TREATING ADOLESCENTS AND YOUNG ADULTS (AYA) WITH BLOOD CANCER

October 11, 2023

WELCOME AND INTRODUCTIONS

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Senior Manager, Professional Education Programs
The Leukemia & Lymphoma Society
Rye Brook, NY
**SPEAKERS**

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Emory University School of Medicine  
Director, Leukemia and Lymphoma Program  
Aflac Cancer and Blood Disorders Center  
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Institute for Cancer Outcomes and Survivorship  
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University of Alabama at Birmingham  
Birmingham, AL

**DISCLOSURES**

Sharon M. Castellino, MD, MSc, has a financial interest/relationship or affiliation in the form of:  
Advisory Board/Consultant: Bristol Myers Squibb

The following relationships have ended within the last 24 months:  
Advisory Board/Consultant: Seagen Inc.

Unlabeled Uses in Pediatrics  
Nivolumab  
Brentuximab vedotin (BV) (approved in high-risk; front line)  
Pembrolizumab (approved in rr/HL)

Julie Anna Wolfson, MD, MSHS, has no relevant financial relationships with ineligible companies to disclose for this educational activity.
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Lauren Berger, MPH
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TARGET AUDIENCE

This activity is intended for hematologist/oncologists, nurses, social workers, and other healthcare professionals involved in the care of patients with blood cancer.

EDUCATIONAL OBJECTIVES

After completing this activity, the participant should be better able to:

• Describe blood cancers common in adolescent and young adults (AYAs)
• Identify signs and symptoms of common blood cancers in AYAs and diagnostic tests used
• Explain treatment options, including new and emerging data and the role of clinical trials
• Discuss the management of short and long-term effects, as well as unique considerations for AYAs
• List resources to support patients and their caregivers
CE DESIGNATION

Accreditation, Credit and Support
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Nursing Continuing Professional Development
Approval for nurses has been obtained by the National Office of The Leukemia & Lymphoma Society under Provider Number CEP 5832 to award 1.0 continuing education contact hour through the California Board of Registered Nursing.

Social Worker Continuing Education
The Leukemia & Lymphoma Society (LLS) Provider Number 1105, is approved as an ACE provider to offer social work continuing education by the Association of Social Work Boards (ASWB) Approved Continuing Education (ACE) program. Regulatory boards are the final authority on courses accepted for continuing education credit. ACE provider approval period: 12/10/2020-12/10/2023. Social workers completing this course receive 1.0 clinical continuing education credit.

The Leukemia & Lymphoma Society (LLS) is recognized by the New York State Education Department's State Board for Social Work as an approved provider of continuing education for licensed social workers #0117. LLS maintains responsibility for the program. Social workers will receive 1.0 clinical CE contact hour for this activity.

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This activity was planned by and for the healthcare team, and learners will receive 1.0 Interprofessional Continuing Education (IPCE) credit for learning and change.

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Providers
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Learners must participate in the entire CE activity and submit the online evaluation form to earn credit, by clicking the link at the end of the presentation. Once submitted, the certificate will be generated. If you have questions regarding your certificate, please contact via email at ndane@mlieducation.org.
Adolescents and Young Adults (AYA) with Blood Cancer

The Leukemia & Lymphoma Society

Julie Anna Wolfson, MD, MSHS
Associate Professor, Pediatric Hematology-Oncology
Member, Institute for Cancer Outcomes and Survivorship
Director, AYA Oncology & Oncofertility Program
October 11, 2023

Polling Question #1

What is the NCI definition of an adolescent or young adult (AYA)?

a) 15 years – 39 years
b) 15 years – 24 years
c) 12 years – 21 years
d) 12 years – 24 years
e) They act like a teenager
Adolescents and Young Adults (AYA) with Cancer

- Share diagnoses with older and/or younger patients

Have not seen same improvement in survival over time

AYA GAP

What Blood Cancers are AYAs Diagnosed with?

Rates of New Cases by Cancer Type and Sex

<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>0</td>
</tr>
<tr>
<td>20</td>
<td>5</td>
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<tr>
<td>15</td>
<td>0</td>
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<tr>
<td>10</td>
<td>11.6</td>
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<td>5</td>
<td>4.4</td>
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<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Breast</td>
<td>0</td>
</tr>
<tr>
<td>Thyroid</td>
<td>5</td>
</tr>
<tr>
<td>Testis</td>
<td>0</td>
</tr>
<tr>
<td>Melanoma of the skin</td>
<td>4.6</td>
</tr>
<tr>
<td>Colon and rectum</td>
<td>3.9</td>
</tr>
<tr>
<td>New-Hodgkin Lymphoma</td>
<td>3.5</td>
</tr>
<tr>
<td>N/A</td>
<td>5.1</td>
</tr>
<tr>
<td>4.4</td>
<td>3.2</td>
</tr>
<tr>
<td>4.1</td>
<td>3.2</td>
</tr>
<tr>
<td>3.5</td>
<td>3.5</td>
</tr>
<tr>
<td>Non-Hodgkin Lymphoma</td>
<td>3.4</td>
</tr>
<tr>
<td>Leukemia</td>
<td>3.4</td>
</tr>
<tr>
<td>Hodgkin Lymphoma</td>
<td>3.4</td>
</tr>
<tr>
<td>Cervix</td>
<td>6.4</td>
</tr>
<tr>
<td>Brain &amp; ONS</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Estimated New Cancers Among AYAs in the U.S. in 2023: 65,980

% of All New Cancer Cases at Any Age: 4.4%

Age-adjusted rates of new cases per 100,000. SEER 22, 2016–2026.

Cancer interrupts AYA physical, mental, social development

Unique needs

HRQOL

Outcomes

Disease Outcomes
- Relapse
- Survival

Health-related Quality of Life (HRQL)
- Physical function
- Social function
- Fatigue
- Distress
- Financial
- Employment/Education

The Donabedian model for quality of care

Who treats AYAs with cancer?

Adult Oncology

Pediatric Oncology

UAB

Children’s
Outcomes

- Disease Outcomes
  - Relapse
  - Survival

Health-related Quality of Life (HRQL)
- Physical Function
- Social function
- Fatigue
- Distress
- Financial
- Employment/ Education

Facility/Practice Model*
- (Adult / Pediatric Oncology)
- Yeager JPHO 2006; Howell JCO 2007; Albrighton JCO 2007; Sproaker-Perlman JAYAO 2018; Muffy, Blood Adv 2018

Facility/Practice Size

Healthcare Process
- Bleyer 2006; Bleyer PBC 2010; Muffy Blood Adv 2018; Gupta PBC 2021

Access to Care

Patient Factors

- Healthcare Factors
  - Yeager JPHO 2006; Howell JCO 2007; Albrighton JCO 2007; Sproaker-Perlman JAYAO 2018; Muffy, Blood Adv 2018

Patient Location

Treatment Site:

- Healthcare Factors
  - Yeager JPHO 2006; Howell JCO 2007; Albrighton JCO 2007; Sproaker-Perlman JAYAO 2018; Muffy, Blood Adv 2018

Healthcare Structure

- Yeager JPHO 2006; Howell JCO 2007; Albrighton JCO 2007; Sproaker-Perlman JAYAO 2018; Muffy, Blood Adv 2018

Patient + Location

Summary*

- AYA patients diagnosed with cancer should be recognized as a distinct age group that has unique medical and psychosocial needs.

- Strongly consider a referral for treatment at a cancer center with expertise in management of AYAs and have access to clinical trials for AYAs, particularly for pediatric cancer types.

NCCN Guidelines

- NCICCC/COG: NCI-designated Comprehensive Cancer Center or Children’s Oncology Group Institution

11/15/2023

**Outcomes**

<table>
<thead>
<tr>
<th>Disease Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relapse</td>
</tr>
<tr>
<td>Survival</td>
</tr>
</tbody>
</table>

**Health-related Quality of Life (HRQL)**

- Physical function
- Social function
- Fatigue
- Distress
- Financial
- Employment/Education

**Access to Care**

<table>
<thead>
<tr>
<th>Patient Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Site: Healthcare Factors</td>
</tr>
<tr>
<td>Facility/Practice Model</td>
</tr>
<tr>
<td>Pediatric / Adult Oncology</td>
</tr>
<tr>
<td>Facility/Practice Size</td>
</tr>
<tr>
<td>NCI Designation</td>
</tr>
<tr>
<td>Comprehensive Cancer Center</td>
</tr>
<tr>
<td>Children’s Oncology Group site</td>
</tr>
</tbody>
</table>

**Healthcare Process**

**Healthcare Structure**

<table>
<thead>
<tr>
<th>Facility/Practice Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric / Adult Oncology</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Facility/Practice Size</th>
</tr>
</thead>
</table>

**NCI Designation**

| Comprehensive Cancer Center |
| Children’s Oncology Group site |

**Patient Factors**

**Location**

- Access to Care
- Patient + Location

**Healthcare Factors**

- Treatment Site: Healthcare Factors
- Patient Factors

**Lower Odds of Care at NCICCC/COG**

- Patients ≤21yo
- Age alone

**22-39y: malignancies common to children/ AYAs**

- Public / No Insurance
- Low SES
- Distance from the nearest age-appropriate NCICCC/COG

**22-39y: adult-onset malignancies (AYAs)**

- African-American/Black
- Hispanic/Latino
- Public Insurance
- No Insurance
- Low SES
- Distance from the nearest age-appropriate NCICCC/COG


**NCICCC/COG: NCI-designated Comprehensive Cancer Center or Children’s Oncology Group Institution**
AYA Progress Review Group
NCI + Lance Armstrong Foundation
Closing the Gap: Research & Care Imperatives for AYAs with Cancer

AYA Discipline Committees

Children’s Oncology Group
Southwest Oncology Group
Alliance for Clinical Trials in Oncology

2022 Joint Adult + Pediatric NCTN/SARC AYA Clinical Trials Sarcoma Working Group
Whiteway et al., JAYAO 2023

Launched 2014 (est. 2010)
NCI National Clinical Trials Network
- Focus on increasing awareness of trials for AYAs
- 4 medical oncology, 1 pediatric oncology, 1 international group
- Proportion of CTEP treatment trials represented by AYAs pre/post-creation of NCTN: 9.5% (95% CI, 7.6-11.8) vs. 14.0% (95% CI, 9.9-18.3). Mean difference in proportions: 4.4% (0.7%-8.3%).

Sankaran...Seibel (Cancer, 2022)
Cancer.gov

CTEP: Cancer Therapy Evaluation Program

NCTN Adolescent to Young Adult (AYA) Cancer Trials Portfolio (Open as of 9/15/2023)

<table>
<thead>
<tr>
<th>Newly Diagnosed Disease</th>
<th>Recurrent Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhabdomyosarcoma (RMS)</td>
<td>Acute Lymphoblastic Leukemia (ALL)</td>
</tr>
<tr>
<td>ARST2001 (mp ris)</td>
<td>AML1501</td>
</tr>
<tr>
<td>Osteosarcoma (Pulmonary Met.)</td>
<td>Osteosarcoma (Metastatic)</td>
</tr>
<tr>
<td>AOS1203</td>
<td>AOS1202</td>
</tr>
<tr>
<td>Osteosarcoma (Metastatic)</td>
<td>Classical Hodgkin Lymphoma</td>
</tr>
<tr>
<td>AOS1203</td>
<td>ACHN2001</td>
</tr>
<tr>
<td>Classical Hodgkin Lymphoma</td>
<td>Mediastinal (thymic) large B-cell lymphoma</td>
</tr>
<tr>
<td>ACHN2001</td>
<td>ACHN2001</td>
</tr>
</tbody>
</table>

Legend by Disease Types
- Blue = ALL
- Lime Green = Osteosarcoma
- Light Purple = CNS NOS GCT
- Gray = Pancreas

CTSU (NCI Clinical Trials Support Unit)

2005-2006
AYA Progress Review Group
NCI + Lance Armstrong Foundation
Closing the Gap: Research & Care Imperatives for AYAs with Cancer
Retrospective review of clinical trial data among AYAs (of the same age) with ALL treated on pediatric and adult trials

Superior survival on pediatric trials
Stock, Nachman et al, Blood 2008

Pediatric [DCOG], ages 15-18 yo (n=47) OS 79%
Adult [HO 19-20], ages 19-20 yo (n=44) OS 38%

de Bont et al, Leukemia 2004

Ramanujachar et al, PBC 2007

Pediatric [UK ALL 97/99] ages 15-17 yo (n=61) OS 71%
Adult [UK ALL XII/E2993] ages 15-17 yo (n=67) OS 56%

Boissel et al, JCO 2003

Pediatric [FRALLE 93], ages 15-20 yo(n=77) EFS 67%
Adult [LALA 94], ages 15-20 yo(n=100) EFS 41%
Adherence is the critical factor for achieving molecular responses in patients with chronic myeloid leukemia who achieve complete cytogenetic responses on imatinib


- Median adherence rate 98% (24% to 104%).
- 26.4% had adherence ≤ 90%; 14% had adherence ≤ 80%
- Strong correlation between adherence (≤ 90% or > 90%) and 6-year probability of MMR (28.4% v 94.5%; P < .001)
- Multivariate analysis: adherence was independent predictor for response
- No molecular responses observed when adherence was <80% (P < .001)

“Imatinib works better if you take it!”
Cancer Therapy Confers a Risk for Infertility for AYAs

- National guidelines recommend discussing fertility risks and offering referral for preservation before starting gonadotoxic therapy
- However, fertility preservation referrals are very inconsistent

Polling Question #2

When you refer an AYA for a fertility preservation consultation before they start chemotherapy, how much is able to be done at your institution vs. outside your institution?

a) In-house: Oocyte cryopreservation, embryo cryopreservation, ovarian tissue cryopreservation, sperm banking; Outside referrals: none

b) In-house: Oocyte cryopreservation, embryo cryopreservation; Outside referrals: ovarian tissue cryopreservation, sperm banking

c) In-house: sperm banking; Outside referrals: Oocyte cryopreservation, embryo cryopreservation, ovarian tissue cryopreservation,

d) In-house: none; Outside referrals: Oocyte cryopreservation, embryo cryopreservation, ovarian tissue cryopreservation, sperm banking

e) Other
# Treatment Options and New Emerging Data: Leukemias

**Chronic Myeloid Leukemia: CML**

Acute Lymphoblastic Leukemia: ALL

Acute Myeloid Leukemia: AML

## CML: Staging and Disease Response

### Staging of CML (MD Anderson criteria)

<table>
<thead>
<tr>
<th>Staging</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic phase</td>
<td>None of the criteria for accelerated or blastic phase</td>
</tr>
<tr>
<td>Accelerated phase</td>
<td>Blasts ≥ 15% in blood or BM</td>
</tr>
<tr>
<td></td>
<td>Blasts plus progranulocytes ≥ 30% in blood or BM</td>
</tr>
<tr>
<td></td>
<td>Basophilia ≥ 20% in blood or BM</td>
</tr>
<tr>
<td></td>
<td>Platelets &lt; 100 x 10^9/L unrelated to therapy</td>
</tr>
<tr>
<td></td>
<td>Cytogenetic clonal evolution</td>
</tr>
<tr>
<td>Blast phase</td>
<td>≥ 30% blasts in blood or BM</td>
</tr>
<tr>
<td></td>
<td>Extramedullary disease with localized immature blasts</td>
</tr>
</tbody>
</table>

### Response to TKI is the most important prognostic factor

- Initial response to therapy provides a sensitive measure of future clinical outcome
- Measurement of BCR-ABL1 transcript levels using RT-Q-PCR standardized to the international reporting scale (IS)
- Based on achievement of CCyR or MMR at key time points
- Treatment failure defined as BCR-ABL1 >10% at 6 months and >1% at 12 months

![Response to TKI chart](chart.png)

NCCN Guidelines Version 1.2022:
Chronic Myeloid Leukemia

Slide courtesy of Ravi Bhatia, MD
## Choice of TKIs

<table>
<thead>
<tr>
<th>First Line</th>
<th>Second line</th>
<th>Third line</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Most patients receive imatinib as first-line treatment with good long-term disease control</em></td>
<td>Improved outcomes with second generation TKI after imatinib failure</td>
<td>Standard of care beyond second line therapy is not well defined</td>
</tr>
</tbody>
</table>

Many patients receive a second-generation TKI as frontline treatment - higher risk category - more rapid and deeper molecular response; allows more rapid attempt at TFR - no overall survival benefit - cost, toxicity

*Improved PFS but not OS with second generation TKIs

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## Failure of 2nd generation TKIs

**Treatment decisions based on reason for failure, mutation profile, comorbidities and AE risk profile**

- Transplant
- Alternative 2nd-generation TKI
- Ponatinib-3rd-generation TKI
- Asciminib (ABL Myristoyl Pocket inhibitor)

**Asciminib**

Binds to the myristoyl pocket of BCR-ABL1 and stabilizes the inactive state of the kinase (mimics autoinhibitory mechanism in ABL1 lost in BCR-ABL1)

**Transplant**

T315I mutations and resistance or intolerance to ≥2 prior TKIs

**Clinical trials- Investigational agents**

*Slide courtesy of Ravi Bhatia, MD.*
Clinical Trials

- **HQP1351 (Olverembatinib):** a 3G TKI with in vitro activity against T315I and other mutants
- **PF-114:** 3G TKI with efficacy at nanomolar concentrations against mutated BCR-ABL1, including the T315I mutation; similar to Ponatinib but designed to minimize interaction with VEGFR
- **K0706 (Vodobatinib):** a 2G TKI effective against wild-type and mutated BCR-ABL1 isoforms with reduced off-target activity compared to existing TKIs
- **Non BCR-ABL targets**

Important Considerations for AYAs

- **Women** who take TKIs are at risk of miscarriage and birth defects, and are strongly advised to use birth control
- Women on TKI who become pregnant must choose between ending the pregnancy or stopping the TKI temporarily
- For women who choose to stop TKI treatment and continue with the pregnancy, and require treatment, options include apheresis, and treatment with interferon alfa
- Breastfeeding women are advised to avoid TKIs because these medications are passed into breast milk
Treatment Options and New Emerging Data: Leukemias

Chronic Myeloid Leukemia: CML

Acute Lymphoblastic Leukemia: ALL

Acute Myeloid Leukemia: AML

Polling Question #3

What therapy is the best practice based on guidelines to treat AYAs with Ph-negative Acute Lymphoblastic Leukemia (ALL)?

a) CALGB 10403 or AALL1732
b) DFCI ALL (001, etc)
c) GRALLE-2005
d) PETHEMA ALL-96
e) Hyper-CVAD (without addition of other agents)
f) Hyper-CVAD + Rituximab
g) Hyper-CVAD + other targeted agent(s)
h) Linker 4-drug regimen
i) USC-MSKCC regimen (based on CCG1882)
Presence of MRD is BAD in Adult and Pediatric ALL...

EFS for Pediatric ALL
20 studies with 11,249 patients

EFS for Adult ALL
16 studies with 2,065 patients

... Regardless of MRD Method, Detection Period, or ALL Subgroup

Young Adults: Treatment Standard has Changed

2000: Historical CALGB vs. CCG

CCG OS = 67%
CALGB OS = 46%

16-21yo

2019: CALGB 10403

OS = 73%

16-39yo

Stock et al, Blood, 2008
Stock et al, Blood, 2019

Slide courtesy of Wendy Stock, MD.
Transplant in CR1 for AYAs?
No survival benefit

SCT in CR1 Beneficial for Poor MRD Response

Early MRD eradication should be our goal

Benefit of SCT
- Whole high-risk population
- Patients with MRD1 ≥10^-4

Wieduwilt MJ, et al. Leukemia 2021

MRD<10^-4

MRD≥10^-4

P=0.04 for interaction

P=0.02 if MRD1=10^-4
P=0.67 if MRD1<10^-4

Dhedin et al, Blood 2015

Only 40% of patients are MRD negative early in treatment

Q-PCR following Induction

Stock et al, Blood, 2019

HR = 0.25, p = 0.0006

Early MRD eradication should be our goal

Undetectable 3 yr DFS = 85%

Detectable 3 yr DFS = 56%

Only 40% of patients are MRD negative early in treatment

Q-PCR following Induction

Moving Immune Targeting into Frontline Therapy for B-ALL

Blinatumomab
Inotuzumab

? CD38 targeting

Incorporate for B-cell ALL

Incorporate for T-cell ALL

Slide courtesy of Wendy Stock, MD.
Blina in Frontline Phase III: E1910 for untreated B-ALL 30-60 years old

- Phase III randomized trial adding blina treatment modules at several treatment timepoints in a modified BFM backbone
  - 4 cycles of Blina are given; 2 cycles after intensification; 2 during late consolidation
- Initial goal was to evaluate efficacy of blinatumomab in frontline as treatment for both MRD- and MRD+ disease
- With approval of blinatumomab for MRD+ in 2018, only MRD- were subsequently randomized
- Completed enrollment fall 2019
- ASH 2022: Median follow-up 43 months, survival advantage of Blina (manuscript pending)

B-ALL: The Future - Incorporation of Immunotherapy into Frontline Therapy

- AALL1731
  NCT03914625
  Study Co-Chairs:
  Sumit Gupta, Rachel Rau

- AALL1732
  NCT03959085
  Study Co-Chairs:
  Jennifer McNeer, Maureen O’Brien

- AALL1721
  NCT03876769
  Study Chair:
  Shannon Maude

Slide courtesy of Wendy Stock, MD.

Slide courtesy of Jennifer McNeer, MD.
A041501 for AYAs 18-39 years: Can We Improve EFS to 80%?

**Ph- CD22+ 16-40**

**Induction**

**R**

**2 Cycles INO***

**No INO***

**C10403 Consol. maint.**

**Stratification:**
- **Age**
- LDA card for Ph-like CD20+/−

**Primary end point:** 3-y EFS

**Goal:** improvement in 3-y EFS from 66% to 80%

*INO: Inotuzumab

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**Disease status predicts survival after CAR-T**

**Allogeneic Transplant post CAR-T therapy improves EFS**

**Pediatric ELIANA trial: HCT necessary?**

**Slide courtesy of Wendy Stock, MD.**
Cellular Therapy: New Directions

• "Off the shelf" CART
  • Faster, doesn’t require patient’s cells to manufacture
  • Efficacy proven in early trials

• Dual Targeted CART
  • CD19, CD22 targeted CART cells have high response rates
  • May minimize emergence of resistant CD19 negative clones

• Early phase CD5 targeted CAR-T
  • Ongoing work;
  • Being viewed as bridge to transplant

• Natural Killer (NK)-CAR
  • No need for HLA full matching; NK cells may be derived from cord blood
  • Activity has been demonstrated using CAR-NK cells in CD19+ Lymphoma, CLL,

Slide courtesy of Wendy Stock, MD.

T-ALL: Nelarabine Improves Survival in COG AALL0434

- Nelarabine incorporated into ABFM; six 5-day courses
- AYAs 20-30yo: 3% of the 1895 patients
- 4yr DFS was 88.9% with nelarabine vs. 83% DFS without

Winter SS et al, JCO 2018

TLLy: Improved EFS and OS with Bortezomib (AALL1231)

- Bortezomib incorporated into frontline therapy
- 4-year EFS
  - 76.5% ± 5.1% vs. 86.4% ± 4.0%(p =0.041)
- 4-year OS
  - 78.3% ± 4.9% vs. 89.5% ± 3.6% (p= 0.009)

Teachey et al, JCO 2022

Slide courtesy of Wendy Stock, MD.
T-ALL: Immunotherapy

Target
- CD38
  - Daratumumab
- Phase 2 DELPHINUS study
  - Daratumumab + chemo
  - 24 pediatric, 5 young adult pts
  - ORR
    - Pediatric ALL: 83.3%
    - Young Adult ALL: 60%
    - LLy: 40%

Move to frontline therapy?

Slide courtesy of Jennifer McNeer, MD.

B-ALL: Molecular Diagnostics - Ph-like B-ALL

5y DFS (+ validation cohort)
- Ph-Like: 59.5%
- Ph+: 51.9%
- Other B-lineage: 84%

Current Trials for Philadelphia chromosome-like ALL

- Driven by a variety of signaling pathways
- Potential for targeted therapy in Ph-like ALL
  - JAK/STAT pathway
    - Ruxolitinib (AALL1521, recently closed to accrual)
  - ABL-class fusions
    - Dasatinib, Imatinib (AALL1631)

Roberts et al, NEJM, 2014
Slide courtesy of Jennifer McNeer, MD.
### Treatment Options and New Emerging Data: Leukemias

**Chronic Myeloid Leukemia: CML**

**Acute Lymphoblastic Leukemia: ALL**

**Acute Myeloid Leukemia: AML**

#### 2022 ELN AML Risk-Stratification (Adult)

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Cytogenetic and Molecular Classification</th>
<th>Transplant Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Favorable</td>
<td>• t(15;17)</td>
<td>CR2</td>
</tr>
<tr>
<td></td>
<td>• inv(16)(p13.1q22) or t(16;16)(p13.1;q22)/CBFB::MYH11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• t(8;21)(q22;q22.1)/RUNX1::RUNX1T1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mutated NPM1 without FLT3-ITD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• bZIP in-frame mutated CEPBA</td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>• Mutated NPM1 with FLT3-ITD mutation</td>
<td>CR1 for the majority of patients</td>
</tr>
<tr>
<td></td>
<td>• Wild-type NPM1 with FLT3-ITD (w/o adverse genetic lesions)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• t(9;11)(p21.3;q23.3)/MLLT3::KMT2A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Cytogenetic and/or abnormalities not classified as favorable or adverse</td>
<td></td>
</tr>
<tr>
<td>Adverse</td>
<td>• t(6;9)(p23.3;q34.1)/DEK::NUP214</td>
<td>CR1</td>
</tr>
<tr>
<td></td>
<td>• t(v;11q23.3)/KMT2A-rearranged</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• t(9;22)(q34.1;q11.2)/BCR::ABL1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• t(8;16)(p11.2;p13.3)/KAT6A::CREBBP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• inv(3)(q21.3p26.2) or t(3:3)(q21.3;q26.2)/GATA2, MECOM(EV11)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• T(3q26.2:v)/MECOM(EV11)→rearranged</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• -5 or del(5q); -7; -17/17abn(17p)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Complex karyotype, monosomal karyotype</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mutated ASXL1, BCOR, EZH2, RUNX1, SF3B1, SRSF2, STAG2, U2AF1, and/or ZRSR2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• t(9;11)(p21.3;q23.3)/MLLT3::KMT2A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mutated TP53</td>
<td></td>
</tr>
</tbody>
</table>

*Slide courtesy of Kristen O'Dwyer, MD.*

Risk Stratification – Pediatrics (AAML1831)

<table>
<thead>
<tr>
<th>Table 2.1 Risk Stratification</th>
<th>Low Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LR1</strong> 4 chemo courses</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>LR2</strong> 5 chemo courses</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>HR</strong> 3 chemo courses and HSCT</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

**Favorable Prognostic Markers**

- t(8;21) or inv(16)/t(16;16)
- NPM1 or CEBPA
- RAM phenotype or any unfavorable cytogenetic and/or NGS marker except FLT3/ITD allelic ratio > 0.1

**Unfavorable Prognostic Markers**

- inv(3)(q21.3,q26.2) or t(3;3)(q21.3;q26.2)
- RUNX1-MECOM
- t(8;21)(q22;q22)
- NPM1-MLF1
- del(17)(p13.1)(q21.3)
- KMT2A-ADIP1 (MLL-MLLT7)
- t(8;11)(q22;p13.3)
- KMT2A-MLLT3
- t(9;11)(q22;p13.3)
- KMT2A-MLLT4
- t(11;19)(q23;3;p13.3)
- KMT2A-MLLT3
- 11p 5 rearrangement
- 16p 13.3 rearrangement
- Less than 5% ETO
- Deletions 1p21 to include 12p13.2

Updated karyotype/FISH, new immunophenotypic, and NGS data applied retrospectively to prior COG AML patients

Thus, AAML1831 risk stratification more nuanced than prior studies.

Risk groups from AAML03P1
SR 60%
LR 30%
HR 10%

Initially proposed risk groups applied to AAML0531 data (~30% in each group)

Applying EOI MRD 0.1% to SR group then further stratifies them into HR vs LR groups

Slide courtesy of Jennifer McNeer, MD.
**New/Targeted Therapies in AML**

- **Gemtuzumab**
  - Anti-CD33 conjugated to calicheamicin
  - AAML0531: outcome benefit (Gamis, JCO 2014)
    - CD33 expression (Pollard, JCO 2016)
    - FLT3/ITD (Tarlock, Clin Cancer Res 2016)
    - KMT2A (Pollard, JCO 2021)
    - Thus – added for all patients (AAML1831)
  - May increase risk of SOS with HSCT
  - FDA-approved 2017: adult CD-33+ AML, and peds ≥ 2 yrs with R/R CD33+ AML

- **Sorafenib, Gilteritinib**
  - Sorafenib: Multi-target TKI that targets FLT3, c-KIT, PDGF, VEGF, RAF/MED/ERK (AAML0531)
  - Gilteritinib: Multi-target TKI that targets FLT3 (ITD and TKD), with weak activity against c-Kit, and inhibits AXL (implicated in FLT3 inhibitor resistance) – AAML1831

- **CPX-351**
  - Liposomal 5:1 preparation of cytarabine:daunorubicin
  - Less cardiotoxicity
  - FDA-approved 2017 for adults with t-AML, or AML with MDS-related changes
    - COG AAML1421 (r/r), COG AAML1831 (de novo)

- **Venetoclax**
  - BCL2 inhibitor (BCL2 is anti-apoptotic)
  - 2016/2017 – Breakthrough designation for AML

- **Azacitidine, Decitabine**
  - Epigenetic Modifiers
  - AML16 (St. Jude trial)

**Recent AML Updates**

- **AAML1031: Up front study**
  - Randomization ± Bortezomib
    - No benefit with bortezomib
  - 4 cycles of chemo
    - 4 cycles inferior to 5 when compared to historical data

- **AAML1331 (recently closed)**
  - Phase 3 study of arsenic and ATRA for APML
  - Omit anthracycline for standard-risk patients
  - Minimize anthracycline for high-risk patients

- **AAML1531**
  - Disease-response based treatment for DS-AML
    - >90 days and <4 years
  - Original study – omit HD-AraC for standard-risk patients.
    - Worse outcomes than historical control
      - 2-year EFS 85.6% vs 93.5%, p=0.0002
      - HD-AraC re-introduced
Diagnoatic and Management Considerations for AYA with Lymphoma

LLS Webinar
Sharon M Castellino, MD, MSc
Professor of Pediatrics, Emory School of Medicine
Program Leader: Pediatric Leukemia and Lymphoma
October 11, 2023
Poll Question #4

What is the most common lymphoma in patients age 15-39 in the U.S.

a) A. Nodular Sclerosing Hodgkin Lymphoma (HL)
b) B. DLBCL
c) C. Primary CNS lymphoma
d) D. Nodular lymphocyte predominant HL

Epidemiology

Lymphoma accounts for 20% of cancers in AYA

Disparities in Outcomes for AYA with Lymphoma

• Compared to pediatric patients:
  – AYA patients more likely to present with:
    • Advanced stage disease
    • B symptoms
  – Clinical presentation:
    • Indolent: HL
    • Acutely ill with rapid progression in many NHL

• Diagnosis
  – Challenges associated with evolving molecular features in NHL subtypes
Drivers of Disparities in AYA Lymphoma

- Timely Access to care
  - Lack of insurance; underinsurance; non-continuous coverage
  - Distance to care
  - Delays in diagnosis
  - Lack of access to AYA resourced care (i.e. cancer centers)
  - Lack of enrollment to clinical trials
- Non-White Race
- Social determinants of health
- Lack of guideline concordant care through the continuum of post treatment/survivorship
- Unmet psychosocial needs → impact adherence to therapy

Cancer trajectory: AYA

- Quality of life:
  - School
  - Work

Experience of healthcare Mediators
- Symptom experience
- Age appropriate information
- Communication
- Social support
- Financial impact
- Evidence based Treatment
- Clinical trial

Mediators
- Symptom experience
- Communication
- Social support
- Financial impact
- Evidence based Treatment
- Clinical trial

End of treatment
- Re-establish Identity
- Achieving life goals
- Return to normality
- Fear of recurrence
- Late effects

Survivorship care

Financial Stress
- Adult Life
- Ability to cope
- Financial impact

Survival
- Palliation/End of life care

Adapted from Holland 2023.
Diagnostic Workup: Lymphoma in AYA

- **Essential for Lymphoma:**
  - History and physical
    - B symptoms, lymph node, splenomegaly
  - Excisional Node Biopsy
  - CBC with differential
  - ESR and/or CRP
  - Complete metabolic panel
  - Echocardiogram
  - Chest X-ray: PA and lateral views
  - FDG-PET/CT or FDG-PET/MRI

- **Additional for NHL:**
  - LDH; uric acid
  - Hepatitis B/C testing
  - Bilateral bone marrow
  - Lumbar puncture
  - Immunodeficiency
  - Tissue Diagnostics (not comprehensive)
    - IHC
      - CD20, CD30, Ki-67, Tdt
      - ALK
    - Flow cytometry: surface kappa/lambda
    - FISH
      - MYC, BCL2, BCL6; t(8;14)
    - Microarray: 11 q aberrations


AYA Specific Considerations at Diagnosis of Lymphoma

- Pulmonary function test
- HIV
- Health Insurance
- Sexual health assessment
- Pregnancy test
- Fertility preservation-discussion and services
- Psychosocial assessment
- Counseling on substance use and smoking cessation
- Work/school issues
- Social support/network
- Financial toxicity
AYA Lymphoma: Goals

- Balancing risk of relapse against:
  - Acute toxicity
  - Late toxicity
  - Quality of life
- During Therapy:
  - Understand tolerability through Patient Reported Outcomes (PRO)
  - Understand how symptomatic and non symptomatic AEs contribute to adherence to dose intensity of therapy

Hodgkin Lymphoma: Peds vs. Adult Oncology Approaches

- Histology distribution varies: younger patients; race/ethnicity
- Risk classification
  - Bulk – definitions differ between adults and peds
  - Prognostic scores- created in older adult cohorts treated with conventional therapy
- Treatment approaches: Risk based, response adapted
  - Chemotherapy back-bone (ABVE-PC vs. ABVD/BEACOPP)
  - Combined modality
    - Tailored radiation use and dose in older adolescents and YAs
- Trial Endpoints (EFS) – events include subsequent malignant neoplasms (SMN)
  - Goals of care: Person-years of life considered, HRQL
  - Late effects: Cardiac; fertility
Collaboration ➔ Accelerate Novel Approaches … and AYA enrollment

- **NCTN (National Clinical Trials Network)** - launched 2014
  - Goal: Increase trial participation in rare cancers and in AYA
    - Central support: CTSU; NCI CIRB
  - Increase in phase 3 trials
  - Increase in AYA enrollment ; 9.5% ➔ 14.0%

- **Pharma**
  - > 10 years (avg.) between regulatory approval and labeling of innovative therapy for adults and children
  - Prolonged off label use in pediatric patients

- International and other consortium partnerships
HL: Exploiting biology of HRS cell and the Tumor Microenvironment

HRS = Reed-Sternberg cell

“A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age > 12 years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma.”

S1826 (NCT03907488)– Activated 7/19/2019

SWOG Chairs: Alex Herrera, MD; Jonathan Friedberg MD, MMSc
Pediatrics/COG Chair: Sharon Castellino, MD, MSc
COG Champion: Angela Punnett MD
QOL Chair: Susan Parsons, MD, MRP

Herrera A. JCO 41, no. 17_suppl (June 10, 2023)
LBA4-LBA4.
S1826 Study Design

**N-AVD x 6 cycles**
Nivolumab 240mg days 1,15<sup>a</sup>
Doxorubicin, Vinblastine, Dacarbazine days 1,15<sup>a</sup>
*G-CSF optional

470 pts

**Bv-AVD x 6 cycles**
Bv 1.2mg/kg days 1,15
Doxorubicin, Vinblastine, Dacarbazine days 1,15<sup>b</sup>
*G-CSF required

470 pts

Newly diagnosed Stage III-IV Hodgkin lymphoma

1:1

Stratification:
- Age (12-17/18-60/>60)
- IPS (0-3/4-7)
- EOT RT intended (Y/N)

Primary endpoint: PFS

1-year PFS
N-AVD 94%
Bv-AVD 86%

1. Nivolumab 2mg/kg for ages ≤17, max 240mg

Median follow-up 12.1 months

Alex F. Herrera, MD ASCO 2023.
Successful Collaboration with the Adult NCTN

- Earlier access to novel agents for adolescents
- Harmonize approaches across pediatric and adult providers for AYAs with advanced stage HL
- Parallel design: Compare Bv-AVD against Bv-AVEPC (AHOD1331)
- Evaluation of the role of RT in the setting of new agents
- PROs will facilitate measurement of tolerability of new agents across the age spectrum

S1826 Accrual (n=994) (enrollment closed Oct 5, 2022)

ACCRUAL BY GROUP

<table>
<thead>
<tr>
<th>COG</th>
<th>32.6%</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1%</td>
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</tr>
<tr>
<td>8.5%</td>
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<tr>
<td>38.5%</td>
<td></td>
</tr>
<tr>
<td>13.6%</td>
<td></td>
</tr>
</tbody>
</table>

Cumulative Chemotherapy Dosing

<table>
<thead>
<tr>
<th>AHOD1331* (BV-AVE-PC x 5)</th>
<th>S1826 (N-AVD x 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brentuximab Vedotin</td>
<td>9 mg/kg</td>
</tr>
<tr>
<td>Nivolumab</td>
<td>36 mg/kg</td>
</tr>
<tr>
<td>Adriamycin</td>
<td>250 mg/m2</td>
</tr>
<tr>
<td></td>
<td>300 mg/m2</td>
</tr>
<tr>
<td>Vincristine</td>
<td>7 mg/m2</td>
</tr>
<tr>
<td>Vinblastine</td>
<td>72 mg/m2</td>
</tr>
<tr>
<td>Etoposide</td>
<td>1875 mg/m2</td>
</tr>
<tr>
<td>Prednisone</td>
<td>1400 mg/m2</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>6000 mg/m2</td>
</tr>
<tr>
<td>Dacarbazine</td>
<td>4500 mg/m2</td>
</tr>
<tr>
<td>Radiation dose</td>
<td>21 Gy</td>
</tr>
<tr>
<td></td>
<td>9 Gy boost to sites of residual avidity on EOT PET</td>
</tr>
<tr>
<td></td>
<td>30-36 Gy</td>
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</table>

*S. Castellino et al. NEJM 2022
Chemotherapy Administration

<table>
<thead>
<tr>
<th></th>
<th>AHOD1331 (BV-AVE-PC x 5)</th>
<th>S1826 (N-AVD x 6)</th>
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</thead>
<tbody>
<tr>
<td>Cycle Length</td>
<td>21 days</td>
<td>28 days</td>
</tr>
<tr>
<td>Total Duration</td>
<td>105 days</td>
<td>168 days</td>
</tr>
<tr>
<td>Days of IV chemo</td>
<td>Day 1, 2, 3, and 8</td>
<td>Day 1 and 15</td>
</tr>
<tr>
<td>Total days of IV chemo</td>
<td>20 days</td>
<td>12 days</td>
</tr>
<tr>
<td>Growth Factor</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td>Dexrazoxane</td>
<td>Permitted not required</td>
<td>Permitted not required</td>
</tr>
</tbody>
</table>

AHOD2131 (NCT05675410): Stage I/II – Activated April 2023

- **ABVD x 2 cycles**
  - Neg Randomize
  - Pos Randomize

- **PET2**
  - Randomize

- **A(B^F)VD x 2^F – 4^U cycles**
- **Bv-Nivo x 4 cycles**
- **eBEACOPP x 2 cycles + ISRT**
- **Bv-Nivo x 4 cycles + ISRT**

---

*1 cycle = 28 days*
*^PET2 positive defined as Deauville 4 or 5*
*F favorable; U unfavorable*

Study Chairs: T. Henderson; K. Kelly; B. Hu
Non-Hodgkin Lymphoma in AYA

• More Common Pediatric/Adolescent NHL
  – Mature B-cell lymphomas
    • Diffuse Large B-cell Lymphoma
    • Burkitt Lymphoma
    • Primary Mediastinal B-cell Lymphoma
  – Anaplastic Large Cell Lymphoma
  – Lymphoblastic Lymphoma/Leukemia
    • T differentiation
    • B differentiation
  – Post-transplant lymphoproliferative disease (PTLD)

• Less Common Pediatric/Adolescent NHL
  • Pediatric follicular lymphoma
  • Marginal zone & MALT lymphoma
  • Primary CNS lymphoma
  • Peripheral T-cell lymphoma NOS

• Lack of harmonization in staging systems in NHL
  – Ann Arbor Staging (adults)
  – International Pediatric NHL Staging System
  – Lack of Prognostic scores relevant to younger patients

Novel Agents in combination with chemotherapy in Frontline Regimens for NHL

▪ Anti-CD 30: Brentuximab vedotin
▪ Anti-CD20: Rituximab
▪ ALK inhibitor: crizotinib
▪ Amplified PD1- Checkpoint inhibitors
▪ Anti-CD 79b – Polatuzumab vedotin
▪ Bruton tyrosine kinase inhibitor : ibrutinib

▪ AYA with a mature B cell lymphoma could receive vastly different therapy depending on point of presentation (adult vs. pediatric provider)
  ▪ Providers are encouraged to check the NCCN guidelines and to consider offering a clinical trial
▪ Many emerging novel agents for NHL are in trial in relapsed setting
▪ Most have undergone relatively little study in AYA

El-Mallawany et al. eJHaem 2023
Primary Mediastinal B-cell Lymphoma

- Rare subtype of NHL
- Peak incidence in AYA, F>M
- Presents as large mediastinal mass
  - Pleural, pericardial effusions common
- Biology overlaps with classic HL
  - CD30+
  - Overexpression PD-1
  - Sensitive to immune checkpoint blockade

ANHL1931 (NCT04759586): Randomized phase III trial of nivolumab in PMBCL

Physician declares chemotherapy backbone:
R-CHOP or DA-EPOCH-R

- R-CHOP or DA-EPOCH-R x 6 cycles
- Nivo + R-CHOP or Nivo + DA-EPOCH-R x 6 cycles

Consolidative RT permitted only in the following circumstances:
1) Physician declares R-CHOP + RT regardless of EOT imaging
2) + biopsy at EOT

Primary Endpoint: PFS as determined by independent review committee

Open NCTN wide across all age groups

Opened to accrual June 2021
Anticipated to enroll 186 patients over 3.8 years

Courtesy: L G Roth.
POLLING QUESTION #5

- What percent of AYA patients with a blood cancer should receive a survivorship care plan?
  A) 11-25%
  B) 26-50%
  C) 50%
  D) 100%

Addressing the Survivorship Gap… Begin With the End in Mind

Refine and Titrate frontline therapy

Screen and Intervene to attenuate the risk of late effects

Secondary Prevention

Children’s Oncology Group Guidelines: Exposure based

- Need for new models for AYAs who often do not return to treating institution
- Opportunities for mHealth
- Evidence will be a long time in coming for novel agents
- Need biomarkers for late toxicity

Survivorship Care Plans

- Document that summarizes an individual patient’s treatment-cumulative doses and modalities of therapy received

- Summary of:
  - Therapy associated late effects
  - Recommendations for follow-up care
  - Health promotion for screening and health behaviors
Thank You

FREE LLS RESOURCES FOR HEALTHCARE PROVIDERS

- CME and CE courses: www.LLS.org/CE
- Fact Sheets for HCPs: www.LLS.org/HCPbooklets
- Videos for HCPs: www.LLS.org/HCPvideos
- Podcast series for HCPs: www.LLS.org/HCPpodcast
FREE LLS RESOURCES FOR PATIENTS

- **Information Specialists** – Personalized assistance for managing treatment decisions, side effects, and dealing with financial and psychosocial challenges (IRC).

- **Clinical Trial Nurse Navigators** – RNs and NPs provide a personalized service for patients seeking treatment in a clinical trial, sift through the information and provide information to bring back to their HC team (CTSC).
  
  - [www.LLS.org/CTSC](http://www.LLS.org/CTSC)

- **Nutrition Education Services Center (NESC)** – LLS provides Nutrition Education Services to patients and caregivers of all cancer types. Our registered dietitians have expertise in oncology nutrition. To schedule a free consultation:
  
  - visit [www.LLSnutrition.org](http://www.LLSnutrition.org)
  - call 800-955-4572

- **Reach out** Monday–Friday, 9 am to 9 pm ET
  
  - Phone: (800) 955-4572
  - Live chat: [www.LLS.org/IRC](http://www.LLS.org/IRC)
  - Email: infocenter@LLS.org
  - HCP Patient Referral Form: [www.LLS.org/HCPreferral](http://www.LLS.org/HCPreferral)

FREE LLS RESOURCES FOR PATIENTS AND CAREGIVERS

- **Webcasts, Videos, Podcasts**:
  
  - [www.LLS.org/Webcasts](http://www.LLS.org/Webcasts)
  - [www.LLS.org/EducationVideos](http://www.LLS.org/EducationVideos)
  - [www.LLS.org/Podcast](http://www.LLS.org/Podcast)

- [www.LLS.org/youngadults](http://www.LLS.org/youngadults)

- **Support Resources**
  
  - Financial Assistance: [www.LLS.org/Finances](http://www.LLS.org/Finances)

  - Other Support: [www.LLS.org/Support](http://www.LLS.org/Support)
    - LLS Regions
    - Live Online Weekly Chats: “Living with NHL”
      - Facilitated by Oncology SW
    - LLS Community Social Media Platform
    - First Connection Peer to Peer Program
FREE LLS RESOURCES FOR YOUR PATIENTS

BOOKLETS AND FACT SHEETS

English – www.LLS.org/Booklets
Spanish – www.LLS.org/Materiales

Questions?

Ask a question by web:
- Click “Ask a question”
- Type your question
- Click “Submit”
INSTRUCTIONS FOR CREDIT

Participants must complete the evaluation to receive credit. After completing this process, your certificate will automatically generate.

Link to complete evaluation: https://mli.link/llsaya

For questions or concerns, please contact Profeducation@lls.org

THANK YOU!

We have one goal: A world without blood cancers