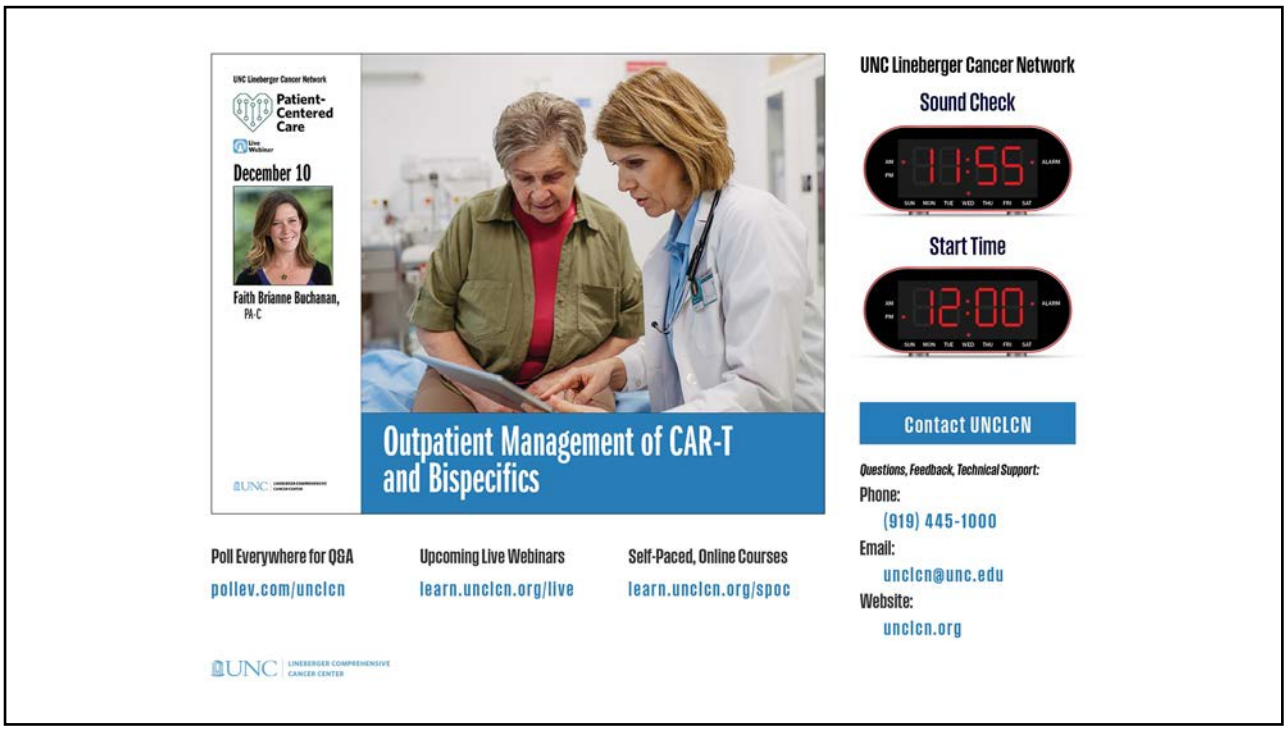
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Patient-Centered Care
Live Webinar
December 10
Faith Brianne Buchanan, PA-C
Outpatient Management of CAR-T and Bispecifics
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Sound Check
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Start Time
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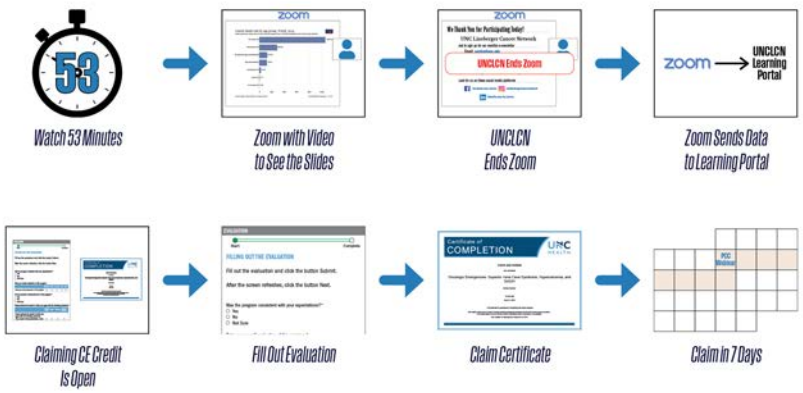

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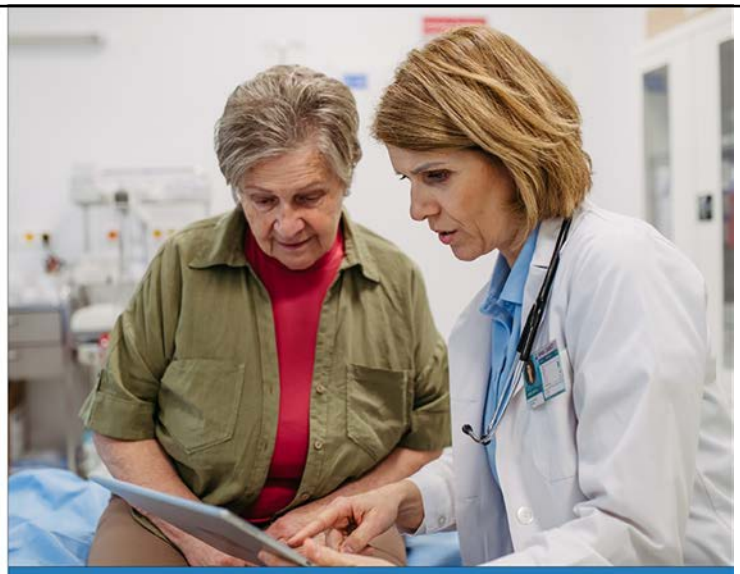
UNC Lineberger Cancer Network

Patient-Centered Care

Live Webinar

December 10

Faith Brianne Buchanan, PA-C



Outpatient Management of CAR-T and Bispecifics

UNC Lineberger Comprehensive Cancer Center

7

Our Presenter

F. Brianne Buchanan, PA-C

Brianne Buchanan is a Physician Assistant working in the Bone Marrow Transplant and Cellular therapy Program at the University of North Carolina Chapel Hill since 2013. Her clinical focus is working with patients receiving both commercial and research CAR-T therapies and on CAR-T program development, which she has been extensively involved with since 2016. Prior to working at UNC, she worked in both Bone Marrow transplant and outreach oncology at Duke University, and received her PA degree from George Washington University in 2005.

8

Our Presenter

9

Our Presenter

5. Prior to PA school, Brianne Buchanan worked as a medical assistant for a small Gynecologic Oncology practice, and that was what began her love of oncology patients.

10

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4. She had the opportunity to choose Bone Marrow Transplant at the NIH as an elective in school, and knew she wanted to pursue this later in her career when she had the opportunity.

11

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12

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13

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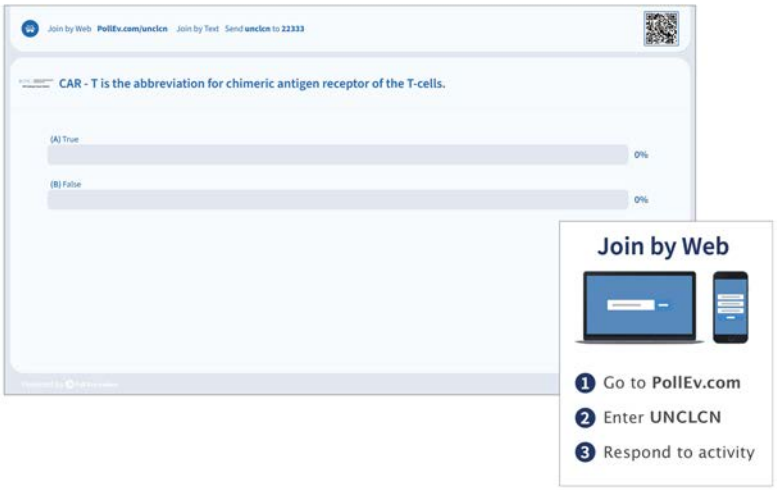
1. She participates in more than 20 cellular therapy clinical trials, and seeing first hand what the future can become is one of the greatest things about her job.

14

Sample Poll Everywhere Question



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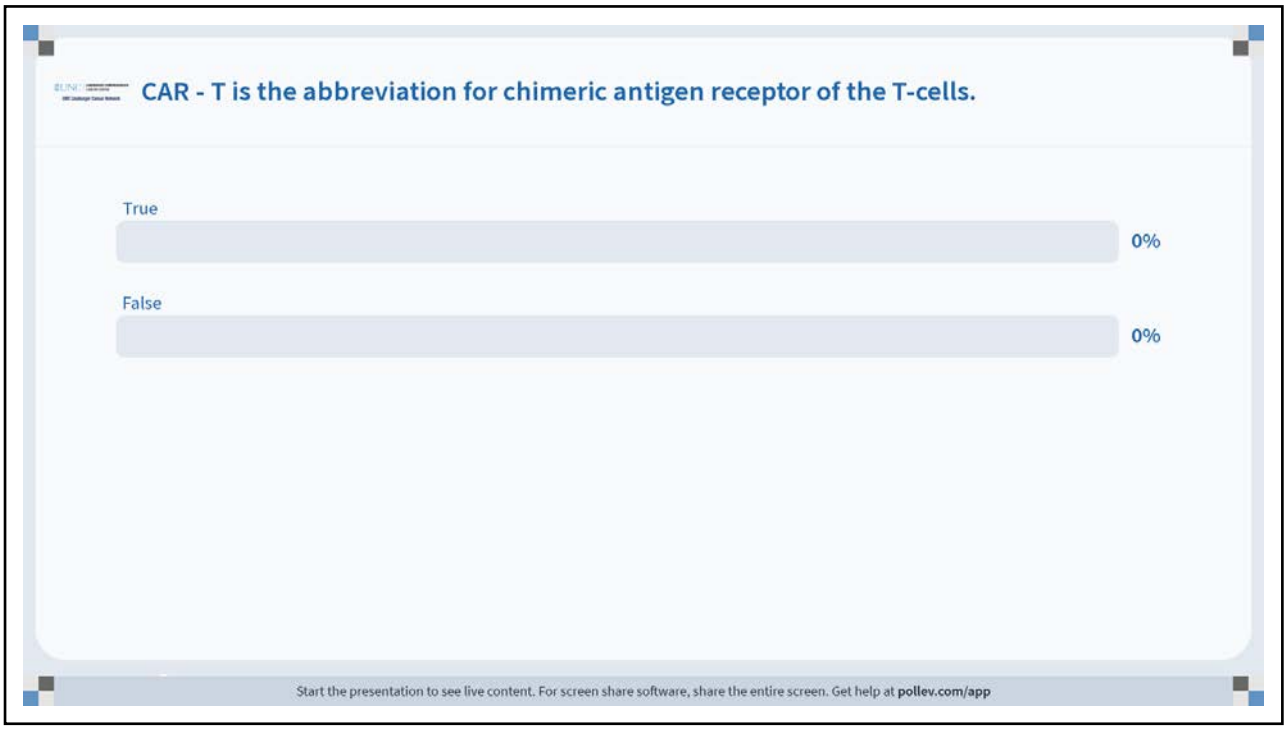


16

Outpatient Management of CAR-T and Bispecifics

F. Brianne Buchanan, PA-C
University of North Carolina
Bone Marrow Transplant and Cellular Therapy Program

17

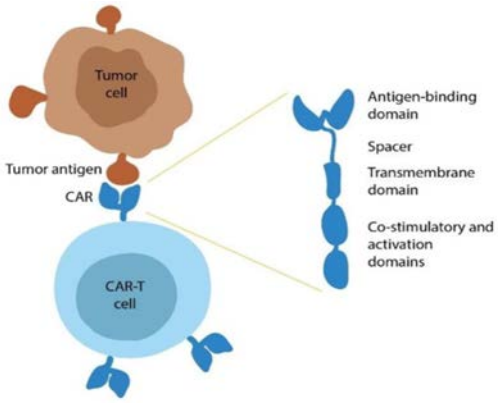
Learning Objectives

1. Explain a brief overview of CAR-T cell therapies and bispecific antibodies, including their mechanisms of action, treatment administration, and current clinical indications.
2. Identify appropriate candidates for outpatient administration of CAR-T cell therapy and outline monitoring protocols and management strategies for associated toxicities, including CRS and ICANS.
3. Describe the unique considerations for outpatient management of patients receiving bispecific antibodies, including early recognition and intervention for adverse events.
4. Discuss strategies for interdisciplinary coordination and communication to ensure safe and effective outpatient care across clinical settings.

18

What is CAR-T therapy?

- Genetically engineered autologous T-cells
- CAR attachment targets CD19+ antigen on lymphoma and leukemia cells, and BCMA+ antigen on myeloma cells
- CAR-T cells engage with cancer cell and cause cell death
- Risk of CRS and ICANS

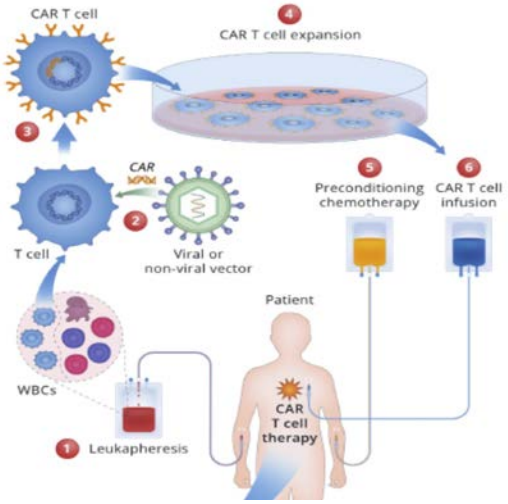


Graphic sourced from: Titov A, et al. *Cancers*. 2020;12:125 (Creative Commons Attribution (CC BY) license 4.0).

19

CAR-T Treatment Process

- T-cells collected via leukapheresis and re-engineered with a CAR
- Manufacturing ~3-4 weeks
- Lymphodepleting chemotherapy with Fludarabine and Cyclophosphamide x 3 days
- 2 days of rest
- Cells infused via an IV
- Monitored intensively minimum 2wks



Ganatra, Sarju, et al. "Chimeric Antigen Receptor T-Cell Therapy for Cancer and Heart: JACC Council Perspectives." J Am Coll Cardiol. 2019 Dec 24;74(25):3153-3163. doi: 10.1016/j.jacc.2019.10.049. https://pubmed.ncbi.nlm.nih.gov/31856973/

20

CAR-T Indications

Lymphoma		Breyanzi Liso-cel	Yescarta Axi-cel	Kymriah Tisa-cel	Tecartus Brexu-cel
DLBCL	2L	X	X		
DLBCL	3L	X	X	X	
Follicular	3L	X	X	X	
CLL/SLL	3L	X			
Mantle Cell	3L	X			X
Multiple Myeloma		**Carvykti Cilta-cel**	**Abecma Ide-cel**		
	2L	X			
	3L	X	X		
B-Cell ALL		**Tecartus Brexu-cel**	**Aucatzyl Obe-cel**	**Kymriah Tisa-cel**	
Pediatric R/R				X	
Adult R/R		X	X		

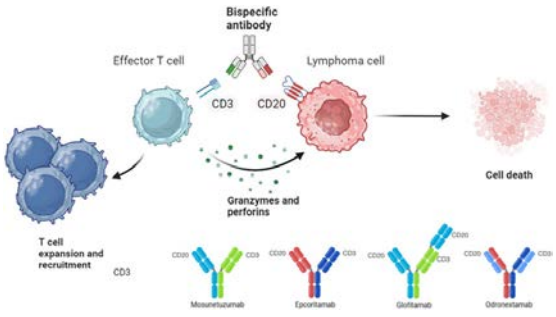
FDA Approved CAR-T:
Breyanzi: Lisocabtagene maraleucel
Yescarta: Axicabtagene ciloleucel
Kymriah: Tisagenlecleucel
Tecartus: Brexucabtagene autoleucel
Carvykti: Ciltacabtagene ciloleucel
Abecma: Idecabtagene vicleucel
Aucatzyl: Obecabtagene autoleucel

Breyanzi package insert, Yescarta package insert, Kymriah package insert, Tecartus package insert, Carvykti package insert, Abecma package insert, Aucatzyl package insert

21

What is Bispecific antibody (BsAb) therapy?

- Pharmaceutical redirects immune cells to cancer cells within the body
- Binds via an antigen on each cell
- BsAbs specifically utilizing T-cells to attack cancer cells are called BiTEs (Bispecific T-cell Engagers)
- BiTEs are primarily used in cancer, and utilize CD3+ antigen on T-cells plus a tumor antigen

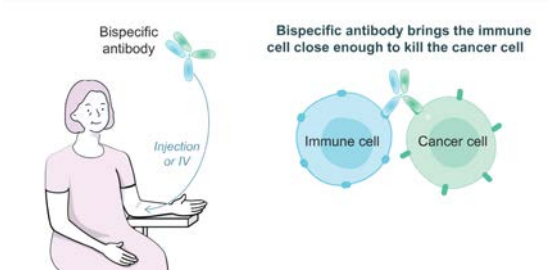


Van de Donk NWCJ, Zweegman S. T-cell-engaging bispecific antibodies in cancer. Lancet. 2023 Jul 8;402(10396):142-158
Graphic: Trial watch; bispecific antibodies for the treatment of relapsed or refractory large B-cell lymphoma

22

Bispecific treatment process

- Continuous or intermittent infusion, or subcutaneous injection
- Utilize step-up dosing to reduce toxicity
- Monitor for CRS, ICANS, cytopenias, and infections



Verma V, Sharma G. Bispecific antibodies in clinical practice: Understanding recent advances and current place in cancer treatment landscape. Clin Exp Med. 2024 Nov 28;25(1):11
Graphic: www.explorecelltherapy.com

23

Bispecific (BiTE) Indications

Lymphoma		**Lunsumio** Mosunetuzumab	**Epkinly** Epcoritamab	**Columvi** Glofitamab	
DLBCL	3L		X	X	
Follicular	3L	X	X		
Multiple Myeloma		**Tecvayli** Teclistamab	**Talvey** Talquetamab	**Elrexfio** Elranatamab	**Lynozyfic** Linvoseltamab
BCMA+	5L	X		X	X
GPRC5D+	5L		X		
B-Cell ALL		**Blincyto** Blinatumumab			
Adults and Peds: R/R, MRD+, Consolidation		X			

Lunsumio package insert, Epkinly package insert, Columvi package insert, Tecvayli package insert, Talvey package insert, Elrexfio package insert, Lynozyfic package insert, Blincyto package insert

24

Major toxicities of T-cell engagers

CRS (Cytokine Release Syndrome)

- **Onset:** 2–7 days
- **Fever, hypotension, hypoxia**

Tx:

- **Tocilizumab (1st line)**
- Dexamethasone, Anakinra (2nd line)
- **Tylenol and Dexamethasone may be used as 1st line for CRS in BsAbs**

ICANS (Neurotoxicity)

- **Onset:** 2–10 days
- **Encephalopathy, seizures, cerebral edema**
- **Tx:**
  - **Dexamethasone (1st line)**
  - Anakinra (2nd line)
  - Cytotoxic therapies (chemotherapy)

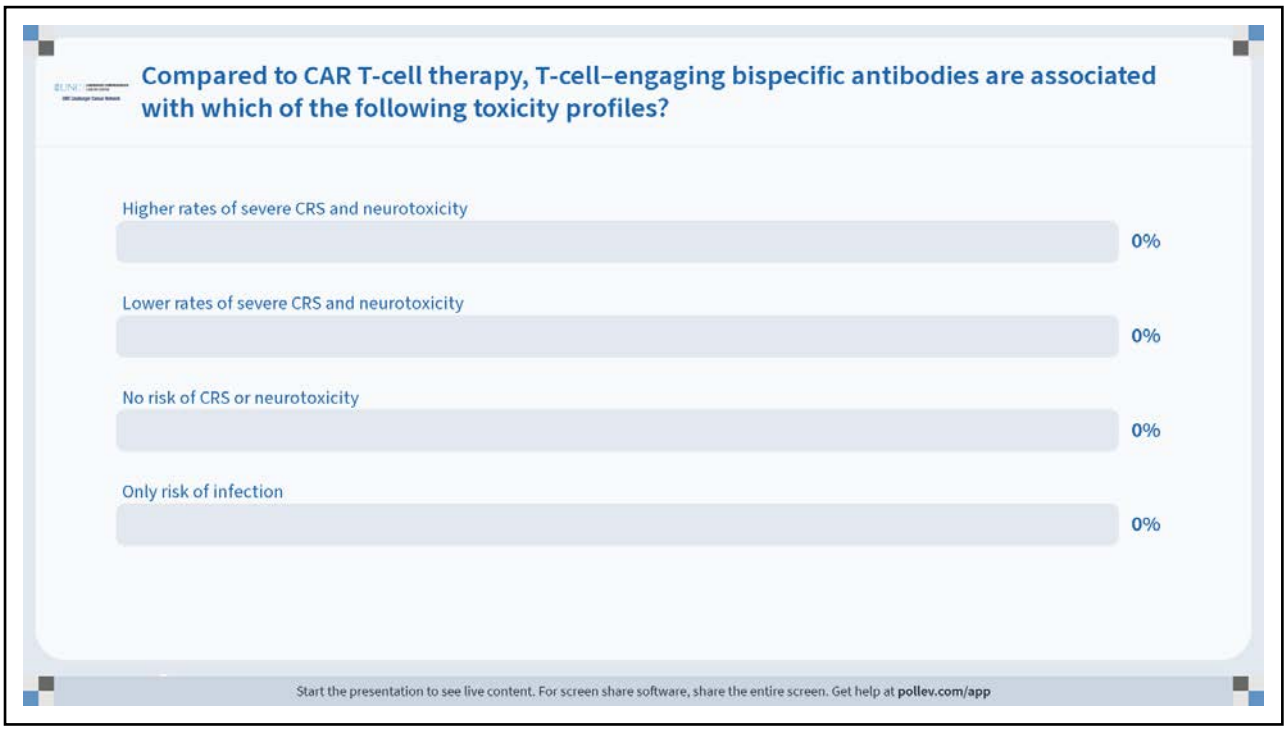
25

Incidence of Toxicities: CAR-T vs BsAbs

	Any CRS	Gr >/= 3 CRS	Any ICANS	Gr >/=3 ICANS
CAR-T	57-93%	2-23%	20-70%	4-17%
Bispecifics	17-80%	2-4%	2-8%	1-3%

NCCN: B-Cell Lymphomas, Acute Lymphoblastic Leukemia, Multiple Myeloma, Management of CAR-T cell and Lymphocyte Engager-Related Toxicities, Neurotoxicity Associated with Chimeric Antigen Receptor T-cell Therapy.

26



27

Outpatient management of CAR-T therapy

28

Who is an outpatient candidate?

Disease burden

Higher disease burden increases risk of severe toxicities

Risk of Tumor lysis syndrome (TLS)

Comorbidities

Adequate organ function

Cardiac and pulmonary comorbidities carry higher risk of toxicities

CRS has risk of hypotension and hypoxia

Performance status

Very important in deciding inpatient vs outpatient during intensive monitoring period

Shouse, et al; A validated composite comorbidity index predicts outcomes of CAR T-cell therapy in patients with diffuse large B-cell lymphoma. *Blood Adv* 2023; 7 (14): 3516–3529
Valtis YK, Chin K, Nemirovsky D, et al. Barriers to Chimeric Antigen Receptor T-Cell Therapy. *JAMA Oncol*. 2025;11(7):781–784
Alexander, et al. Chimeric Antigen Receptor T Cell Therapy: A Comprehensive Review of Clinical Efficacy, Toxicity, and Best Practices for Outpatient Administration, Transplantation and Cellular Therapy, Volume 27, Issue 7, 2021, Pages 558-570,

29

Support and Logistical considerations

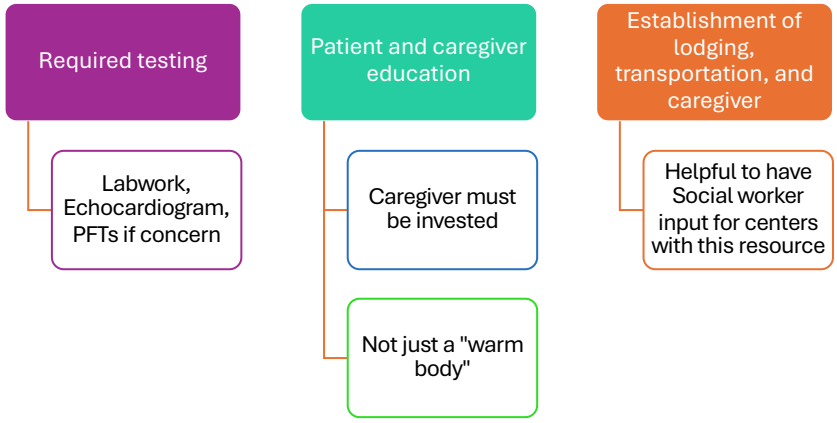
Required:
- Availability of 24/7 caregiver x 2wks
- Distance from treatment center
- Reliable 24/7 transportation for complications

Concerns:
- History of noncompliance with medications or visits
- Substance use
- Psychiatric comorbidity

Abrams, et al. National Landscape of Logistical and Non-Medical Requirements for Transplantation and Cellular Therapy. Transplant Cell Ther. 2025

30

Pre-Treatment Preparation



31

Monitoring protocols (Days 0-14)

- Daily monitoring x 7 days per PI
- Visits in second week vary per institution, typically 2x/week
- Visits >2wks vary, typically at least weekly until 4wks
- Patients are often admitted for signs of CRS
- Visits include:
  - Lab monitoring for cytopenias and organ function
  - Vitals
  - Neurologic assessments (ICE Score)

- ICE score: Immune-effector cell encephalopathy score; a scoring system for assessing neurotoxicity

32

Recognizing CRS

- Patient/caregiver education on symptoms
  - Who to call and when
  - Typical timelines to expect symptoms
- Ensure functioning thermometer
  - When/how often to check
- Some centers are investigating use of remote monitoring
- CRS risk varies by product, some have lower rates
  - Breyanzi has lower severe CRS rates and may be more feasible as outpatient

Maihail et al. Outpatient Administration of Chimeric Antigen Receptor T-Cell Therapy Using Remote Patient Monitoring. JCO Oncol Pract. 2025 Apr 18

Linares et al. OUTREACH: phase 2 study of lisocabtagene maraleucel as outpatient or inpatient treatment at community sites for R/R LBCL. *Blood Adv* 2024; 8 (23): 6114–612

33

Recognizing ICANS

- Symptoms and typical timeline
  - Word-finding difficulties
  - Change in attention
  - Confusion
  - Typically occurs during or shortly after CRS
- ICE Score
  - 10pt scoring system
- When to escalate
  - Educate caregivers on when to call
  - Worsening or new neurologic symptoms or changes

34

Outpatient management of Bispecific antibodies

35

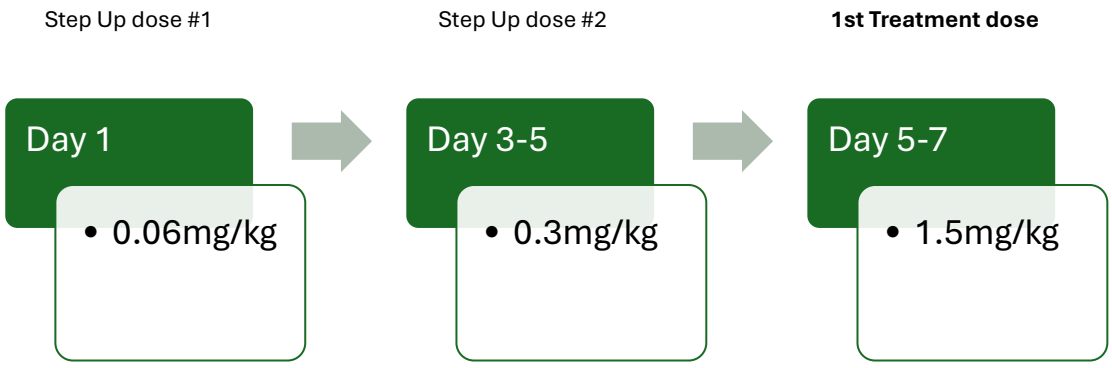
Bispecific step-up dosing

- Important to develop institutional SOPs for outpatient management
- Dosing in increasing increments to reduce CRS risk/severity
- Required for all BsAbs
- Pre-medication prior to each step up dose with:
  - Corticosteroid
  - Antihistamine
  - Antipyretic

NCCN, B-cell Lymphomas, Multiple Myeloma

36

Step-up dosing example [Teclistamab-MM]

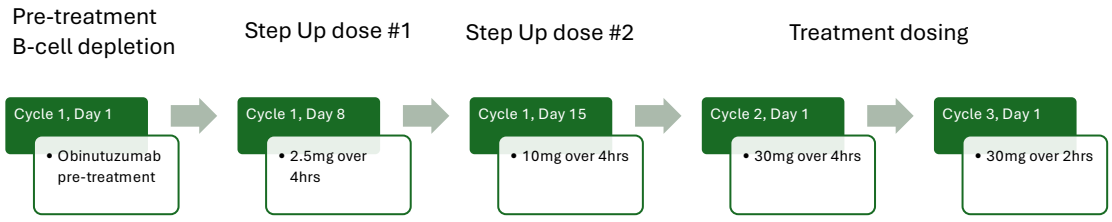


*Minimum 2 days between each dose
*If tolerated can begin weekly or biweekly dosing

Tecvayli package insert

37

Step-up dosing example [Glofitamab-NHL]



Columvi package insert

38

CRS outpatient management in BsAbs

Step-up dosing:

- Educate patients on signs and symptoms
- Establish clear communication pathways 24/7, caregiver available until tolerating treatment dose
- Should reside within close proximity of treatment center until step-up dosing is completed
- Grade 1 CRS may be able to be managed outpatient with close monitoring and Tylenol/Dexamethasone
- Grade 2 or higher is typically admitted, or fever in settings of neutropenia

Treatment doses:

- Once tolerating full dose subsequent doses can be given safely outpatient
- Outpatient feasibility is product dependent: Blinatumumab has higher rates of CRS and severe ICANS

Puttkammer et. al. Outpatient Management of Bispecific Related Toxicities: An Observational Study of Safety Outcomes and Resource Utilization. JCO Oncol Pract. 2025 Apr 15:OP2400930.

39

ICANS outpatient management in BsAbs

Less frequent, but important to recognize early

Patients and caregivers need education on signs and symptoms

Use of dexamethasone pre-medication reduces risk and severity of side effects

During step-up dosing will need admission for new ICANS

Ferreri, et al. Prophylactic dexamethasone (dex) with outpatient step-up dosing (SUD) of bispecific antibodies (BsAb) in multiple myeloma (MM) vs standard of care (SOC) inpatient observation.. *J Clin Oncol* **43**, e19506-e19506(2025)

40

Outpatient Step-up Dosing Candidate Considerations

- High risk BsAbs
  - Blinatumumab
- Previous Tox
  - Gr >/=2 CRS
  - Gr >/=2 ICANS
- Patient
  - Comorbidities
  - Disease burden

41

Immune function considerations

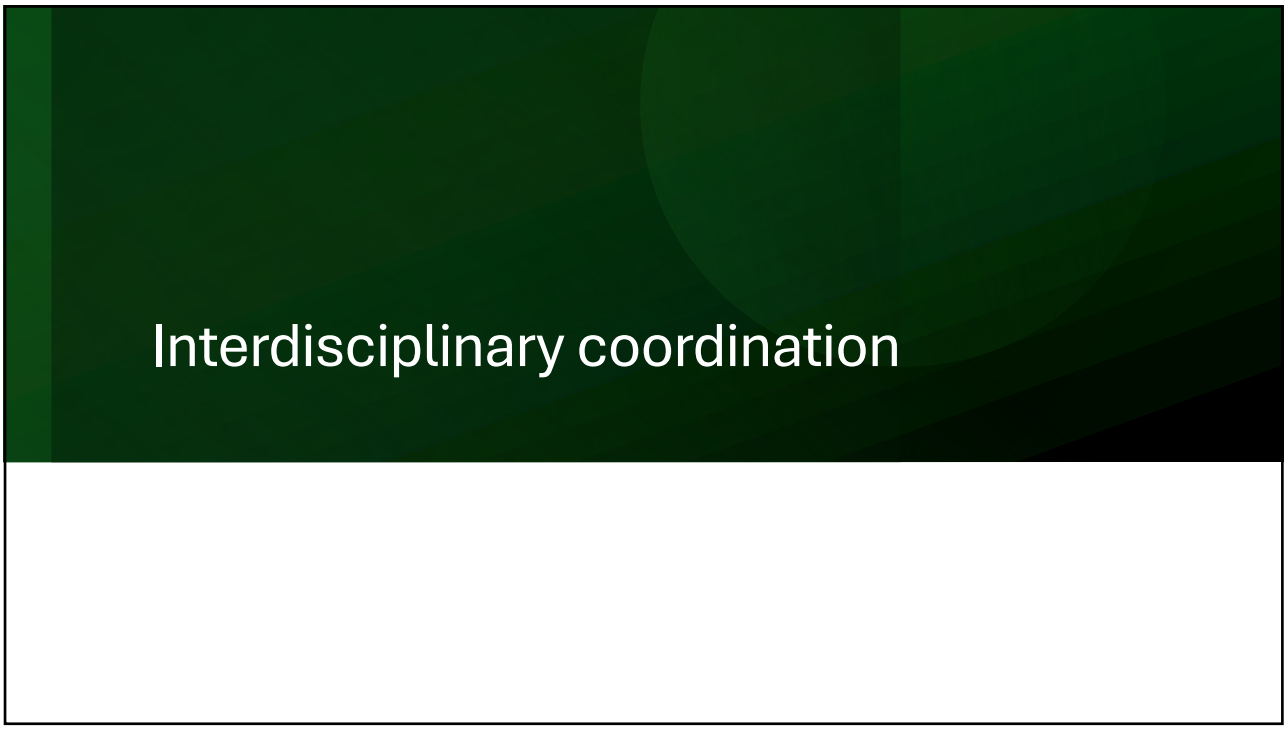
- Infection Prophylaxis (VZV, PJP, Neutropenia prophylaxis)
- Hypogammaglobulinemia:
  - IVIG for severe or recurrent infections in CAR-T pts
  - Empiric replacement in some Bispecifics
    - Multiple myeloma Bispecifics
- Immune Recovery:
  - Revaccination for CAR-T pts

Banerjee, et al. Immunoglobulin prophylaxis should be initiated after bispecific antibody therapy in multiple myeloma, regardless of IgG levels. Blood Adv. 2025 Sep 23;9(18):4720-4726.
Shahid, Zainab et al. Best Practice Considerations by The American Society of Transplant and Cellular Therapy: Infection Prevention and Management After Chimeric Antigen Receptor T Cell Therapy for Hematological Malignancies. Transplantation and Cellular Therapy, Volume 30, Issue 10, 955 - 969

42


Which of the following is the most common reason for unplanned hospitalization within the first week after outpatient CAR T-cell or bispecific antibody therapy?
Cytokine release syndrome (CRS)
0%
Tumor lysis syndrome
0%
Infection
0%
Disease progression
0%
Start the presentation to see live content. For screen share software, share the entire screen. Get help at pollev.com/app

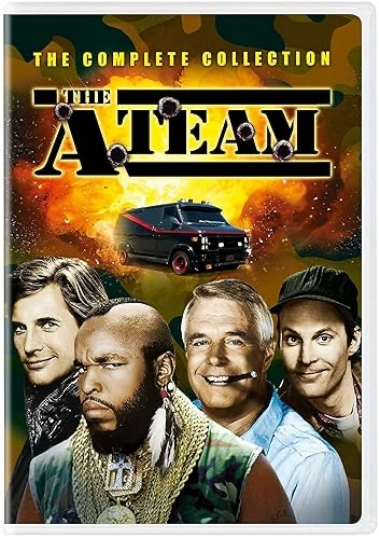
43


Interdisciplinary coordination

44

The Team

- Oncologists/Hematologists
- APPs
- Nurse Coordinators/Navigators
- Nurses
- Pharmacists
- Social Workers and Case Managers
- Critical Care/Emergency medicine
- Infectious disease
- Neurology
- Laboratory and Infusion services
- Radiology services
- Financial coordinators for reimbursement



45

Institutional protocols for dealing with toxicities

- ER education
  - Fast track or other means to ensure timely assessment and treatment
  - Process to ensure cell therapy team is notified
- Intensive Care Unit education
- Admission protocols (Day vs Night)
- Phone tree for patient (24/7)
- EMR designation as CAR-T patient
- Ensure availability of necessary medications (Ie Tocilizumab)

Donnellen, WB. Use of bispecific antibodies (BsAbs) in community practices: Key attributes to develop logistics and workflow for management of cytokine release syndrome (CRS). J Clin Oncol 42, 2024 (suppl 16; abstr e13575)

46

Effective Communication is a must!

- Symptom Triage Lines 24/7
- Shared EMR notes with clear documentation
- Clear hand-offs with responsibilities to community care teams
- Most guidance for protocolized communication pathways is geared for CAR-T therapy, protocols for newer bispecific antibodies is still evolving

NCCN: Management of CAR-T cell and Lymphocyte engager-related toxicities

47

Communication, continued

- Symptom and Triage escalation pathways
- Designation in EMR as high-risk patient
- Rapid means of receiving evaluation and treatment
  - Fast track ER vs Direct admissions to cell therapy teams

Myers GD, Verneris MR, Goy A, Maziarz RT. Perspectives on outpatient administration of CAR-T cell therapy in aggressive B-cell lymphoma and acute lymphoblastic leukemia. J Immunother Cancer. 2021 Apr;9(4):e002056

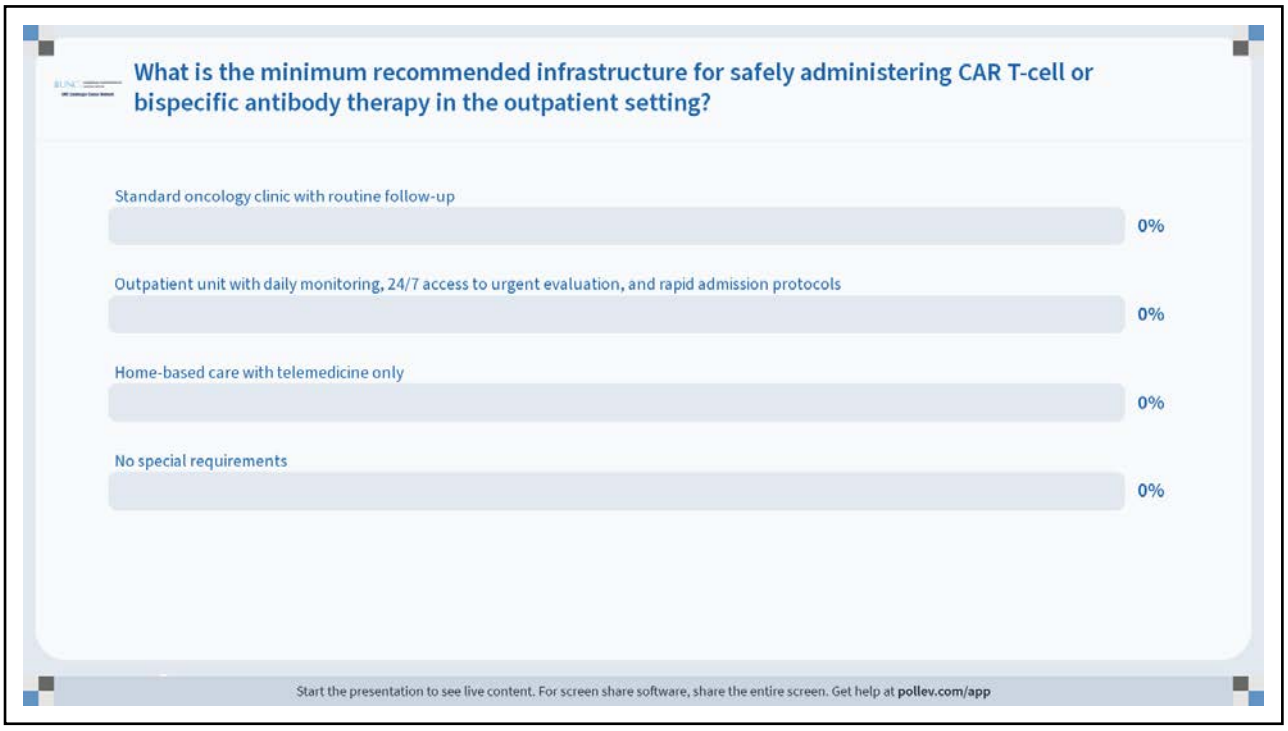
48

Community and Tertiary Care partnerships

- Timely and effective bi-directional communication is critical
- Standardized hand-off protocols
  - Disease monitoring
  - Immune recovery monitoring
  - Infection prophylaxis, treatment and revaccination
- Education of community partners
- Shared management for late and longterm complications
  - Some community clinics may not have needed resources
  - Same-day transfusion support, Pentamidine, etc

Donnellen, WB. Use of bispecific antibodies (BsAbs) in community practices: Key attributes to develop logistics and workflow for management of cytokine release syndrome (CRS). J Clin Oncol 42, 2024 (suppl 16; abstr e13575)

49



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Case Study: Outpatient CAR-T

- 45yo M with relapsed DLBCL
- **Treatment:** Lymphodepletion followed by CD19+ CAR-T therapy with Liso-cel given in outpatient infusion suite.
- **Monitoring:** Daily clinic visits with labs, vitals, and assessment by an APP to include ICE score
- At local lodging with caregiver, pt monitors temperature 3x/day
- On Day 5, patient calls triage line at 10pm with **Grade 1 CRS** (fever of 101.2F)
- **Management:** On-call provider calls pt and instructs to report to ER and puts in note, inpt charge nurse is notified so a bed can be made available

51

Case Study key important points

- Close outpatient monitoring
- Proximity to center and caregiver
- Pt education to recognize symptoms (fever)
- Clear contact instructions for pt
- Consistent hand-offs (Provider note to ER, charge nurse alert, contacting cell therapy inpatient team on arrival)
- CAR-T pt chart identification for ER

52

Case Study: Outpatient BsAb Step-up dosing

- 62-year-old woman with relapsed DLBCL
- **Treatment Plan:** Outpatient BsAb with 3-step step-up dosing (Day 1, 8, 15)
- **Monitoring:** Vitals q2h for 6 hours post-dose; caregiver at home for temperature checks
- Mild **Grade 1 CRS** (fever 38.4°C) after Dose 2
- **Management:** Acetaminophen + IV fluids; observed in clinic; symptoms resolved
- **Outcome:** Successfully escalated to full dose without further toxicity

53

Case Study Key important points

- BsAbs have lower rates of severe CRS and ICANS
- There is less concern of using Dexamethasone earlier when compared to CAR-T therapy
- Again, clear protocols for management are key

54

Conclusion

CAR-T and bispecifics are increasingly being given outpatient.

More centers are finding it's safe and doable, with similar outcomes to inpatient care—as long as the right support and protocols are in place.

Hansen, et al. The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review. Cancers (Basel). 2023 Dec 7;15(24):5746.

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57

Thank you!

Questions?

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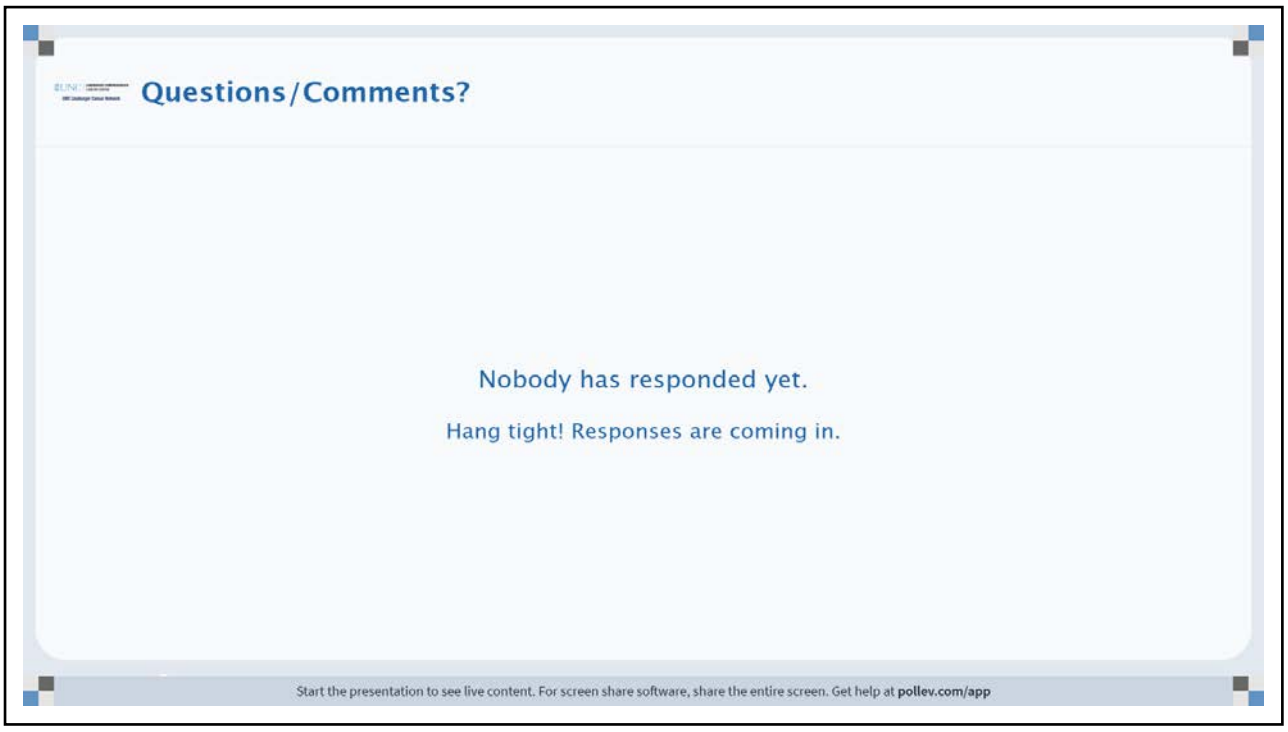
58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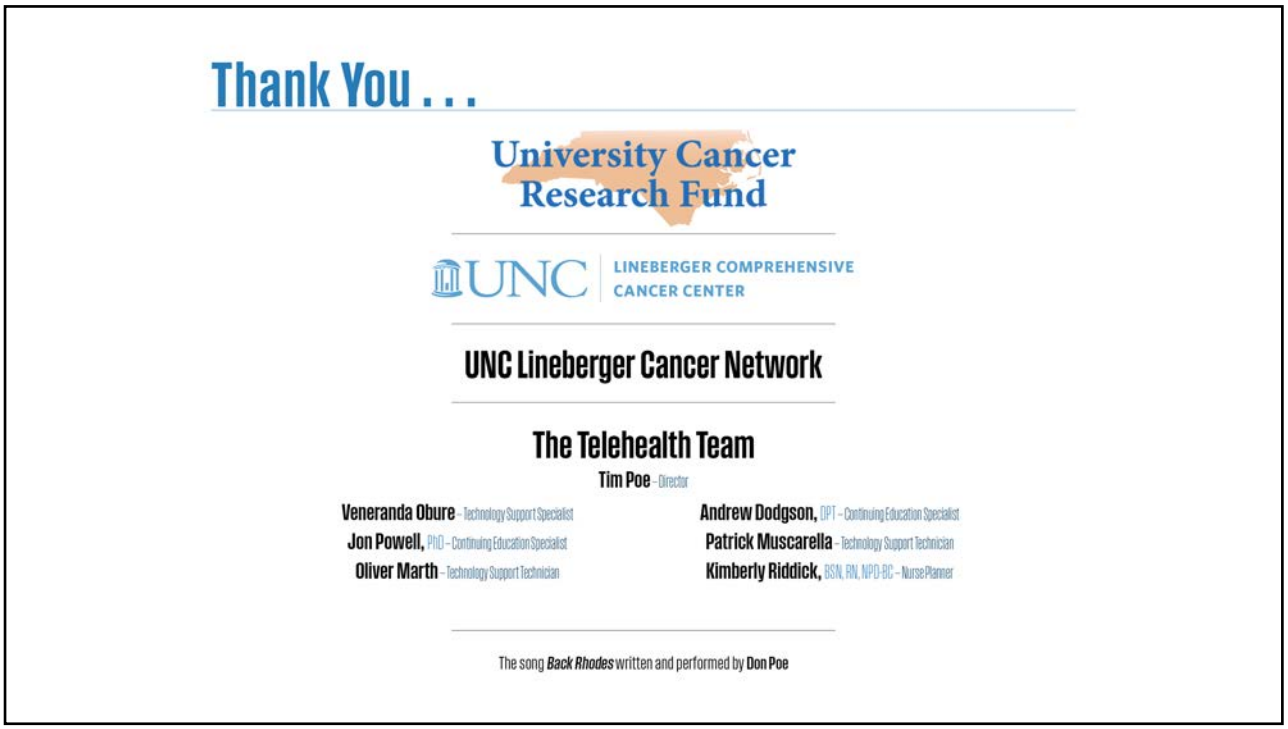
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60

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Gita Mody, MD, MPH

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Inaccurate Cancer Claims on Social Media
Alison Lazard, PhD

Southeastern American Indian Cancer Health Equity Partnership

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Rachel Denlinger, PhD, MPH

61

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Jeffrey Aldrich, MD

Patient-Centered Care

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Melissa Matson, MSN, RN, AGPCNP-BC, AOCNP

Advanced Practice Provider

Coping Skill Development for Health Care Providers Caring for Patients with Cancer
Melinda Manning, JD, MSW, CPC **Rachel Rifkin,** LCSW

62


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63