CAR T-CELL THERAPY IN PATIENTS OF ADVANCED AGE

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WELCOMING REMARKS

Elissa Baldwin
Sr. Manager, Education Programs
The Leukemia & Lymphoma Society

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SUPPORTER ACKNOWLEDGEMENT

This program is supported by:

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Cellular Therapy in Patients of Advanced Age

Peter Riedell, MD
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University of Chicago

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Disclosures

- Peter Riedell has served as a consultant and/or advisory board member for AbbVie, Novartis, BMS, ADC Therapeutics, Kite/Gilead, Sana Biotechnology, Nektar Therapeutics, Nurix Therapeutics, Intellia Therapeutics, CVS Caremark, Genmab, BeiGene, Janssen, and Pharmacyclics. He has served as a speaker for Kite Pharma and has received honoraria from Novartis. Research support from BMS, Kite Pharma, Novartis, MorphoSys, CRISPR Therapeutics, Calibr, Xencor, Fate Therapeutics, Genentech, and Tessa Therapeutics.

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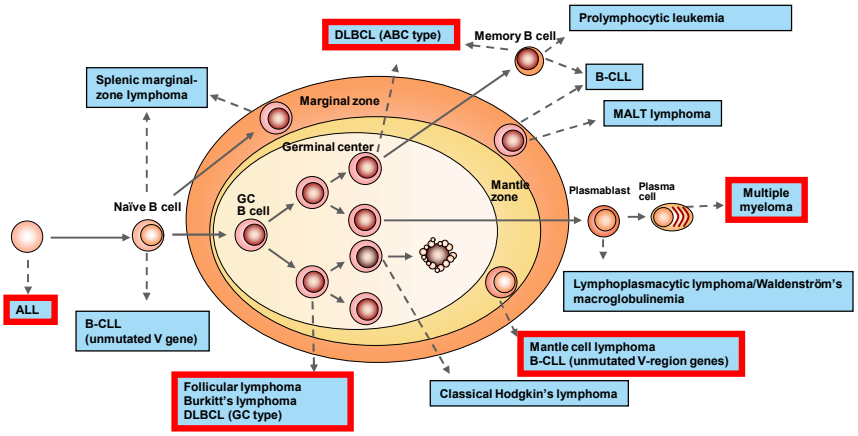
Hematologic Malignancies

B-Cell Lifecycle



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Küppers R. *Nat Rev Cancer.* 2005;5:251-262.

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Basic Stats in the US in 2023:

Non-Hodgkin Lymphoma (NHL)	Multiple Myeloma	Acute Lymphoblastic Leukemia (ALL)
• 80,550 *new cases* diagnosed	• 35,730 *new cases* diagnosed	• 6,540 *new cases* diagnosed
• Estimated 20,180 *deaths*	• Estimated 12,590 *deaths*	• Estimated 1,390 *deaths*
• Median age at diagnosis: **68 years**	• Median age at diagnosis: **69 years**	• Median age at diagnosis: **17 years**
• Estimated 5-year survival: **74.3%**	• Estimated 5-year survival: **59.8%**	• Estimated 5-year survival: **71.3%**

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SEER Cancer Stat Facts- 2023

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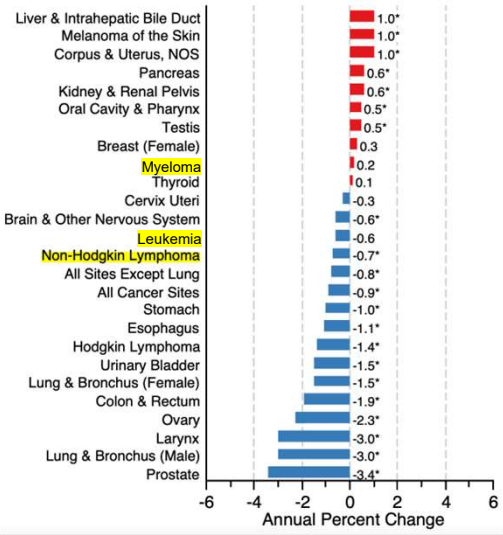
Incidence by Primary Cancer Site: 2009-2018



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Howlader N, et al. *SEER Cancer Statistics Review; 1975-2018.*

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Treatment Options for Myeloma, Lymphoma, and Leukemia

- Chemotherapy
- Radiation therapy
- Immunotherapy
  - Monoclonal antibodies
  - Antibody-drug conjugates
  - Bispecific antibodies
- Targeted agents
- Stem cell transplantation
- **Chimeric Antigen Receptor (CAR) T-cell therapy**

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Chimeric Antigen Receptor (CAR) T-cell Therapy

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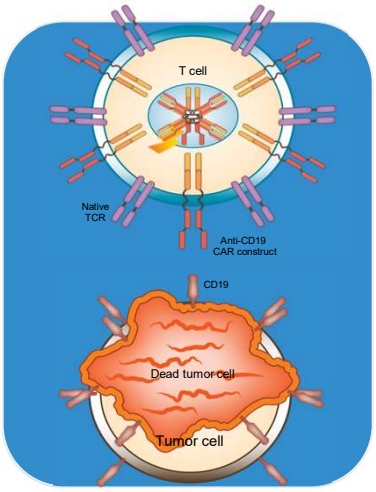
Chimeric Antigen Receptors (CAR) T-cells

- **Uses patients own cells**
- **Tumor specific**
- **Can be applied to multiple malignancies**



Courtesy of N. Frey

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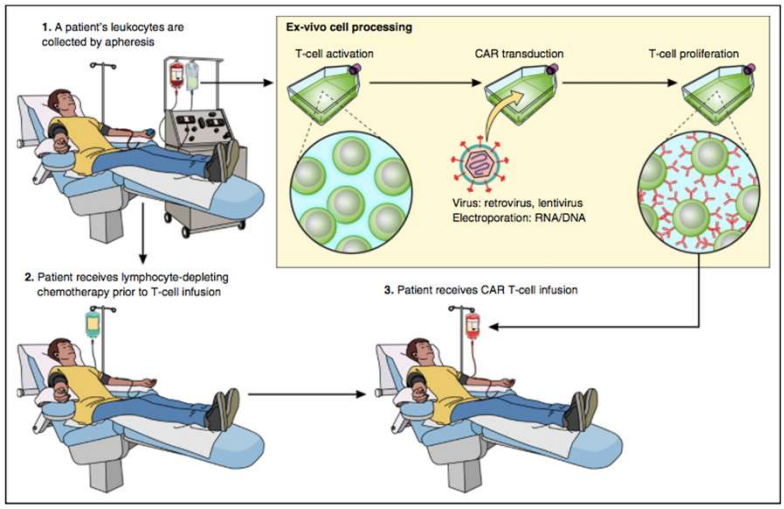
CAR T Cell Treatment



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Mikkilineni L, et al. *Blood*. 2017;130:2594

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FDA Approved CAR T Cell Products

- Axicabtagene ciloleucel (axi-cel)—Yescarta
  - Aggressive large B-cell lymphoma
  - Follicular lymphoma
- Tisagenlecleucel (tisa-cel)—Kymriah
  - Aggressive large B-cell lymphoma
  - Follicular lymphoma
  - Acute lymphoblastic leukemia- *pediatric*
- Lisocabtagene maraleucel (liso-cel)—Breyanzi
  - Aggressive large B-cell lymphoma
- Brexucabtagene autoleucel (brexu-cel)—Tecartus
  - Mantle cell lymphoma
  - Acute lymphoblastic leukemia- *adult*
- Idecabtagene vicleucel (ide-cel)—Abecma
  - Multiple myeloma
- Ciltacabtagene autoleucel (cilta-cel)—Carvykti
  - Multiple myeloma

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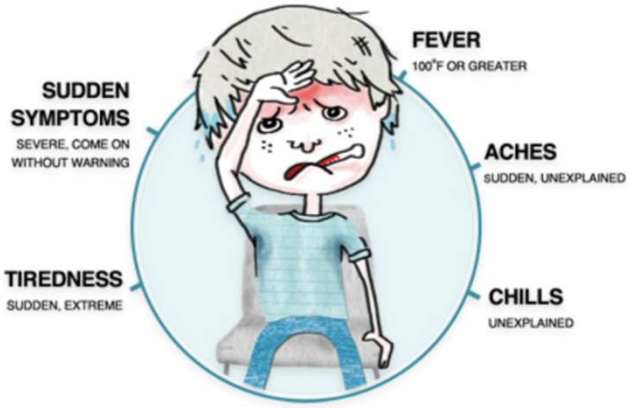
Cytokine Release Syndrome

•Symptoms similar to the Flu virus:



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Cytokine Release Syndrome (CRS)

•Occurs as a result of high-level immune system activation

•Massive release of signaling molecules from CAR T cells, and other cells

Clinical symptoms

Organ System	Symptoms
General	Fevers +/- shaking chills, fatigue, loss of appetite, muscle and joint aches, nausea, vomiting, headache
Skin	Rash
Gastrointestinal	Nausea, vomiting, diarrhea
Respiratory	Increased breathing rate, low oxygen saturation
Cardiovascular	Increased heart rate, low blood pressure, decreased heart function
Blood coagulation	Bleeding, bruising
Renal	Decreased urine output

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Adapted from Lee DW et al. Blood. 2014;124(2):188-195.

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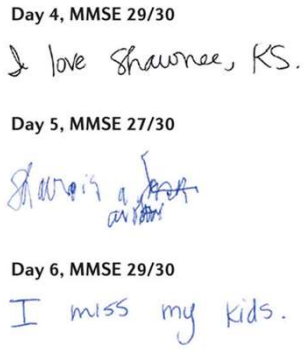
Neurologic Toxicity

•Can present with:

- Headache
- Mental status changes
- Confusion
- Word finding difficulties, loss of the ability to talk
- Hallucinations
- Tremor
- Lack of coordination
- Altered walking
- Seizures



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Neelapu SS et al. Nat Rev Clin Oncol. 2018;15:47-62.

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Guiding Principles of Patient Selection for CAR T-cell Therapy

- **Is there a likely therapeutic benefit?**
- **Is there an increased risk of toxicity?**
- **Is there sufficient physiologic reserve?**
  - Could the patient survive a "worst case scenario"?

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CAR T-cell Therapy in Aggressive Large B-cell Lymphoma Patients of Advanced Age

Characteristic	≥ 65y (N=24)	< 65y (N=77)	Overall (N=101)
Investigator-assessed ORR, n (%)	22 (92)	62 (81)	84 (83)
CR	18 (75)	41 (53)	59 (58)
PR	4 (17)	21 (27)	25 (25)
Ongoing response with ≥ 2 years follow-up, n (%)[a]	10 (42)	29 (38)	39 (39)
24-Month OS Rate, %	54%	49%	51%

[a]Patients in response as of data cutoff.
CR, complete response; ORR, objective response rate.

Patients ≥ 65 years old demonstrated similar rates of survival 2-years following CAR-T compared to those <65 years old

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Adapted from Neelapu SS, et al. ASCO Annual Meeting; 5/31/19-6/4/19; Chicago, IL. Abstract 7555.

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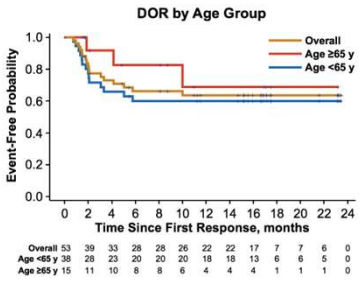
Change of Responding to CAR-T Therapy is Similar in Patients of Advanced Age with Aggressive Large B-cell Lymphoma

ORR Across Subgroups

ORR, 54% (95% CI, 43%-64%); 40% CR

		N	ORR, %
All patients	All patients	99	53.5
Age	<65 years	75	50.7
	≥65 years	24	62.5
Sex	Female	36	61.1
	Male	63	49.2
Prior response status	Refractory to last line	50	42.0
	Relapsed to last line	49	65.3
IPI at enrollment	<2 risk factors	27	59.3
	≥2 risk factors	72	51.4
Prior antineoplastic therapy	≤2 lines	52	51.9
	3 lines	29	62.1
	≥4 lines	18	44.4
Molecular subtype	Activated B-cell	45	55.6
	Germinal center	51	49.0
Prior autoSCT therapy	No	55	49.1
	Yes	44	59.1
Rearrangements in *MYC/BCL2/BCL6* genes	Double/triple hits	17	41.2
	Other	82	56.1
Tumor volume	<100 mL	50	56.0
	≥100 mL	31	35.5
	Unknown	18	77.8

0 20 40 60 80 100



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Schuster SJ, et al. ASH Annual Meeting; December 1-4, 2018; San Diego, CA. Abstract 1684.

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Toxicities with CAR-T Therapy are Similar in Patients of Advanced Age with Aggressive Large B-cell Lymphoma

AE, n (%)	≥ 65y (N=27)		< 65y (N=81)		Overall (N=108)	
	Any	Grade ≥3	Any	Grade ≥3	Any	Grade ≥3
Any CRS[b]	25 (93)	2 (7)	75 (93)	10 (12)	100 (93)	12 (11)
Any NE	21 (78)	12 (44)	51 (63)	23 (28)	72 (67)	35 (32)

Events shown include those with ≥10% Grade ≥3 events in either age group.
[b]CRS graded per modified Lee Criteria
[c]NEs graded per Common Terminology Criteria for Adverse Events, v 4.03
AE, adverse event; CRS, cytokine release syndrome; NE, neurologic event.

Patients ≥ 65 years old demonstrated similar rates of CRS following CAR-T compared to those <65 years old
- Slightly higher rates of neurologic toxicity

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Adapted from Neelapu SS, et al. ASCO Annual Meeting; 5/31/19-6/4/19; Chicago, IL. Abstract 7555.

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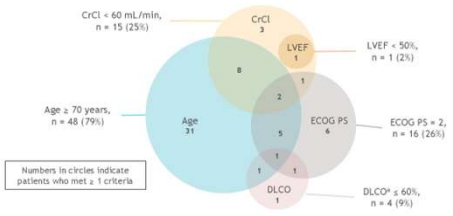
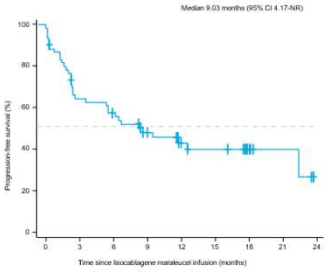
CAR T-cell Therapy in Patients with Advanced Age and/or Comorbidities with Aggressive Large B-cell Lymphoma

Rationale Transplant Not Intended



- Kidney function
- Heart function
- Lung function
- Fitness (i.e., performance status)
- Age

Progression-free Survival



Overall Response rate: 80%
Complete Response rate: 54%

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Sehgal A, et al. Lancet Oncol. 2022;23(8):1066-1077.
Sehgal A, et al. Poster presented at: 2022 American Society of Clinical Oncology Annual Meeting; June 3-7, 2022; Chicago, IL & Online.

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Impact of Age on Outcomes after CD19 Directed CAR-T for Aggressive Large B-cell Lymphoma

Less than 25% of the patients enrolled in CAR-T trials were ≥65 years

- Large CIBMTR analysis of 1916 patients
  - 44% were >65 years

Findings:

- Age did not impact survival, the chance of experiencing cancer relapse, or severity of CRS
  - Notably there was a lower risk of disease progression/relapse in patients 65-74 years of age
- There was an increased risk of neurologic toxicity in patients of advanced age

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Mirza A-s, et al. *Blood.* 2022;140:4633-4635.

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CAR-T Therapy in Mantle Cell Lymphoma

Table 1. Baseline characteristics of patients who received brexu-cel infusion (n=93)

Variables	Number	Variables	Number
Age, median (range)	67 (34-89)	**Disease status**	
Sex, male	75 (81%)	Relapsed after last line	52 (56%)
ECOG PS, ≥2	8 (9%)	Refractory to last line	41 (44%)
Simplified MIPI		**Not meeting ZUMA-2 eligibility**	68 (73%)
Low risk (0-3)	30 (12%)	**Reasons for ZUMA-2 ineligibility**	
Intermediate risk (4-5)	52 (56%)	ECOG PS ≥2	8 (9%)
High risk (6-11)	11 (32%)	CNS involvement by lymphoma	6 (7%)
Ki-67, ≥30%	66/86 (77%)	No prior BTKi	17 (18%)
Histology		Prior lines of therapy >5	10 (11%)
Classic	46/84 (55%)	Prior AlloSCT	4 (4%)
Blastoid/pleomorphic	38/84 (45%)	Prior anti-CD19 therapy	1 (2%)
***TP53* mutation or deletion**	31/67 (46%)	No prior CD20 antibody /anthracycline/bendamustine	1 (2%)
Complex karyotype	8/28 (29%)	ANC <1000/μL	5 (5%)
Stage, III-IV	81/92 (88%)	Platelet <75,000/μL	5 (5%)
CNS involvement	6/84 (7%)	ALC <100/μL	1 (2%)
Bone marrow involvement	25/57 (44%)	Creatinine >1.5 mg/dL	9 (10%)
Bulky disease (≥10 cm)	10 (11%)	Total bilirubin >1.5 mg/dL	3 (3%)
Prior therapies		AST/ALT >2.5xULN	1 (2%)
Total lines, median (range)	3 (1-9)	Another malignancy	4 (4%)
Prior CD20 antibody	92 (99%)	LVEF ≤50%	3 (3%)
Prior anthracycline or bendamustine	80 (86%)	Pericardial effusion	3 (3%)
Prior cytarabine	42 (45%)	CNS disorder (e.g., seizure, stroke, etc.)	2 (2%)
Prior AutoSCT	25 (27%)	Requiring steroids for another medical condition	2 (2%)
Prior rituximab maintenance	40 (43%)	HIV/Hepatitis B/ Hepatitis C	2 (2%)
Prior BTKi	76 (82%)	Pleural effusion	1 (2%)
Prior lenalidomide	21 (23%)	Active infection requiring IV antibiotics	2 (2%)
Prior venetoclax	30 (32%)		

- Analysis included patients up to the age of 89
- 73% of patients in this analysis would have been ineligible for the original clinical trial
- This study showed similar effectiveness and safety compared to the clinical trial

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Wang Y, et al. *Blood.* 2021;138(suppl 2):Abstract #744

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Considerations for Cellular Therapy in Adults of Advanced Age

Older patient may not tolerate severe CRS or neurologic toxicity

- Baseline comorbidities
- Neurologic dysfunction (prior stroke, history of seizure disorder)

Patients present with active and often growing cancer

- Ongoing toxicities from recent anti-cancer treatment
- Patients may have abnormalities in their cardiac, pulmonary, hepatic, renal, or hematologic systems

Discern etiology of impairments

- Is poor performance status *disease related* (and possibly reversible)?
- Secondary to other co-morbidities?

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Considerations for Cellular Therapy in Older Adults

Treatment Considerations

- 24/7 caregiver during hospitalization
  - Active member of the medical team
  - Consider back-up caregiver
- Reduce fludarabine dose in the setting of kidney dysfunction
- Consider earlier/preemptive use of medications to treat CRS and neurologic toxicity

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CAR T-cell Therapy in Older Adults: Summary

Age is NOT a barrier

- Data show the safety and effectiveness of CAR-T is largely similar in older adults
- Be mindful of relevant comorbidities

Utilize multidisciplinary GA to discern impairments and optimize as able

- Are impairments secondary to disease or co-morbidities?
- Early referral to cardio-oncology, neurology, ID, etc.
- Proceed with speed due to disease status

Bolster support with 24/7 caregiver during hospital stay

Consider altering treatment (i.e. LD chemo) and toxicity management in light of relevant medical comorbidities

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CAR-T Therapy in Older Adults

Mariam Nawas MD
Leukemia & Lymphoma Society
6.28.23

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CAR-T therapy is underutilized in older adults

- Relapsed blood cancers treated by CAR-T are diseases of older adults
  - Average age of diagnosis of MM: 69-70 years
  - Average age of diagnosis of DLBCL: 67-70 years
- Yet older adults far less likely to receive CAR-T
  - In recent years:
    - 44% of patients who received commercial CAR-T for DLBCL >65 years*
    - 10% >75 years*

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*Mirza et al. ASH 2022 abstract – Impact of age on Outcomes after CD19 Directed CART for LBCL

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Determining candidacy of older adults for CAR-T is a challenge
Barriers: lack of tools to predict toxicity & outcomes
What role does frailty play?

- **"Fit for CAR-T"** is undefined
  - Barriers: lack of clinical tools to predict toxicity & outcomes
- **Frailty** more informative than chronological age in determining patient fitness for CAR-T

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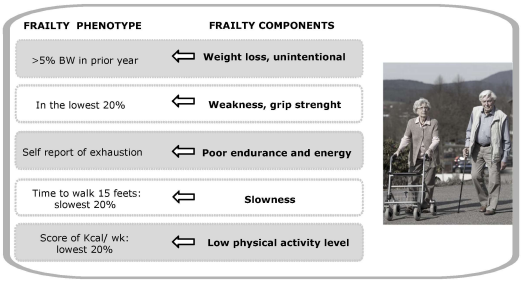
Frailty: weight loss, weakness, fatigue, slow mobility, decreased activity, Frailty impacts outcomes after CAR-T

- Frailty is an aging-related syndrome of diminished physiologic reserve
- Frailty phenotype defined by presence of ≥3:
  - Unintentional weight loss, weakness, exhaustion, slow mobility, and decreased activity



Garcia-Gimenez et al. *Int. J. Environ. Res. Public Health* 2021

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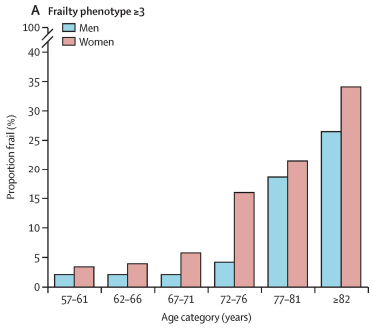
Frailty and age are related but not the same
You can be young and frail, or old and fit



Age is not the best determinant of patient fitness and ability to tolerate medical stressors

Hoogendijk et al *The Lancet* 2019

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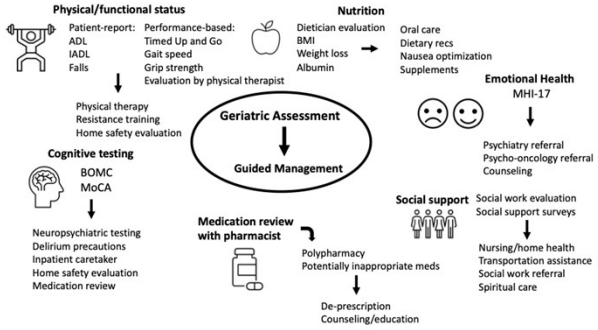
Frailty can be measured by geriatric assessment
Geriatric assessment involves multiple domains of health



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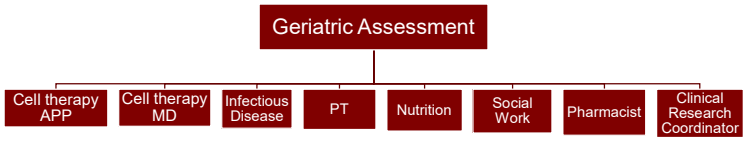
~~Transplant~~ Cell Therapy Optimization Program @ UCM

Pts ≥70 yrs are evaluated in our multidisciplinary clinic prior to admission



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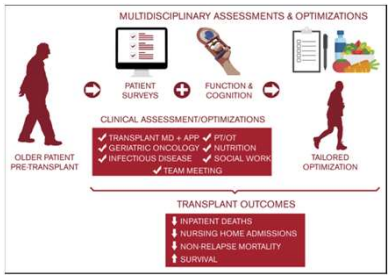
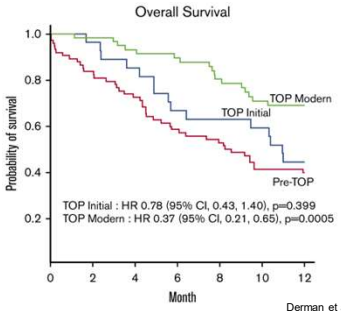
~~Transplant~~ Cell Therapy Optimization Program @ UCM

Enabling Older Adults to Have Access to Cell Therapy with Better Outcomes

Since 2013, >500 patients evaluated in our clinic (transplant and CAR-T)





Derman et al, Blood Adv. 2019

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What is the value of geriatric assessment in older adults treated with CAR-T?

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Multidisciplinary clinic recommendations and implementation

N = 58 pts

- Yes 45 pts (41)
- No 5 pts (2)
- Defer 8 pts (7)

Receipt of CAR-T:

Yes	No
50 (41 Y, 9 N/D)	8

92% were ≥ 70 yo

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We found significant differences in treatment outcomes based on treatment recommendation

- Compared to pts recommended D/N, pts recommended Y had:
  - shorter length of stay (median: 17 vs 23 days)
  - less likely to require rehab after discharge (10% vs 56%)
  - fewer ICU admissions: 2/39 (Y) vs 4/9 (D/N)

Y: recommended yes; D/N: recommended defer/no

Yates et al. TCT 2022 Abstract

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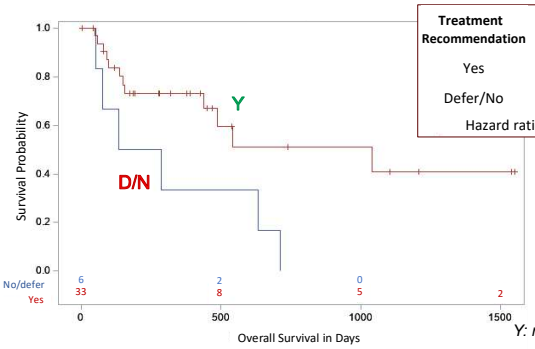
Overall survival among pts receiving anti-CD19 CAR-T differed based on TOP recommendation



Treatment Recommendation	Median Overall Survival (95% CI) *mo*
Yes	35.7 (15.4 - not reached)
Defer/No	8.7 (3.6 - 24.2)

Hazard ratio for death, 3.03 (95% CI, 1.10 – 8.37)

p=0.021

Y: recommended yes; D/N: recommended defer/no

Yates et al. TCT 2022 Abstract

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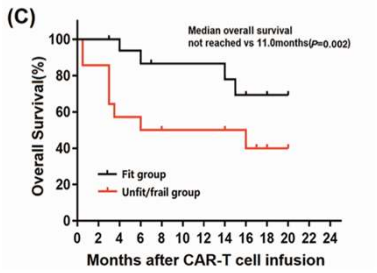
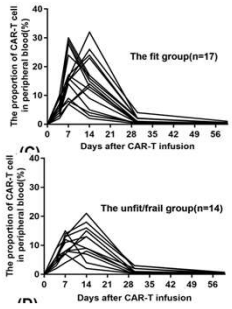
Other studies also show the impact of frailty on CAR-T outcomes





- Impaired CAR T-cell expansion in frail vs fit patients
- Frail patients suffered inferior responses and survival

Zhang et al Leukemia & Lymphoma 2022

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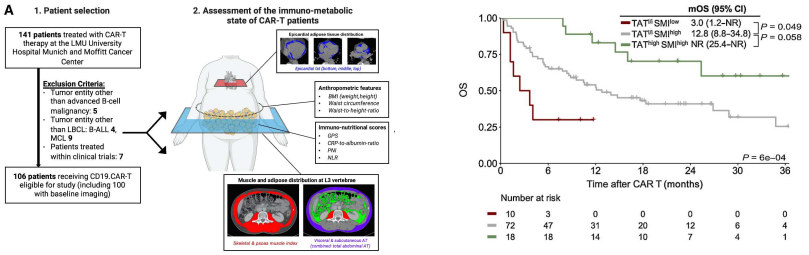
Body composition + nutritional status impacts survival after CAR-T



- ⬆ abdominal adipose & muscle tissue associated with excellent survival after CAR-T
- Nutritional markers associated with survival

Rejeski et al Cancer Immunol Res. 2023

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Comorbidities can influence outcomes after CAR-T…

» Comorbidity index:
- **Respiratory**, **upper GI**, **renal**, **hepatic** systems had strongest impact on survival
- High comorbidity score was associated with worse survival, higher rates of severe CRS and more relapse-related mortality

Category	Sample Medical Condition
Respiratory (Severe, CIRS score >2)	Oral steroids or daily prn inhalers, acute pneumonia, supplemental oxygen or ventilation support, lung or pleural neoplasm, 50 or more pack-year smoking history
Upper GI (Severe, CIRS score >2)	Documented PUD, acute or chronic pancreatitis, melena, prior gastric cancer, history of perforated ulcer
Renal (Severe, CIRS score >2)	Serum creatinine >3 mg/dl, active pyelonephritis, nephritic syndrome, colic symptoms, dialysis, renal carcinoma
Hepatic (Severe, CIRS score >2)	Active or chronic hepatitis/cirrhosis, marked elevation of transaminases or bilirubin (>3x ULN), acute cholecystitis, biliary obstruction, any liver or biliary tree carcinoma

Comorbidity scores poorly correlate with performance status in adult cancer patients

Shouse et al Blood Advances 2023

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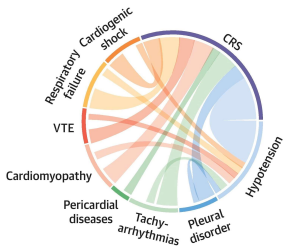
…but they usually are not prohibitive

- Patients treated with CAR T may experience heart > lung complications, primarily during CRS.
- **Among patients with good functional status, cardiac & pulmonary comorbidities should not prevent patients from being offered CAR-T**
- We obtain baseline ECG and echo, but **we do not use specific EF cut off and focus more on general functional status, NY Heart Association functional status, and heart failure history**
- We usually do not advocate delaying CAR T specifically for optimization, **unless a patient is clearly not a candidate because of poor functional status and decompensated/end-stage cardiac or pulmonary comorbidities**. However, if there is a possibility that some of the comorbidities can be reversed/optimized, and patient does not require immediate treatment, CAR-T may be delayed with future reevaluation



Gutierrez Blood 2023

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Conclusions

- Frailty more informative than chronological age in determining patient fitness for CAR-T
- Based on available data, older patients (>65 years) are just as likely to benefit from CAR-T as younger patients
- A strict upper age limit for this type of treatment does not exist

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LLS EDUCATION & SUPPORT RESOURCES

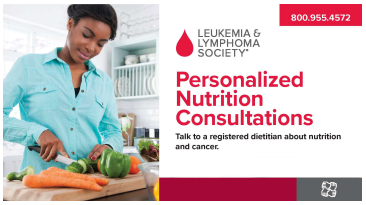
HOW TO CONTACT US:

To contact an **Information Specialist** about disease, treatment and support information, resources and clinical trials:

Call: (800) 955-4572
Monday to Friday, 9 a.m. to 9 p.m. ET

Chat live online: www.LLS.org/InformationSpecialists
Monday to Friday, 10 a.m. to 7 p.m. ET

Email: www.LLS.org/ContactUs
All email messages are answered within one business day.



NUTRITION CONSULTATIONS
Our registered dietitian has expertise in oncology nutrition and provides free one-on-one consultations by phone or email.

www.LLS.org/Consult

CLINICAL TRIAL SUPPORT CENTER
Work one-on-one with an LLS Clinical Trial Nurse Navigator who will help you find clinical trials and personally assist you throughout the entire clinical-trial process.

www.LLS.org/Navigation

LEUKEMIA & LYMPHOMA SOCIETY

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LLS EDUCATION & SUPPORT RESOURCES

Online Chats

Online Chats are free, live sessions, **moderated by oncology social workers**. To register for one of the chats below, or for more information, please visit www.LLS.org/Chat

Education Videos

Community of blood cancer patients, survivors and caregivers supporting each other and giving trusted information and resources, please visit www.LLS.org/EducationVideos

Patient Podcast

The Bloodline with LLS is here to remind you that after a diagnosis comes hope. To listen to an episode, please visit www.TheBloodline.org

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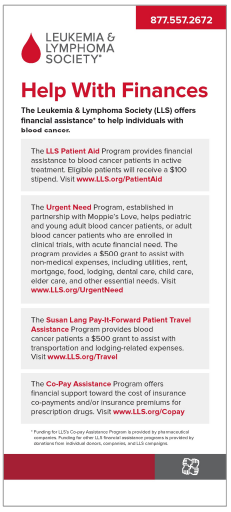
LLS EDUCATION & SUPPORT RESOURCES


877.557.2672

LEUKEMIA & LYMPHOMA SOCIETY®

Help With Finances

The Leukemia & Lymphoma Society (LLS) offers financial assistance[1] to help individuals with blood cancer.

The **LLS Patient Aid** Program provides financial assistance to blood cancer patients in active treatment. Eligible patients will receive a $100 stipend. Visit **www.LLS.org/PatientAid**

The **Urgent Need** Program, established in partnership with Moppie's Love, helps pediatric and young adult blood cancer patients, or adult blood cancer patients who are enrolled in clinical trials, with acute financial need. The program provides a $500 grant to assist with non-medical expenses, including utilities, rent, mortgage, food, lodging, dental care, child care, elder care, and other essential needs. Visit **www.LLS.org/UrgentNeed**

The **Susan Lang Pay-It-Forward Patient Travel Assistance** Program provides blood cancer patients a $500 grant to assist with transportation and lodging-related expenses. Visit **www.LLS.org/Travel**

The **Co-Pay Assistance** Program offers financial support toward the cost of insurance co-payments and/or insurance premiums for prescription drugs. Visit **www.LLS.org/Copay**

[1] Funding for LLS's Copay Assistance Program is provided by pharmaceutical companies. Funding for other LLS financial assistance programs is provided by donations from individual donors, companies, and LLS campaigns.

The Leukemia & Lymphoma Society (LLS) offers the following financial assistance programs to help individuals with blood cancer: **www.LLS.org/Finances**

To order free materials: **www.LLS.org/Booklets**

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