CAR T Cell Therapy Program Setup

Bristol Myers Squibb™

CAR T Academy: CAR T Cell Therapy Program Setup

01 Program Oversight

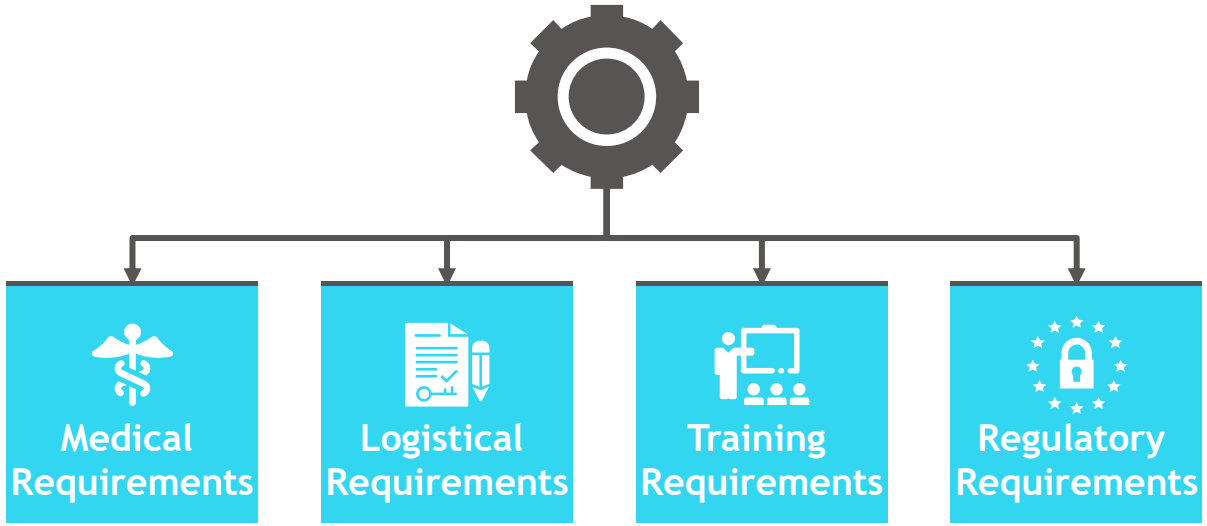
02 Healthcare Professional Considerations

03 Logistical Considerations

Institutional Infrastructure of CAR T Cell Therapy Programs Is Key

- One key factor to consider when establishing a chimeric antigen receptor (CAR) T cell therapy program is oversight of the program
- All CAR T cell therapy programs must have standards and systems in place for management of patients receiving CAR T cell therapy; however, operational approaches can vary

Strong institutional infrastructure for the program is essential to ensure all of the complex requirements for CAR T cell therapy delivery are met



Reference: Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

Factors to Consider when Determining Program Oversight

Given the high demand on institutional resources, oversight is a critical decision to the establishment of a CAR T cell therapy program

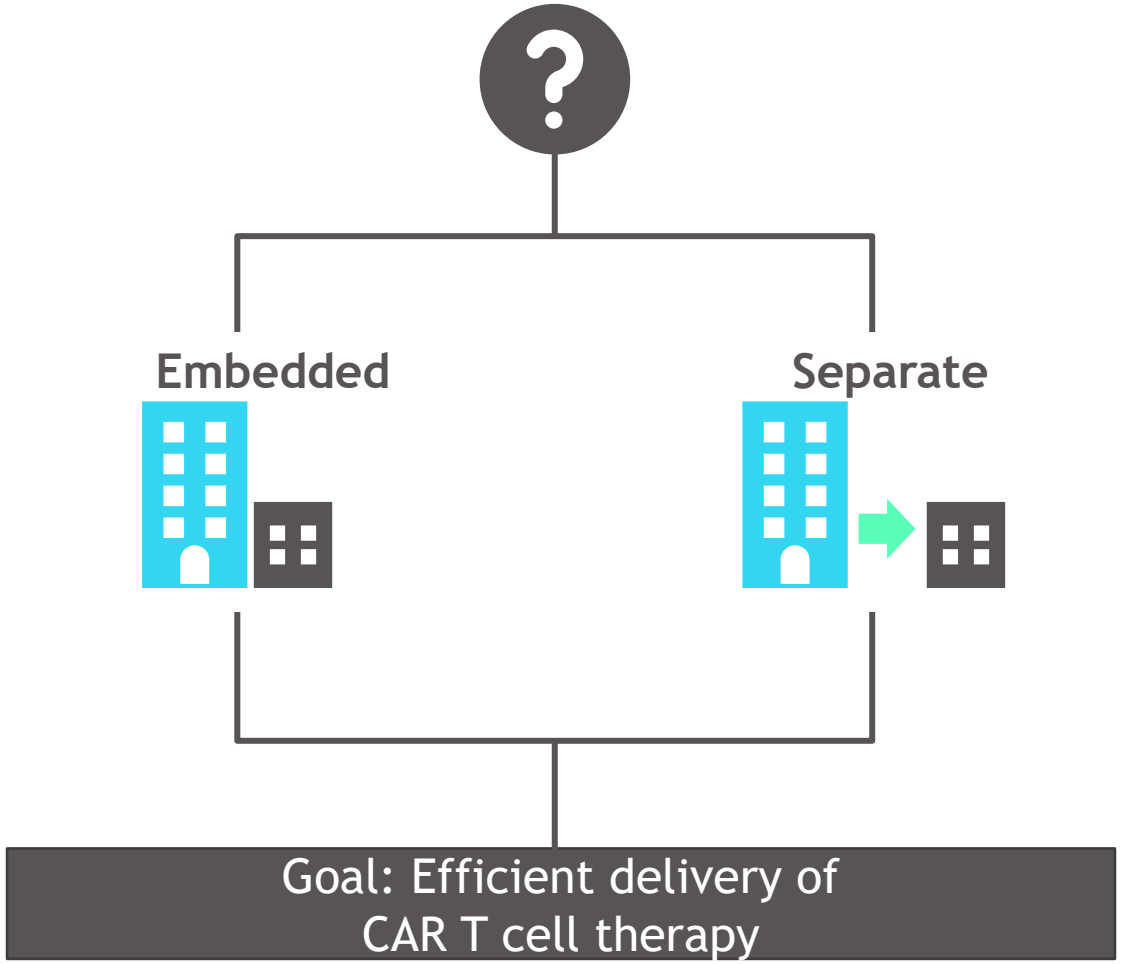
The type of program oversight is based on a number of factors but ultimately should aim to provide efficient delivery of CAR T cell therapy and patient support

Some factors to consider may include:

- **Number and types of CAR T cell therapies offered**
- **Anticipated patient volume**
- **Inpatient/outpatient resources**
- **Pre-existing service lines**

Reference: Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

Determining the Type of Program Oversight



- CAR T cell therapy programs may be part of existing institutional blood and marrow transplantation (BMT) programs
- Other institutions may choose to develop distinct programs with a cell therapy focus, or based on primary disease service (eg, leukemia or lymphoma team)

BMT, blood and marrow transplantation.

Reference: Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

CAR T Cell Therapy Programs Embedded Within a Blood and Marrow Transplant (BMT) Program[1]

This type of program leverages existing BMT infrastructure, but requires additional features specific to CAR T cell therapy programs, such as:

- Appropriate training of management of CAR T cell therapy associated toxicities (eg, CRS, neurologic toxicity, infection)[1]
- REMS program training[2]

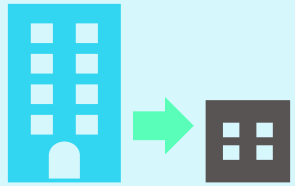
- Avoids system redundancy by utilizing systems that already meet similar requirements for BMT therapies
  - Data and quality management
  - Documentation methods and flow sheets
- Capitalizes on existing workflows and adapting to include CAR T-specific policies or support where needed
  - Apheresis support already meeting current standards
  - Existing policies for cell thaw and infusion
  - Existing policies for care and management of medically complex, immunocompromised patients

CRS, cytokine release syndrome; REMS, Risk Evaluation and Mitigation Strategies.

References: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26. **2.** Beaupierre A et al. *Clin J Oncol Nurs*. 2019;23:27-34.

CAR T Cell Therapy Programs that are Separate From BMT Programs

- May be able to accommodate increasing patient volume
- May be able to readily incorporate new CAR T cell products
- Patients are referred to CAR T cell therapy service from internal disease teams or from external HCPs for treatment and management
- CAR T cell evaluation, treatment, and posttreatment AE monitoring are managed entirely by an independent CAR T cell therapy service line
- Referrals are managed through coordination between administrative staff and HCPs/investigators to provide access to clinical care or relevant clinical trials



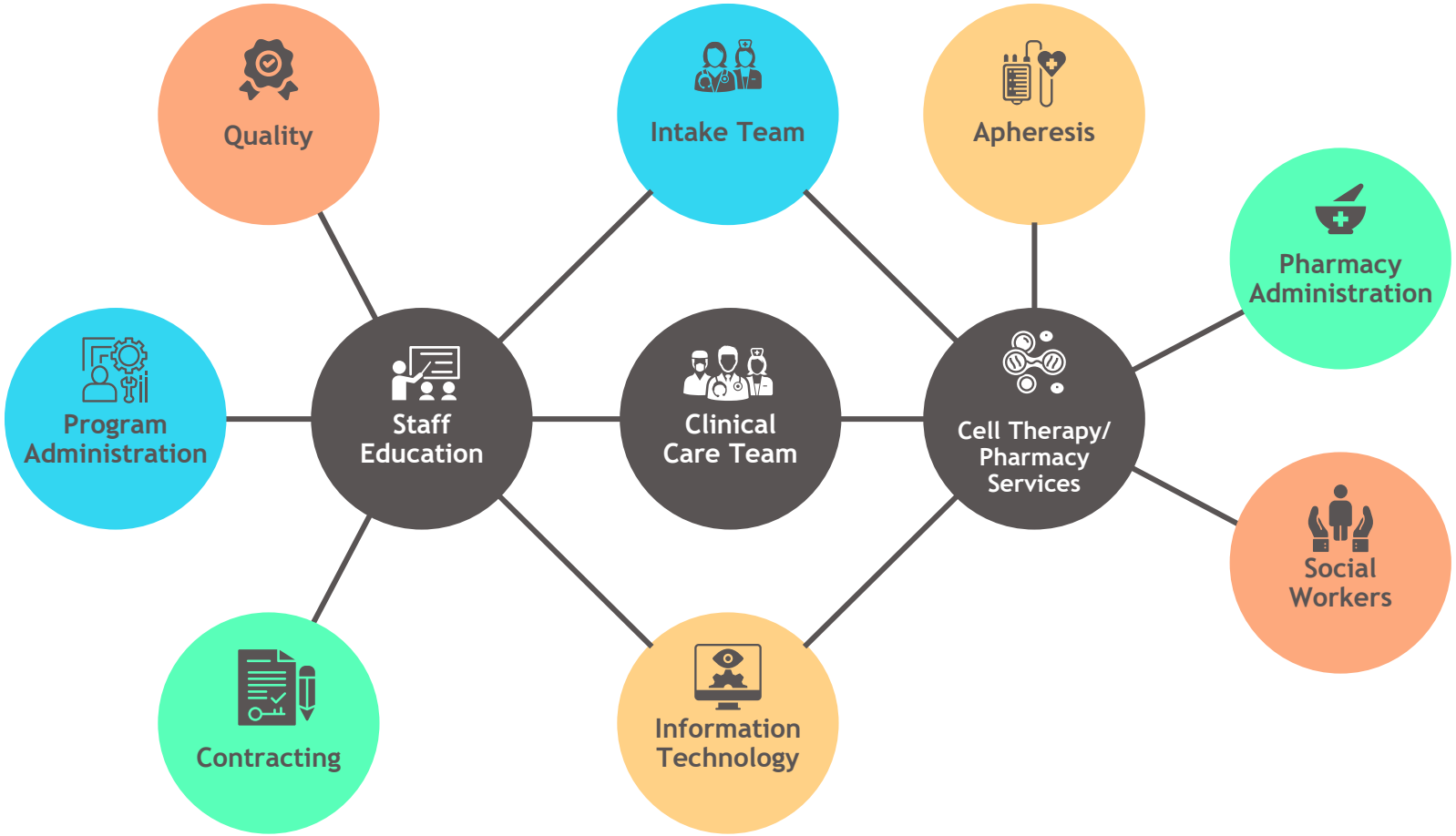
Independent CAR T cell therapy programs establish an independent service line for CAR T cell therapy:

- Expert care from a dedicated care team for therapy delivery and AE management
- Separate from BMT programs

AE, adverse event; HCP, health care provider.

Reference: Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

Considerations for CAR T Cell Therapy Program Roles & Operations[1-3]



The same types of specialized interprofessional teams are needed to support the complex infrastructure and patient care needs for CAR T cell therapy delivery, regardless of the type of program oversight[4]

References: 1. McGuirk et al. *Cytotherapy*. 2017;19:1015-1024. **2.** Perica K et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141. **3.** Beaupierre A et al. *Clin J Oncol Nurs*. 2019;23:27-34. **4.** Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

CAR T Cell Therapy Program Roles & Operations

01 Program Admin

- Includes CAR T cell therapy program director, program coordinator, REMS authorized representative
- Oversee program
- Establish benchmarks
- Develop quality-care plans and manage SOPs
- Plan and allocate resources

02 Quality

- Perform auditing and outcomes reporting
- REMS authorized representative and manufacturer REMS administration
- Transfer data for CIBMTR registry reporting, FDA adverse event reporting

03 Contracting

- Negotiate contractual agreements with manufacturers

04 Information Technology Services

- Create EHR documentation, alerts, and order sets
- Set up database infrastructure for quality reporting

CIBMTR, Center for International Blood and Marrow Transplant Research; EHR, electronic health record; FDA, US Food and Drug Administration; REMS, Risk Evaluation and Mitigation Strategies; SOPs, standard operating procedures.

References: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26. **2.** Perica K et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141.

CAR T Cell Therapy Program Roles & Operations

05 Staff Education

- Provide training on REMS programs
- Provide education on product handling, preparation and administration, as well as therapy-specific competencies

06 Intake Team

- Prescreen patients for eligibility
- Provide consultation and education
- Develop treatment plans
- Coordinate with patients, outside providers, and other services
- May identify housing and caregiver resources

07 Social Work

- Can arrange lodging and transportation
- Provide resources for patient support

08 Pharmacy

- Prepare plans for lymphodepleting chemotherapy
- Verify tocilizumab supply
- Track and receive cell products
- Pharmacy billing
- Formulary oversight

REMS, Risk Evaluation and Mitigation Strategies.

References: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26. **2.** Perica K et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141.

CAR T Cell Therapy Program Roles & Operations

09 Apheresis Center

- Viral screening
- Cell collection
- Store and ship collected material to manufacturing facility
- Chain-of-custody tracking

10 Cell Therapy/ Pharmacy Services

- Receive and store CAR T cell product from manufacturer
- Prepare CAR T cell product for administration
- Chain-of-custody tracking

11 Clinical Care Team

- Provide patient care that requires cooperation across departments in potentially both the inpatient and outpatient settings and across subspecialties
- Communicate and coordinate between cross-functional care team, including physicians, APPs, nurses, pharmacists, nurse coordinators, administrators, and social workers

APP, advanced practice providers.

References: 1. Korell F, et al. 2020;9(5):1225 **2.** McGuirk et al. *Cytotherapy*. 2017;19:1015-1024. **3.** Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

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Healthcare Professional Preparation

Healthcare professionals (HCPs) overseeing patients receiving CAR T cell therapy require training and proficiency in:

- Management of hematologic malignancies
- Immunotherapy principles
- Treatment timelines
- Cell infusion procedures
- AE management (eg, CRS, neurotoxicity)
- Management of immunocompromised patients
- Product-specific REMS training

CAR T cell therapy programs can help educate HCPs by:

- Creating, providing, and supporting therapeutic training and resources for foundational and continuing education
- Offering periodic competency assessment
- Providing updates about evidence-based delivery of care

AE, adverse event; CRS, cytokine release syndrome; REMS, Risk Evaluation and Mitigation Strategy.

Reference: Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

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Logistical Considerations for CAR T Cell Therapy

- Although some treating physicians may choose to treat appropriate patients in the outpatient setting, most patients will still require inpatient admission during therapy for monitoring and/or AE management[1]
- Transportation and accommodation: patients will need to stay within 2 hours of the treating facility for 4 weeks or more after infusion[1]
- Emergency care or hospitalization for AEs[1]
- Immediate access to therapies for management of AEs[2]
- Follow-up appointments for disease and side effects monitoring[1]

The CAR T cell therapy patient journey from evaluation through infusion should be timely and as streamlined as possible to help avoid treatment delays[2]

AEs, adverse events.

References: 1. Buitrago J et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **2.** McGuirk et al. *Cytotherapy*. 2017;19:1015-1024.

Professional Guidance May Serve as a Roadmap for Potential Facilities

- Professional medical organizations may provide guidance to help facilities address care along the patient journey
- For example, FACT Standards provide a blueprint to help accommodate various models of patient care and use of cellular therapy products[1]
- Additional information about FACT standards is available at the FACT website: http://www.factwebsite.org

Example FACT Standards for Cellular Therapy Products[2]

- A dedicated outpatient care area will be designated during treatment
- Access to an intensive care unit (ICU) or equivalent coverage must be available
- Prompt evaluation and treatment on a 24-hour basis to treat expected complications
- There shall be written guidelines for communication, patient monitoring, and transfer or triage of patients to ICU, emergency department, or equivalent when needed

ICU, intensive care unit

References: 1. Smith S, Essell J. *J Clin Pathways*. 2018;4(8):42-47. **2.** Foundation for the Accreditation of Cellular Therapy. FACT Standards for Immune Effector Cells. First Edition 1.1. http://www.factwebsite.org/IECStandardsDownload/. Accessed July 6, 2020.

Summary

- Initiating programs for CAR T cell products requires significant specialized expertise, resources, and organization, as well as coordinated efforts from a multitude of cross-functional clinical and operational teams across an organization
- Adequate staffing, appropriate training, educational resources, and streamlined processes are key to establishing a well-functioning, comprehensive, and effective CAR T cell therapy program

Thank you for completing this module of CAR T Academy

We hope you found it informative and educational

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