



ASHP CENTER FOR NEXT-GENERATION THERAPEUTICS
LEADERSHIP AND INNOVATION FORUM

***NEXT-GENERATION THERAPEUTICS IN
PRACTICE: NAVIGATING INNOVATION,
ACCESS, AND PATIENT CARE***

VIRTUAL FORUM REPORT

MAY 14, 2026

ashp PHARMACY EXECUTIVE
Leadership Alliance

INTRODUCTION

On May 14, 2026, the American Society of Health-System Pharmacists (ASHP) Center for Next-Generation Therapeutics and the Pharmacy Executive Leadership Alliance® (PELA®) collaborated to convene a virtual forum, Next-Generation Therapeutics in Practice: Navigating Innovation, Access, and Patient Care. Next-generation therapeutics (NGTs) encompass a range of cutting-edge treatments, including cellular and gene therapies (CGTs), tissue-engineered products, targeted drug delivery, personalized medicine, theranostics, rare disease therapies, and other specialty and ultra-high-cost medications. ASHP launched its Center for Next-Generation Therapeutics with the commitment to prepare the profession for the evolution of these novel therapies and to help guide clinical, operational, safety, ethical, and financial considerations associated with these therapies. The May 14 virtual event was a forum for health-system pharmacy clinician leaders and executives to discuss experiences, challenges, opportunities, and innovative strategies to improve patient access to NGTs and to support the evolution of the pharmacists' role in the safe and cost-effective delivery of these therapies.

Next-generation therapies are expanding disease-altering and curative treatment options for patients. But the complexity of these therapies pushes the boundaries of traditional care delivery systems and infrastructure.¹ The ASHP Commission on Goals met in March 2026 to discuss NGTs, specifically CGTs and other ultra-high-cost drugs, and commission members recognized that CGTs are evolving rapidly beyond rare diseases and hematologic malignancies, and health systems must be prepared for this expansion.¹ Several recent publications, including ASHP's Pharmacy Futures 2025: Summit on Advanced Therapeutics, have also described pivotal roles for pharmacists in the coordination and delivery of NGTs.^{2,3,4}

Welcoming and opening remarks for the May 14 forum were provided by **ASHP President Melanie Dodd** and **ASHP Executive Vice President and CEO Samuel V. Calabrese**, who emphasized that pharmacy is uniquely positioned to provide leadership within organizations to balance access to these novel therapies with their clinical and financial implications. Considering the strategic importance of this topic for the pharmacy enterprise, the virtual forum's objectives were:



Samuel V. Calabrese



Melanie Dodd

- Identify opportunities for health-system pharmacy to improve patient access and optimize use of NGTs.
- Discuss what changes will be required for the pharmacy of the future to appropriately review, handle, prepare, and monitor novel therapies.
- Describe health-system investments in facilities, interprofessional teams, and provider competencies necessary to support NGTs.

Pharmacy leaders from over 130 health systems participated in the forum, including clinical services directors and managers, advanced therapies coordinators, investigational drug services managers, formulary and medication management leaders, directors of pharmacy, chief pharmacy officers, and others involved in implementation of NGTs. Key issues were explored by gaining insights from an expert physician panel; a discussion with clinician leaders representing peer organizations; and small breakout discussion groups designed to gain insights from the field. The panel discussion and breakout groups

focused on infrastructure supports and gaps, governance and strategic planning, patient access needs and barriers, building effective interdisciplinary collaboration, financial considerations, and pharmacy's role when implementing NGTs.

KEYNOTE PANEL DISCUSSION: FROM STRATEGY TO PRACTICE

KEYNOTE PANEL



**Mandy Leonard, PharmD, BCPS
(Moderator)**

Senior Director, Pharmacy Clinical Services, Drug Use Policy, Formulary Management, and Research
Cleveland Clinic
Chair — ASHP Center for Next-Generation Therapeutics Steering Committee



Jeffrey A. Cohen, MD

Hazel Prior Hostetler Endowed ChairProfessor
Neurology Director, Experimental Therapeutics
Mellen Center for Multiple Sclerosis, Cleveland Clinic



Rayne H. Rouse, MD

Cell and Gene Therapy Physician Scientist, Medical Director
Commercial CAR T Program — Baylor College of Medicine
Associate Professor of Pediatrics — Texas Children's Hospital

Mandy Leonard, senior director of pharmacy clinical services, drug use policy, formulary management, and research at the Cleveland Clinic and chair of the ASHP Center for Next-Generation Therapeutics Steering Committee, moderated the keynote panel discussion, which featured physicians **Jeffrey A. Cohen** and **Rayne H. Rouse**, who are leaders in the implementation of NGTs at their organizations. Cohen's practice focuses on neuroimmunology at the Cleveland Clinic, and he is a professor of neurology at the Cleveland Clinic Lerner College of Medicine. Rouse practices at Texas Children's Hospital and is an associate professor in the Department of Pediatrics in the Division of Hematology-Oncology at the Baylor College of Medicine. The panelists discussed their experience with cell therapies, emphasizing how these agents have helped establish the foundation for implementing other therapies. Rouse started the session with a primer on cell therapies that are most often used in hematology, oncology, and pediatrics. The panel discussion expanded to how this early implementation experience supports the expansion to non-oncology indications, including autoimmune diseases.

A FOUNDATION FOR GROWTH: BUILDING UPON EARLY EXPERIENCE

Rouse said immune cells can now be genetically reprogrammed to target virtually anything, and she reviewed how chimeric antigen receptor (CAR) T-cell therapy works at the cellular level. A genetically modified viral vector enters T cells, resulting in the expression of artificial receptors that bind to and

kill targeted cells (**Figure 1**). Because cancerous blood cells are readily accessible, and side effects of treatment are easily managed, CAR T-cell therapies were first developed for hematologic cancers. The full vein-to-vein CAR T-cell therapy process is complex and lengthy (**Figure 2**).

Cohen said the expansion of CAR T-cell therapies into the treatment of autoimmune diseases may offer potential advantages to existing therapies, including monoclonal antibodies (mAbs). He noted that mAbs target cells in the bloodstream, while CAR T cells can additionally seek out cells in the tissues. He said this could be particularly relevant in the treatment of multiple sclerosis if CAR T-cell therapies are developed that can access the central nervous system. Cohen cautioned that when treating autoimmune diseases, potential complications of CAR T-cell therapy are clinically similar to some manifestations of the disorders that are being treated, highlighting the need for careful monitoring and evaluation. Cohen added that he is optimistic that CAR T-cell therapies may reset patients' immune systems, resulting in long-lasting efficacy.

FIGURE 1. CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELLS

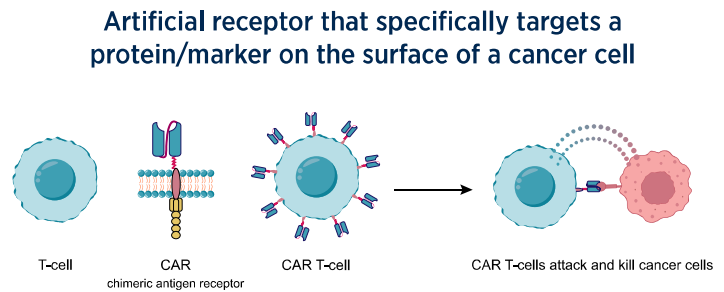
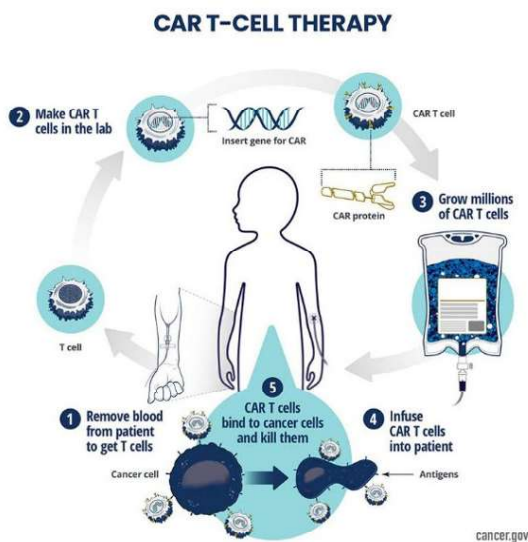


FIGURE 2. CAR T-CELL THERAPY



Source: National Cancer Institute. <https://www.cancer.gov/research/leading-progress/scientific-topics/cell-therapy/car-t-cell-therapy-infographic>. CAR T-Cell Therapy Infographic was originally published by the National Cancer Institute. Accessed June 3, 2026.

INFRASTRUCTURE AND ACCESS

Rouce also stressed that, due to inherent complexities, equitable expansion of advanced therapies and broad access to patients within new specialties and disease states will be challenging. In addition to financial and procurement complexities, cost-effective and simplified processes are needed across the entire delivery model. Currently, there are multiple approaches: a traditional centralized pharmaceutical model, a centralized point-of-care model, a decentralized academic model, and decentralized academic model with distribution.⁵ Models are still evolving, and the ideal scenario may vary depending on the organization and the geography of the potential patient population.

Other issues that will require creative approaches include overcoming regulatory and licensing hurdles, addressing patient-specific access barriers, and establishing alternative cost and payment models. To increase access and reduce costs, additional off-the-shelf products and alternative manufacturing models, such as point-of-care (decentralized) manufacturing and mobile manufacturing facilities, are needed.⁶

Both physician panelists agreed that the current infrastructure for oncology provides a foundation for expansion of advanced therapies into new disease states. But the active engagement of clinicians is needed to address implementation gaps. Legacy processes and regulatory, manufacturing, and organization-specific requirements are also adapting as stakeholders gain experience in implementing advanced therapies. For example, more therapies are now being administered in ambulatory clinics rather than acute care settings. Finally, it is important to recognize that these highly personalized therapies require a lot from the patient. To expand access, care teams that include social workers and financial counselors must focus on the patient journey — where the patient starts, where we want to get them to — and on reducing the complexity of the care process.

PHARMACY'S ROLE

Rouce noted that, at her organization, pharmacists participate in several segments of the cell therapy delivery process, including the selection and harvesting phase. Pharmacists help manage the patient's condition in the interim by giving bridging therapies to keep the disease under control with minimal adverse effects. Medications are needed to prepare the patient for cell therapy, and toxicity management and supportive care are part of the treatment process. Tumor lysis can result in cytokine release syndrome, which requires rapid recognition and treatment with specific medications that must be readily available. Other roles for pharmacists may include establishing protocols, documenting chain of custody, creating the order for the therapies, and receiving and dispensing the therapies. Pharmacists can also advocate to ensure that key stakeholders, including the disease experts and patients, are informed and involved in the care plan.

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*Advocating for pharmacists to have a **seat at the table** from a very early point, including their role extending beyond direct patient care, is key.*

- RAYNE H. ROUCE, MD

KEY TAKEAWAYS

- CAR T-cell treatments are rapidly expanding beyond hematology/oncology to other specialties, including neurology and immunology.
- The experience in oncology has already provided a foundation for how to apply the therapies in other disease states.
- While much of the work from oncology can be adapted to other diseases, there are key differences in infrastructure readiness, provider knowledge and engagement, and patient selection and management that must be considered and addressed.
- Engagement of disease-specific experts is required at every step of implementation.
- There is high complexity with delivering these products and advance preparation, including conducting dry runs, is imperative when delivering new products or familiar products for new disease states.

PHARMACY EXPERT PANEL: NEW THERAPIES, NEW RESPONSIBILITIES

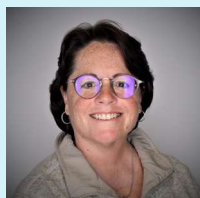
A panel of pharmacy experts was asked to share their experience and take a deeper dive into the implications for pharmacy practice when delivering NGTs as well as considerations important for the entire pharmacy enterprise. The session was moderated by **Heidi Trinkman**, advanced therapeutics program manager at Children's Health Care System and vice chair of the ASHP Center for Next-Generation Therapeutics Steering Committee. Trinkman was joined by her colleagues **Emilie Aschenbrenner**, pharmacy program lead for CGT and bone marrow transplant at Froedtert Hospital; **Zahra Mahmoudjafari**, Director of Pharmacy-Advanced Therapeutics, University of Kansas Cancer Center; **John Valgus**, executive director of pharmacy for UNC Health; and **Kevin Zinchuk**, manager of investigational drug services at Brigham and Women's Hospital.

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*Build adaptable processes; therapies coming next will likely **challenge the assumptions** that we are making today.*

- **KEVIN ZINCHUK, PHARM.D, CCRP**

PHARMACY EXPERT PANELISTS



Heidi Trinkman,
PharmD, BCOP

Advanced
Therapeutics Program
Manager
Cook Children's
Health Care System
(Moderator)



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Director of
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**Emilie
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Pharmacy Program
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Therapy and Bone
Marrow Transplant
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John Valgus,
PharmD, MHA

Executive Director of
Pharmacy
UNC Health



Kevin Zinchuk,
PharmD, CCRP

Manager,
Investigational Drug
Services
Brigham and Women's
Hospital

OPERATIONAL PLANNING AND EXECUTION

Zinchuk laid the groundwork for the panel discussion with an overview of operational planning and execution of NGTs, and he stressed that implementing these therapies will require a shift in mindset; these are not new drugs, but rather, entirely new care delivery models. He emphasized that whenever possible, operational planning should begin even before Food and Drug Administration (FDA) approval and, certainly, before the first patient referral. If health systems can successfully do this, translation becomes easier when products make the jump from clinical research to standard of care. These

therapies often introduce operational complexities that pharmacy has not historically managed at scale, such as strict cold chain requirements, chain-of-identity and chain-of-custody controls, and coordination across multiple disciplines. Roles, handoffs and accountability, and other key elements of the operational implementation of NGTs must be clearly defined upfront (**Figure 3**).

FIGURE 3. ELEMENTS OF NEXT-GENERATION THERAPEUTICS IMPLEMENTATION

PRE-PROGRAM PREPARATION	OPERATIONAL EXECUTION	GOVERNANCE AND STRATEGIC PLANNING	FINANCE AND FORECASTING	INTERDISCIPLINARY COLLABORATION
				
- Adaptable Processes - Staff Training - Handoffs and Accountability - Informatics Support	- Leveraging Existing Infrastructure (e.g., IDS) - Product Requirements - Facility Readiness	- Forecasting and Pipeline - Approval Processes - Engaging Stakeholders - Quality and Safety	- Contracting - Patient Access - Budgeting - Payment Reconciliation	- Clinical Practice Alignment - Transitions of Care - Onboarding and Education

*Adapted with permission from Zinchuk. Images created by slide design in PPT.
IDS = investigation drug service*

Zinchuk also stressed that operational execution of NGTs needs to be flexible and that designing systems that can evolve is just as important as getting it right the first time. Processes must support the rapid expansion of cellular therapies beyond hematology and oncology and into rare diseases, cardiology, neurology, and autoimmune conditions. He recommended leveraging investigational drug and oncology experience to support expansion into new indications and specialty areas. Delivery models also need to adapt. For example, as organizations shift from inpatient to ambulatory care for CGTs, operational support is needed to respond to acute adverse drug events that may occur at home. Other operational considerations include facilities requirements, capacity, staff education and training, and informatics support.

GOVERNANCE AND STRATEGIC PLANNING

Mahmoudjafari shared her insights on governance and strategic planning to support access to NGTs. She indicated that her organization uses an intentional, multidisciplinary, forward-thinking governance structure that considers the full life cycle of therapy, including pipeline and formulary review, operational feasibility and readiness, patient access strategy, care planning, financial risk considerations, and staff education. Other aspects of implementation include a process to assess safety and quality.

Mahmoudjafari stressed that the governance structure for NGTs must be multidisciplinary and enterprise-wide to balance innovation and access. Key stakeholders in a strong governance process include organizational and clinical leaders and people with expertise in finance and revenue cycle, managed care, informatics, pharmacy, laboratory, nursing, and social work. It may be beneficial to include an ethicist when tough decisions must be made. Formal governance processes should be developed for pipeline surveillance and prioritization, site-of-care decision-making, and contracting. These processes should also align with existing capabilities of stakeholders and understanding of

potential staffing impacts. Other panelists echoed Mahmoudjafari's comments that strong governance requires a proactive, multidisciplinary approach that brings key stakeholders together early on. Participants noted that most specialties that want to provide CGTs are not as well-resourced as oncology. A governance structure that includes non-oncology clinicians who are prescribing, or considering prescribing, NGTs is a way to share institutional expertise. Several panelists noted that pharmacy experts in investigational drugs or hematology/oncology have taken on broad roles in governance. One organization has a NGT program manager with responsibilities across departments. Pharmacy is well-positioned to pull diverse stakeholders together, because pharmacy's role transcends traditional service-line boundaries.

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Pharmacy has a central role in bridging perspectives across disciplines and service lines, designing plans that balance clinical, operational, and financial needs.

- PHARMACY LEADER

FINANCIAL CONSIDERATIONS

Valgus stressed that pharmacy leaders must understand the budgetary impact of NGTs and be able to explain those impacts to senior financial leaders. NGTs continue to increasingly affect health-system and hospital budgets and margins, and organizations budget these dollars in different ways. The dollars may be in pharmacy's budget, within clinical service lines, or mixed in multiple areas. Valgus observed that those responsible for the budget tend to be engaged in the NGT implementation process to ensure it goes well as financial decisions are made. Margins, not just cost, are also important pieces of the value equation. While the costs of these agents are high, margin is relatively low and may even be zero or negative. Thus, managed care and contracting colleagues also need to be involved in budgeting decisions. Valgus reiterated other panelists' recommendation to view NGTs more as programs than as drugs. Some panelists envisioned collaborative relationships among regional providers to deliver therapies through stewardship in a financially sustainable environment that ensures equitable and timely access for patients.

CLINICAL PRACTICE AND INTERDISCIPLINARY COLLABORATION

Aschenbrenner rounded out the panel discussion by sharing important considerations for clinical practice and interdisciplinary collaboration. She noted that her organization's traditional pharmacy and therapeutics (P&T) committee and an oncology subcommittee have evolved to also include a high-dollar innovative therapies committee that is chaired by an oncologist and includes other specialties. The committee has established new working groups (e.g., pharmacy and nursing steering committee) and sought to integrate pharmacy into structured interdisciplinary team meetings to provide ongoing communication, education, and transparency. Nursing is key for many aspects of implementation, including staff education, patient education, adapting workflows, and developing patient triage protocols. To support effective handoffs and define roles, checklists and standardized operating procedures and workflows were developed, including guidance for safe handling of products. Aschenbrenner said collaborating on key process indicators (KPIs) and working together to improve overall performance drives excellence. Panelists indicated that outcome and financial measures were their most frequently tracked KPIs, but additional process measures, such as time from order to treatment, are also being implemented.

KEY TAKEAWAYS

- NGTs cannot be treated as individual product launches and require an intentional institutional infrastructure and programmatic approach.
- Governance for NGTs must be forward-thinking, interdisciplinary, and include actively engaged key stakeholders.
- Strategic governance for NGTs should look beyond the pipeline and formulary review to operational readiness, care planning, payment and reimbursement considerations, and staff education needs.
- Understanding the budget and revenue impact is critical to explaining budget trends to senior finance leaders.
- Developing a streamlined financial review of NGTs will optimize equitable and timely patient access.
- Interdisciplinary collaboration is key and can be supported by adding to existing committee structures and developing new work groups.
- KPIs should be expanded beyond outcome and financial measures to include process measures to monitor operational performance.

BREAKOUT SESSIONS: LEADING THROUGH THE EVOLUTION OF NEXT-GENERATION THERAPIES

The forum attendees were invited to participate in virtual breakout sessions to reflect on the panel discussions and gain broader insight into current strategies and practice. Session facilitators posed several questions to participants to generate conversation about the current state of NGTs implementation, including challenges, successes, and lessons learned. Topic areas that emerged as top of mind included strategic planning and governance structures; operational models and infrastructure support; financial considerations and forecasting; and building teams for effective collaboration.

GOVERNANCE STRUCTURES AND STRATEGIC EXECUTION

Breakout participants (BPs) generally agreed that a governance structure coupled with a strategic focus is critical to successful implementation of NGTs. Engagement from a broad group of stakeholders was deemed critical for effective governance and implementation. Pharmacists are well-positioned to lead interdisciplinary governance frameworks to ensure these therapies are introduced safely, ethically, and sustainably.

GOVERNANCE STRUCTURES

Cross-functional alignment of key stakeholders and leadership engagement are essential, but BPs indicated that their governance structure and processes are still evolving. Governance committee responsibilities described by BPs included:

- Monitoring clinical trials and pipeline developments
- Establishing timeline and projections for expected therapies
- Determining formulary strategy and ownership
- Ensuring resources are matched to projections (i.e., operational readiness)
- Establishing and monitoring key performance measures

The degree to which NGT implementation has progressed to disease states beyond oncology and therapies beyond CGT varies. Most organizations have a layered governance structure that includes the responsible committee and specialized subcommittees (e.g., CAR T-focused or for ultra-high-cost drugs). These committees must be agile and able to make decisions quickly, because traditional P&T timelines may be too slow for time-sensitive therapies. Final approval for high-cost therapies typically involves C-suite leadership and finance teams. Operational models should include checks and balances within the revenue cycle, from the point of contracting to reimbursement capture.

BPs said some organizations have hired program managers to address siloed functions and quarterback NGT onboarding and implementation. Generally, governance models with senior leadership visibility, engagement of the right stakeholders, and pharmacists acting as system educators and coordinators have emerged as early best practices.

KEY STAKEHOLDERS

Committees typically include multiple stakeholders from medical staff, pharmacy, managed care, nursing, quality, administration, informatics, finance and revenue cycle, and clinical service line leadership, with each group bringing relevant perspectives and skill sets. BPs said cross-functional coordination is also essential for scale. For example, significant structural support is required for information systems to capture and aggregate data and to support patient care (e.g., order sets, patient lists, collaborative care). Ethics or legal representatives are sometimes included in governance committees, and strong physician engagement improves effectiveness of governance. Committees usually meet regularly (e.g., monthly or bimonthly), to support patient case evaluation, onboarding, protocol development, and staff education.

QUALITY, SAFETY AND VALUE

BPs said health systems must ensure consistent standards of quality and safety across all processes. The NGT governance structure should provide oversight of safety and process improvements and identification and monitoring KPIs. Some organizations actively track KPIs, but most are just beginning to build out measures beyond financial and quality KPIs. Participants agreed on the need for standardized value metrics that include process measures. Operational models should ensure the safety of patients and staff; several participants indicated that they have a process to identify and address biosafety for product handling.

INSIGHTS

- A wide variety of governance and committee structures support NGTs, but most leverage existing structures and emphasize the need for broad representation and a multidisciplinary approach.
- Having a governance structure that includes engaged clinicians and executive leaders is critical to timely and fiscally responsible NGT implementation.
- Governance must support a strategic, programmatic approach that balances access with financial and clinical considerations.
- Financial and outcomes measures are commonly tracked, but there is also a need for KPIs for clinical and process measures.

OPERATIONAL MODELS AND INFRASTRUCTURE SUPPORT

Operational models must be proactive and flexible and be able to anticipate demand, ensure timely treatment, and eliminate waste. Participants agreed that engaging providers early and often is critical for gauging uptake and predicting operational needs. As workflows evolve, process drift is a concern; standardization of processes, with clear lines of accountability and measurement, are necessary to ensure reliability, safety, and efficiency. Some organizations have developed checklists to assist with NGT onboarding and implementation.

EXPANDING ACCESS

Expanding access to NGTs can be particularly challenging at organizations without investigational drug experience. Early adopters of NGTs tend to be research sites that already have some expertise and infrastructure to build upon. This will likely change as more off-the-shelf products become available and processes are simplified. One BP's health system partners with an academic medical center to refer patients for CAR T-cell therapy and collaborates to ensure smooth transitions closer to home.

INFRASTRUCTURE INVESTMENTS

Most organizations have leveraged their existing resources but require additional resources and infrastructure for NGTs as their indications have expanded and ambulatory clinic administration options have grown. Some BPs said their organizations' C-suite hesitates to commit to NGT expansion beyond CGTs. As the use of NGTs increases, so does the need to scale for capacity and invest in infrastructure and resources. Several BPs indicated they were making capital investments, including the expansion of pharmacy and lab space and ultra-cold storage capabilities.

A robust data infrastructure system is also needed for NGTs. Key informatics support includes protocol and order set standardization and the integration of lab systems, the electronic health record, pharmacy, and the revenue cycle. Systems integration is an opportunity to improve product tracking, documentation, care coordination, and analytics. Connecting clinical and financial data will also support fiscally responsible decision-making, such as site-of-care optimization.

Infrastructure requirements can be a challenge to NGT implementation. One BP indicated that, to offer these therapies, their organization would need to expand infusion center capacity. Streamlined care models may also require investment in or partnering with co-located cellular therapy labs. One BP noted they are establishing a Gene Therapy Center of Excellence to develop best practices.

INSIGHTS

- Organizations should build upon existing infrastructure, when possible, rather than creating entirely new systems for NGTs.
- Expansion of therapies to new indications and settings will likely require infrastructure and resource investment.
- Standardize processes where possible and develop KPIs to support quality improvement efforts.
- Pharmacists are well-positioned to have a leading role in designing and implementing processes.

FINANCIAL CONSIDERATIONS AND FORECASTING

Evaluating new, high-cost therapies is a major challenge, and financial stewardship is critical for sustainability. Pharmacy brings experience and insightful perspectives on operational and clinical decisions that balance patient access and clinical value with financial impact.

FORECASTING AND BUDGETING

BPs indicated that pharmacists and physicians typically collaborate to monitor the NGT pipeline and develop utilization projections for potential new therapies. Forecasting should occur before FDA approval and include active monitoring of clinical trials with input from multidisciplinary workgroups. Reimbursement uncertainty for high-cost NGTs is a major barrier to accurate budgeting and may limit uptake of these therapies. Reimbursement beyond the cost of goods is difficult to obtain. Other factors that must be considered include new infrastructure needs, labor intensity, onboarding time, and other administrative and clinical overhead expenses.

ACCESS AND FINANCIAL STEWARDSHIP

Financial sustainability is critical to ensure expanded access to NGTs. Organizations have concerns due to low (and sometimes no) margins and high structural support requirements, especially at community hospitals. Broad input from the finance team is important since allocation of costs and revenue is not often aligned, and the significant overhead cost to deliver these complex therapies must be considered. Some organizations have established a separate cost center for CGTs, for example, to assist with cost accounting and differentiate these products from the general pharmacy budget, which may make it easier to explain variances.

Pharmacy has taken the lead at many organizations in reviewing NGT revenues and costs. Some BPs noted that pharmacy staff members worked with revenue cycle teams to evaluate reimbursements. One organization created a dashboard, maintained by the pharmacy team, which gave visibility to the chief financial officer and other key stakeholders about pharmacy's role in the financial stewardship of NGTs.

Managed care and contracting team input is also important to define potential patients, catchment area, and site-of-care options and to streamline the contracting process, with the goal to move away from single-case reimbursement. Few alternative payment models have been implemented; most sites primarily see single-case agreements, which often require months of lead time before the delivery of the therapy. There has been limited uptake of outcome-based contracts, likely due to uncertainty and risk, interest in value-based models seems to be emerging. Some institutions have gained experience through the Cell and Gene Therapy Access Model from the Center for Medicare and Medicaid Innovation.⁷

BPs noted that prior authorizations and claims tracking were completed by pharmacy or revenue

cycle departments to varying extents, but all were implementing some type of back-end checks. One challenge has been that the low volume limits trend analysis. Payment delays vary by payer, and the course of therapy can exceed three months. One BP noted that they meet with payors quarterly, try to be transparent, and discuss the number of anticipated patients. Reimbursement must include time dedicated to the process, because NGT implementation requirements are well outside the normal workflow and require extra time and attention. Pharmacy can provide key information to the payer on what it takes to complete the onboarding of therapy and administer it to patients.

INSIGHTS

- Enhanced analytics and cost accounting methods are needed to understand the true costs of delivering NGTs.
- Pharmacy has a central role in bridging perspectives of internal and external stakeholders and helping to design plans that balance clinical, operational, and financial needs.
- To scale NGTs and improve time to treatment, there must be a move away from single-case contracts.
- Pharmacy has taken the lead at many organizations to close the finance loop, reviewing revenue as well as costs.

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*These therapies are **non-traditional**; payment models need to be non-traditional, too.*

- PHARMACY LEADER

BUILDING TEAMS FOR EFFECTIVE COLLABORATION

Operational and organizational alignment remains a barrier to large-scale implementation of NGTs. A structured interdisciplinary group can be effective in increasing opportunities for access and ensuring a smooth patient journey. Teams must embrace creativity, adaptability, and openness to new ideas as foundational investments to support interdisciplinary teamwork for emerging therapeutic areas.

ENGAGING STAKEHOLDERS

BPs said collaboration among many stakeholder groups is essential for finding scalable solutions to NGT implementation. Critical stakeholders include laboratory technicians, care managers, social workers, and intake and billing coordinators. A physician champion often drives adoption and onboarding decisions and can support peer-to-peer education. Most BPs agreed that pharmacy should both be at the table and lead the implementation of NGTs, but pharmacists must be proactive early on and not wait for an invitation to participate in the process.

EDUCATIONAL PRIORITIES

BPs said educational models that support NGTs must be enterprise-wide and include all stakeholder groups. Priorities for education and training include NGT preparation, storage, and delivery requirements; safety protocols; regulatory considerations; and financial management. One organization has developed operational and clinical competencies for pharmacy staff. Core elements include standard operating procedures for product handling and administration, chain-of-custody and identity requirements, and mandatory documentation. As NGT use expands to new specialties, education must include new disease- and drug-specific criteria, side effect profiles, and reimbursement models.

PHARMACY ENTERPRISE STRUCTURE, INTEGRATION AND ROLES

Discussions among BPs described pharmacists bringing value to their organizations on many aspects of complex therapy coordination. Leadership roles will require pharmacy to shift from highly task-oriented toward more relationship-building and strategic thinking. BPs described a variety of pharmacy roles (**Table 1**). Pharmacy's unique and broad expertise encompasses therapeutic evaluations, financial management, product preparation, medication management, adverse effect monitoring, and data analytics. Pharmacy has also been a pioneer for NGT governance and onboarding. Onboarding activities can involve the drug product, the patient, and providers within new specialties. By building upon existing experience with CGTs, one organization has dedicated its CGT pharmacist to the implementation of other NGTs, and another organization engages its investigational drug service pharmacist as a key NGT resource. The dedicated CGT pharmacist is involved with analytics, workflow coordination, and benefits investigations and coverage assessments. Organizations also involve pharmacy in advanced therapy coordination, reimbursement, strategic planning, financial oversights, and transitions of care.

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*Building relationships and trust through **strong connections** with the clinical team and leadership is critical.*

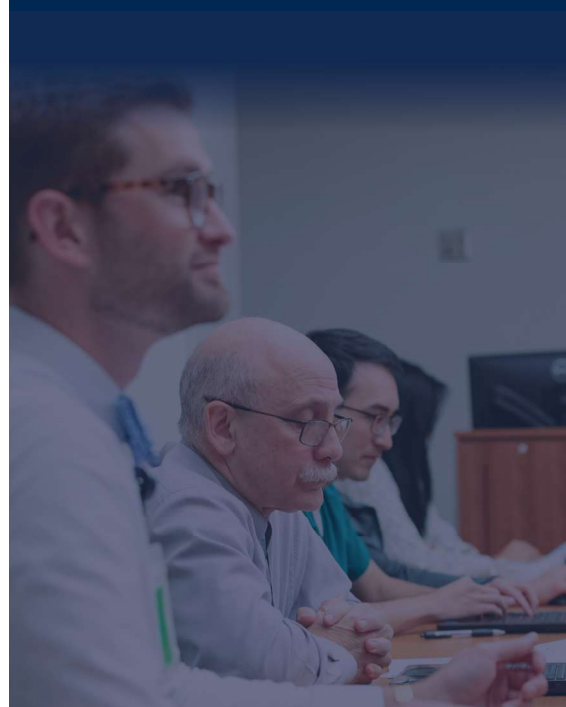
- PHARMACY LEADER

INSIGHTS

- Collaboration across stakeholders is essential for scalable solutions, and this must extend to front-line personnel.
- Pharmacy can have a central role in designing standardized workflows that align clinical teams, procurement, finance, nursing, laboratory, and regulatory stakeholders to prevent treatment delays and minimize operational risks.
- Physician champions can provide support for all aspects of implementation, including adoption, onboarding, and peer-to-peer education.
- Pharmacy is well-positioned to support traditional and non-traditional roles within the scope of implementing NGTs.
- When leading NGT implementation, pharmacists must leverage relationships and shift from being highly task oriented to being strategic.

TABLE 1.

EXAMPLES OF PHARMACY ROLES IN IMPLEMENTING NEXT- GENERATION THERAPIES



GOVERNANCE

- Onboarding and clinical protocol development
- Providing input into strategy development
- Performance reporting/quality improvement

OPERATIONS

- Process standardization
- Provider and patient onboarding
- Identification and implementation of best practices
- Informatics support (e.g., order sets, data analytics)
- Chain-of-custody/chain-of-identity documentation
- Personnel safety policies and procedures

EDUCATION

- Patient education
- Provider education/ancillary team education
- Senior leadership/finance team education

FINANCIAL MANAGEMENT

- Pipeline monitoring and budgeting
- Intake coordination for billing/prior authorization
- Revenue cycle monitoring
- Procurement and contracting

PRODUCT PREPARATION

- Order verification, therapy preparation, and verification
- Product labeling before infusion
- Coordination of administration-related processes

PATIENT CLINICAL MANAGEMENT

- Care coordination/transitions of care
- Patient monitoring and medication management
- Follow-up care/management of adverse effects
- Provide supportive care

CLOSING REMARKS

ASHP President-elect Kim Benner, professor of pharmacy practice and pediatric clinical specialist at Children's of Alabama, provided closing remarks. Benner said pharmacists are uniquely positioned to provide leadership and broad expertise within their organization when implementing NGTs. Pharmacy can bring significant value to the organization by bridging financial, clinical, and operational aspects required to build scalable and sustainable programs that ensure equitable patient access to advanced therapies.



Kim W. Benner

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