system, but also enhances patient experiences (Gatwood et al., 2022). Additionally, this model reinforces the critical role of APPs in the delivery of safe and effective specialized care, as they serve as the primary point of contact for patients, their caregivers, and the larger health-care system. As CAR T-cell therapies continue to expand in scope and indication, this innovative approach may serve as a blueprint for other centers aiming to optimize high-acuity care in a patient-centered environment.

Disclosure

The authors have no conflicts of interest to disclose.

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