EVOLVING TREATMENT STRATEGIES IN PEDIATRIC LEUKEMIA

Recorded on
June 12, 2024

Jointly provided by The Leukemia & Lymphoma Society and Postgraduate Institute for Medicine

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WELCOME AND INTRODUCTIONS

Lesley Hoerst, BSN, RN
Senior Manager
Professional Education Programs
The Leukemia & Lymphoma Society
Rye Brook, NY

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LEARNING OBJECTIVES

- Describe common childhood blood cancers, including ALL and AML
- Identify signs and symptoms of childhood blood cancers and diagnostic tests
- Explain treatments, including the role of clinical trials, and LLS PedAL, a precision medicine clinical trial for pediatric acute leukemia
- Describe strategies for management of short- and long-term side effects of treatment
- Explain the importance of following a care plan, including long-term follow-up and communication between the pediatrician/family physician and the pediatric oncologist
- Describe psychosocial concerns related to patients with pediatric cancer

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CE DESIGNATION

Physician Continuing Medical Education
In support of improving patient care, this activity has been planned and implemented by the Postgraduate Institute for Medicine and The Leukemia & Lymphoma Society. Postgraduate Institute for Medicine is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.
The Postgraduate Institute for Medicine designates this CME activity for a maximum of 1 *AMA PRA Category 1 Credit*(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Registered Nursing Credit Designation
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.

Interprofessional Continuing Education
This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit for learning and change.

Continuing Physician Assistant Education
Postgraduate Institute for Medicine has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. This activity is designated for 1 AAPA Category 1 CME credits. PAs should only claim credit commensurate with the extent of their participation.

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: 12/10/2023-12/10/2026. 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 Departments State Board for Social Work as an approved provider of continuing education for licensed social workers #SW-0117. LLS maintains responsibility for the program. Social workers will receive 1.0 clinical CE contact hour for this activity.

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SPEAKERS

Branko Cuglievan, MD
Assistant Professor, Pediatrics - Patient Care
Section Chief, Leukemia/Lymphoma
Children's Cancer Hospital
The University of Texas MD Anderson Cancer Center
Houston, TX

Romeo Torres, MSN, APRN, FNP-BC, CPHON
Pediatric Leukemia/Lymphoma
Children's Cancer Hospital
The University of Texas MD Anderson Cancer Center
Houston, TX

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DISCLOSURES

- **Branko Cuglievan, MD**
  - **Research Funding:** Astex, Kura Oncology, LLS, Octapharma, Syndax
  - **Travel/Accommodations:** Octapharma
- **Romeo Torres, MSN, APRN, FNP-BC, CPHON, has no disclosures**
- **Lesley Hoerst, BSN, RN, has no disclosures**

The PIM planners and others have nothing to disclose. The Leukemia & Lymphoma Society planners and others have nothing to disclose.

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Pediatric Leukemias

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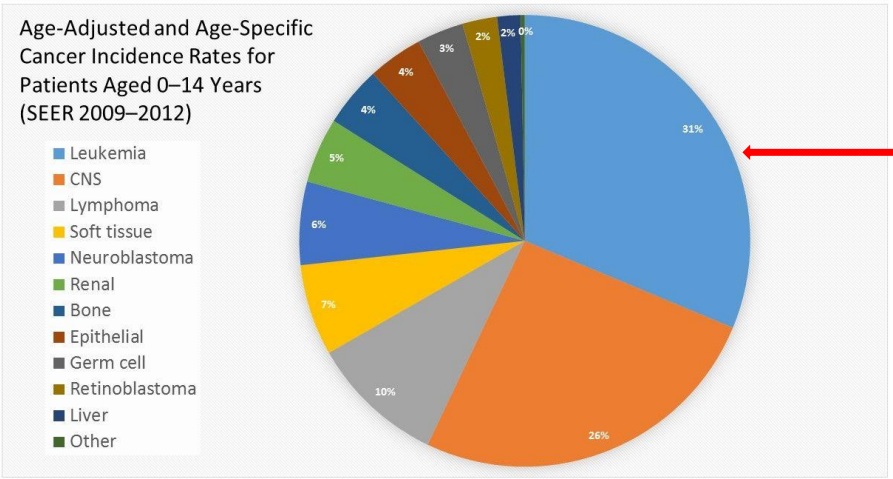
PEDIATRIC NEOPLASMS



~4500 cases/yr

National Cancer Institute: https://www.cancer.gov/types/childhood-cancers/

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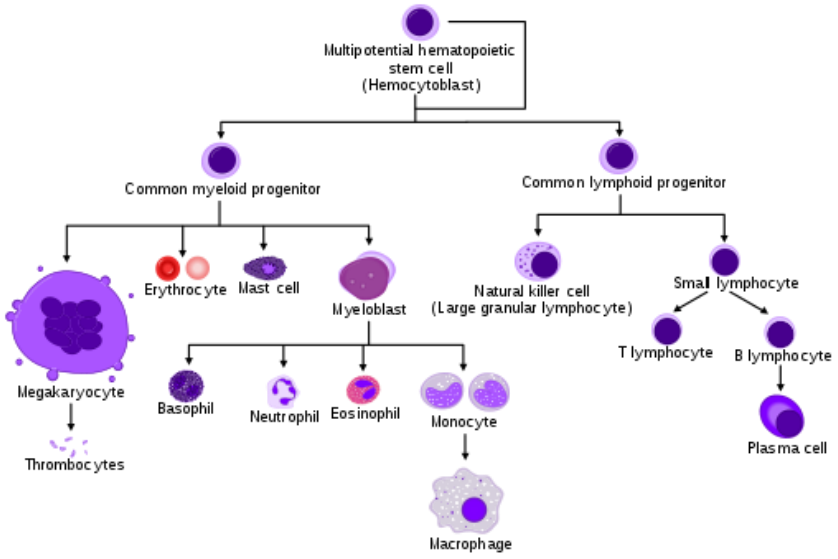
HEMATOPOIESIS



Hematopoiesis simple. A. Rad. M. Haggstrom

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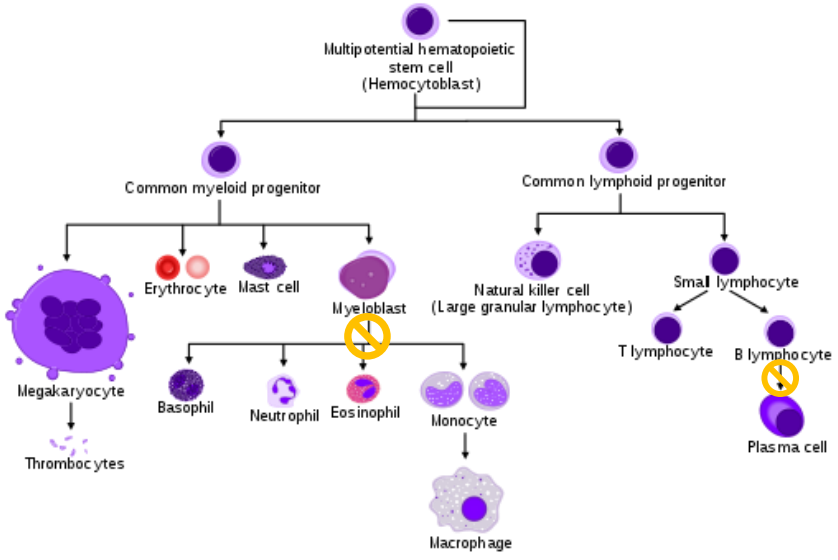
HEMATOPOIESIS



Hematopoiesis simple. A. Rad. M. Haggstrom

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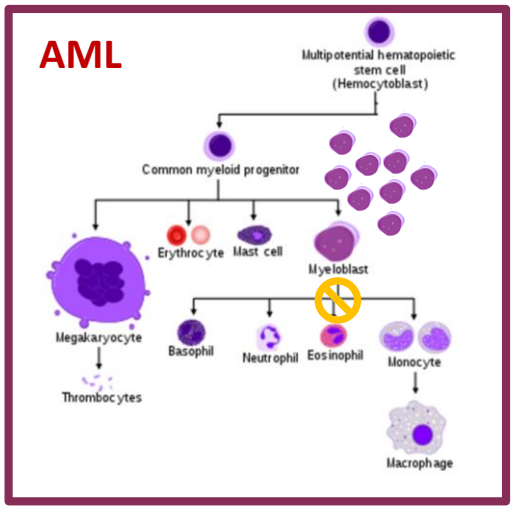
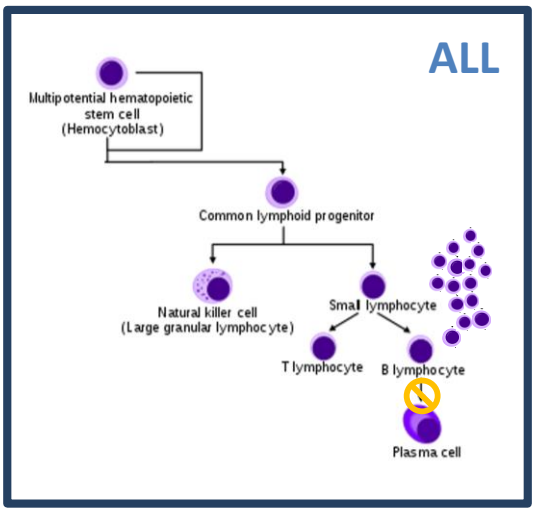
HEMATOPOIESIS





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Hematopoiesis simple. A. Rad. M. Haggstrom

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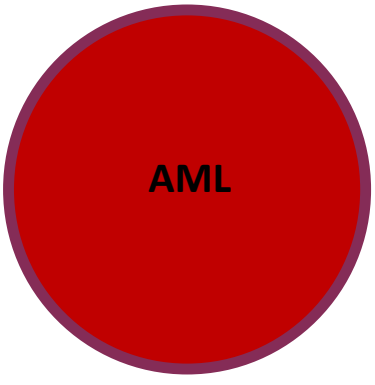
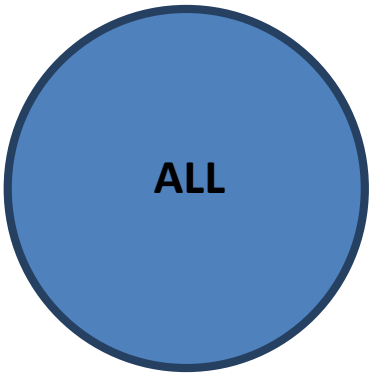
HEMATOPOIESIS



750 cases/year



3,300 cases/year

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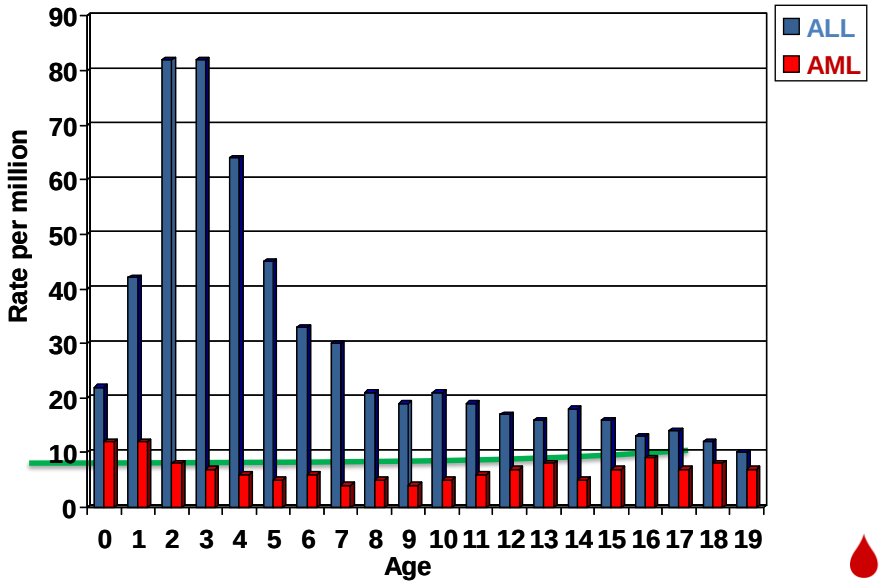
EPIDEMIOLOGY



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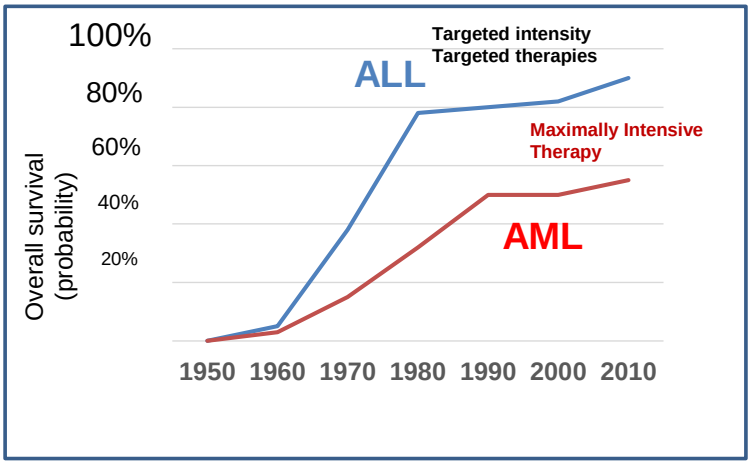
ALL VS. AML – THE HISTORICAL PERSPECTIVE



Adapted from A. Kolb et al.

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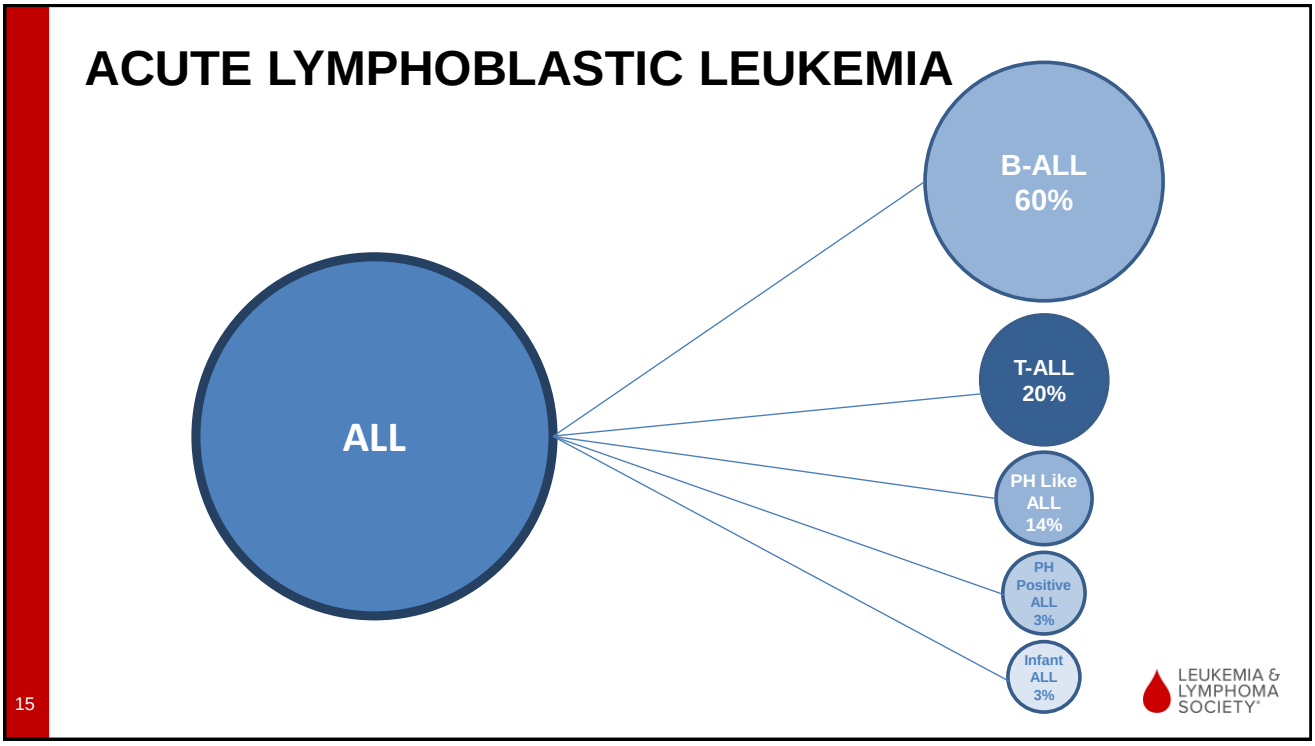
ACUTE LYMPHOBLASTIC LEUKEMIA
ALL
B-ALL 60%
T-ALL 20%
PH Like ALL 14%
PH Positive ALL 3%
Infant ALL 3%
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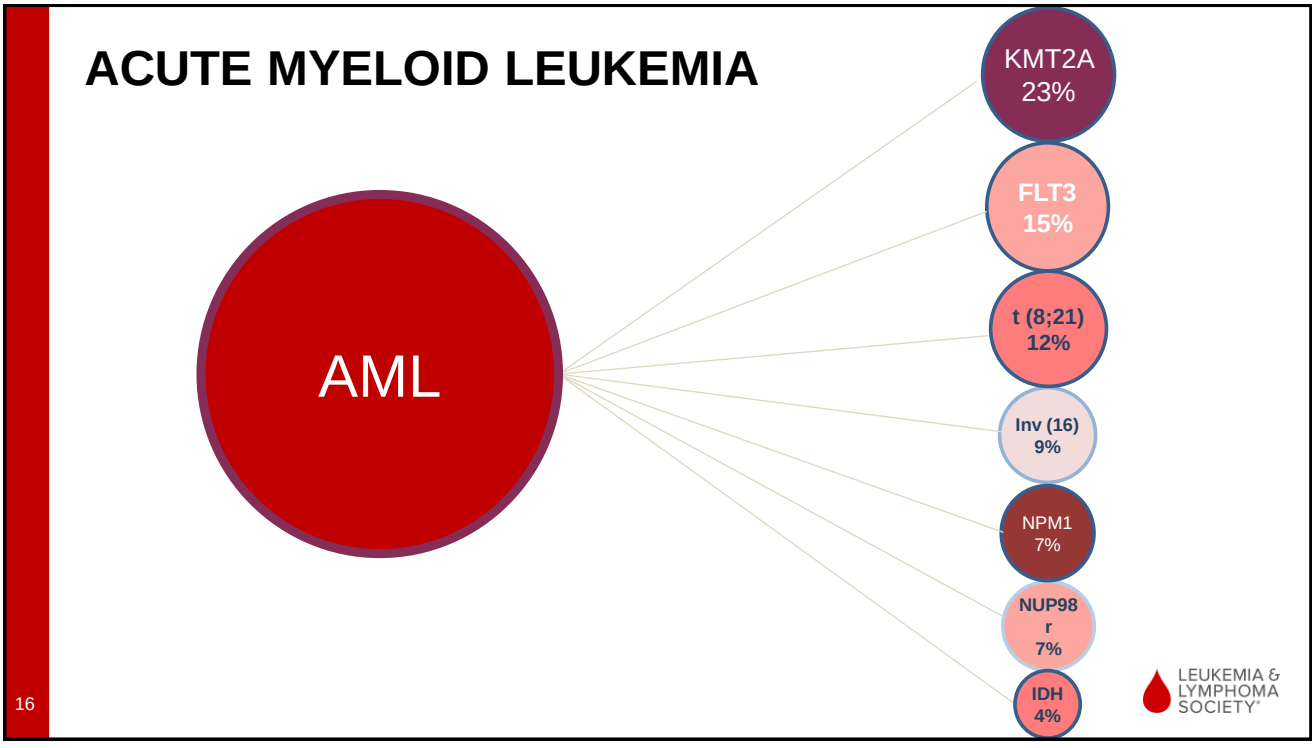
ACUTE MYELOID LEUKEMIA
AML
KMT2A 23%
FLT3 15%
t (8;21) 12%
Inv (16) 9%
NPM1 7%
NUP98 r 7%
IDH 4%
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Clinical Presentation

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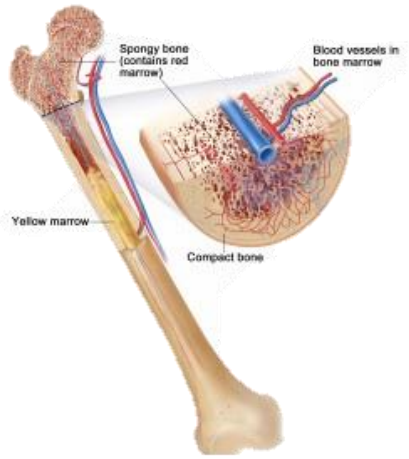
CLINICAL PRESENTATION: LEUKEMIA INFILTRATION



Bone marrow

- Lymphadenopathy
- Hepatomegaly
- Splenomegaly
- Kidney lesions

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TYPICAL ACUTE LEUKEMIA –PRESENTATION

- Fatigue, pallor, tachycardia
- Easy bruising, petechiae
- Frequent infections, fevers
- Bone/Joint pains (sometimes won't want to walk anymore)
- Vague abdominal pains, anorexia (unexplained weight loss)
- Headaches, vomiting, vision changes

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ACUTE LEUKEMIA – PRESENTATION ON EXAM

- Lymphadenopathies
- Hepatosplenomegaly
- Cranial nerve palsies from CN involvement
- Testicular Involvement (boys)
- Chloromas (not as common) – seen in AML
- Leukemia cutis (skin involvement)
- Gingival infiltration

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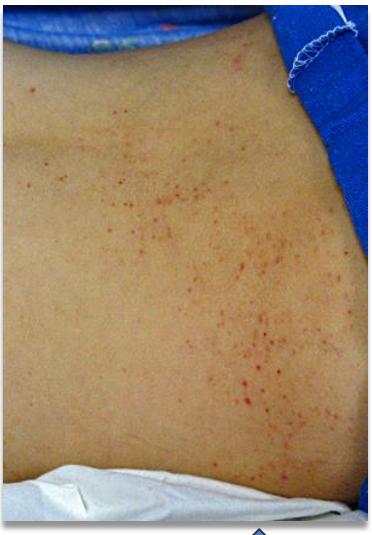
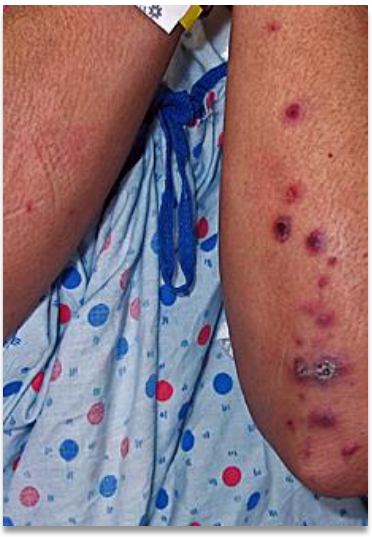


Petechiae[1]

Leukemia Cutis[2]



Gingival Hyperplasia[2]

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Acute Leukemia Workup

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QUIZ QUESTION!

Which of the following is the accepted gold standard for diagnosing suspected leukemia?

a) Flow cytometry on peripheral blood

b) Next gen sequencing from peripheral blood

c) Flow cytometry on bone marrow aspirate

d) Urine catecholamine testing

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QUIZ QUESTION!

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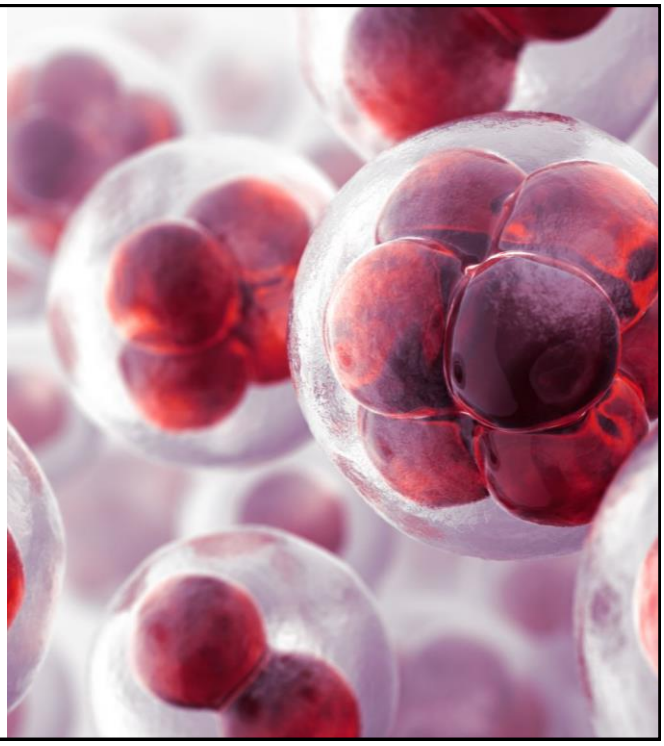
ACUTE LEUKEMIA WORKUP

Laboratory findings:

- CBC can be "normal"
- WBCs: varies – either high or low
- Hemoglobin and platelets: often low
- Differential – Neutropenia & blasts
- Can get preliminary diagnosis from peripheral blood, but not confirmatory
- Gold standard, confirmatory diagnosis is still from bone marrow biopsy & aspiration



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ACUTE LEUKEMIA WORKUP

Chemistry panel:

- Can be normal in pre-treated disease
- Potassium & phosphorus ↑
- Uric Acid ↑
- Calcium (Inverse relationship with ↓ phosphorus)
- Creatinine ↑
- LDH ↑

Tumor lysis!

Coagulation studies:

- Risk for bleeding/clotting
- DIC could be present (APML)
  - PTT, PT/INR increased
  - Fibrinogen decreased
  - D-Dimer increased

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ACUTE LEUKEMIA WORKUP

Infectious studies:

- Varicella (VZV)
- Herpes Simplex Virus (HSV)
- Cytomegalovirus (CMV)
- Hepatitis Studies (Hep A/Hep B)
- HIV
- Epstein-Barr (EBV)

Others:

- Immunoglobulins (Ig)
  - IgG, IgA, IgM
- HLA Typing (Stem Cell)

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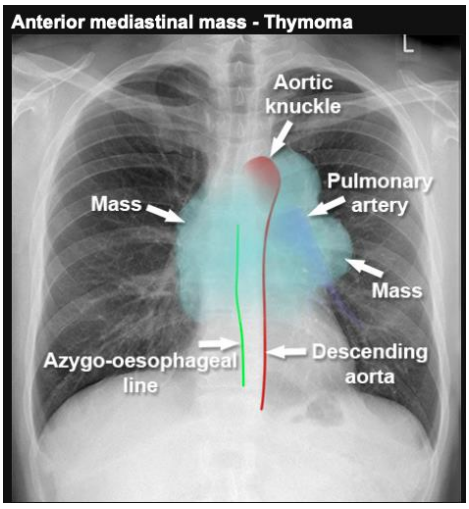
ACUTE LEUKEMIA WORKUP

Chest X-ray[3]

- Performed to rule out mediastinal masses prior to sedation
- Present in 5–10% of ALL (often T-cell ALL)
- Masses can cause respiratory arrest or cardiac dysfunction
- Caution with sedation!



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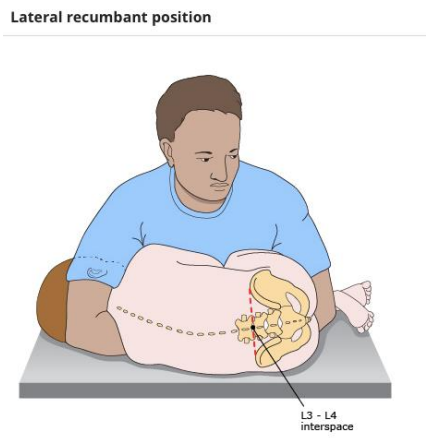
ACUTE LEUKEMIA WORKUP

Lumbar puncture[4]

- Standard for every patient at diagnosis
- Typically done with intrathecal chemotherapy as part of CNS "prophylaxis"
  - Cell count with differential
  - Cytology testing
  - Flow cytometry



The child is positioned near the edge of the examining table. The assistant places one arm around the posterior aspect of the child's neck and the other arm under the child's knees to hold the child in optimal position. The child's hips and shoulders should be kept perpendicular to the table in order to maintain spinal alignment without rotation. The assistant can maintain adequate restraint by holding onto his or her own wrists.

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ACUTE LEUKEMIA WORKUP

Bone marrow aspiration and biopsy

- Gold standard for diagnosis
- Typically done in bone of superior or anterior iliac crest
- Biopsy – Involves a large core needle to pull out a small piece of bone
- Aspiration – Pulls out liquid marrow for evaluation
- Sent for cytogenetics, flow cytometry, molecular diagnostics and "Next Gen" sequencing

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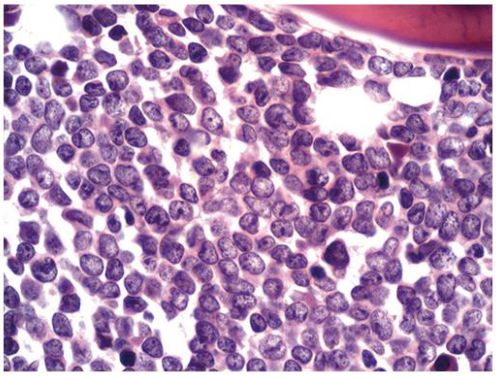
ACUTE LEUKEMIA WORKUP

Bone marrow analysis[5]

- Cellularity
- Hematopathology differential
- Morphology

Bone marrow biopsy of a case of B cell acute lymphoblastic leukemia



Bone marrow biopsy shows total replacement of normal hematopoietic cells with lymphoblasts that shows convoluted or folded nuclei. Hematoxylin and eosin, 100x magnification.

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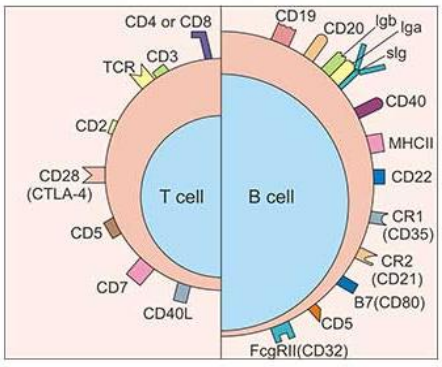
ACUTE LEUKEMIA WORKUP

Immunophenotyping[6]

- Identifies markers present on the cell surface
- Targeted therapies for specific markers exist now (Blinatumomab, Inotuzumab ozogamicin, Rituximab, CAR-T, etc.)
- These studies can also help differentiate lineage and subtypes



Cytogenetics

- Analyze the chromosomes inside the cell
- Identifies number of chromosomes (ploidy)
  - Diploid = 46 chromosomes

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TREATMENTS

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QUIZ QUESTION!

Which of the following has an overall highest rate of survivorship?

a) Osteosarcoma

b) Acute Lymphoblastic Leukemia

c) Hodgkin Lymphoma

d) Acute Myeloid Leukemia

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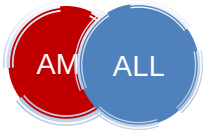
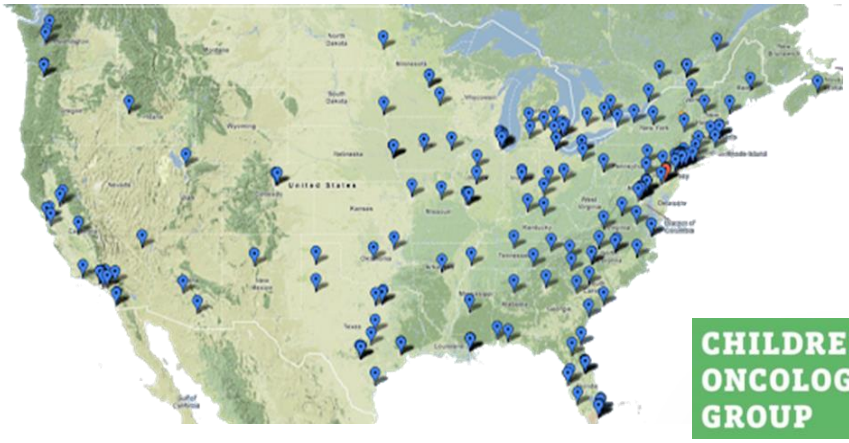
LEUKEMIAS IN CHILDREN





CHILDREN'S ONCOLOGY GROUP

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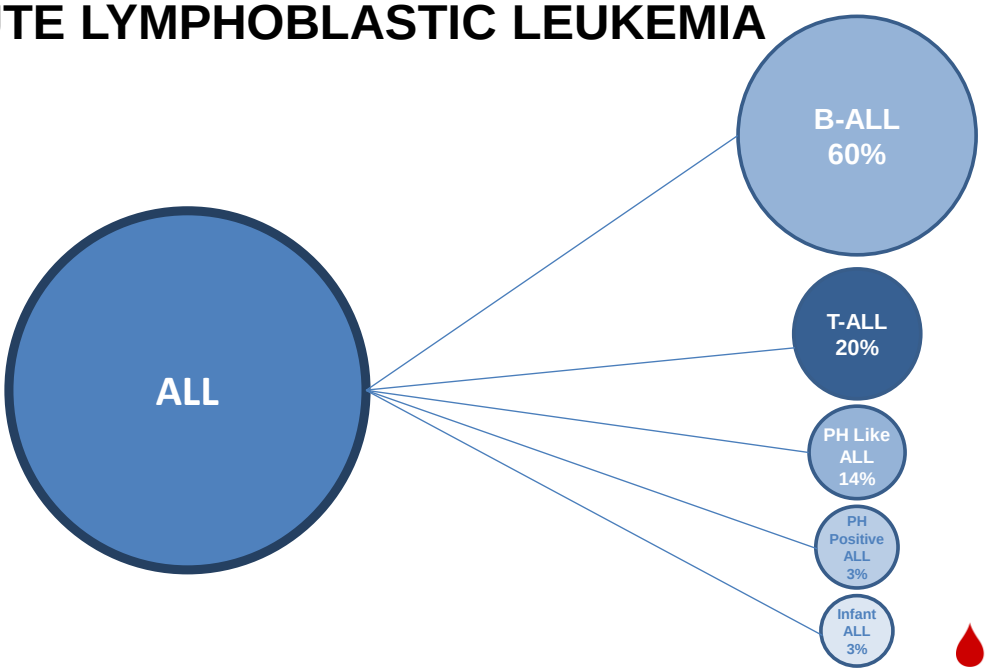
ACUTE LYMPHOBLASTIC LEUKEMIA



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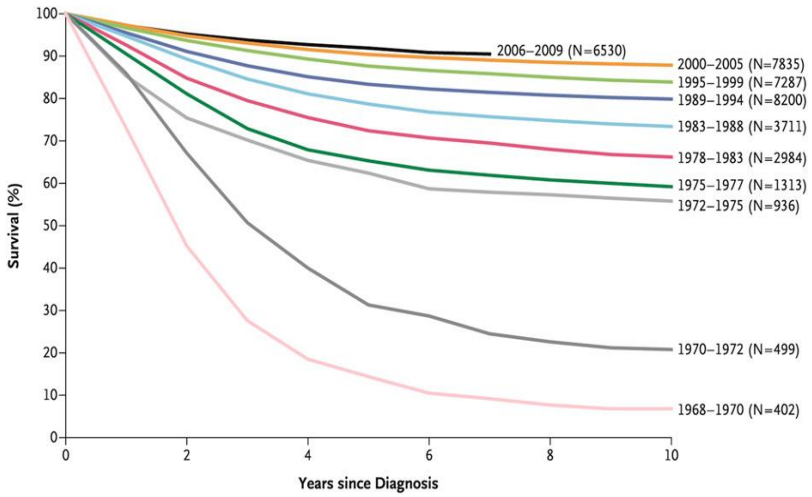
ALL EPIDEMIOLOGY AND SUCCESS

Attributed to the success of:

A. Cooperative group trials
B. IT chemotherapy
C. Stratification and intensification
D. Better drugs



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Hunger SP. Acute lymphoblastic leukemia in children. *N Engl J Med.*

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NCCN GUIDELINES
INITIAL RISK GROUP STRATIFICATION DEFINITIONS

www.NCCN.org

Brown et al. *JNCCN*. 2020;18(1):doi.org/10.6004/jnccn.2020.0001.

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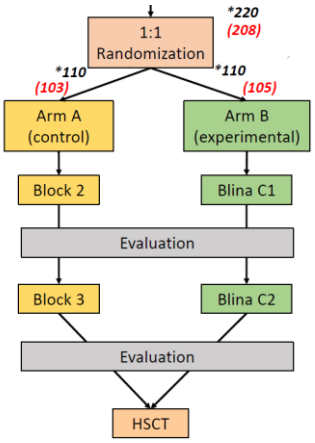
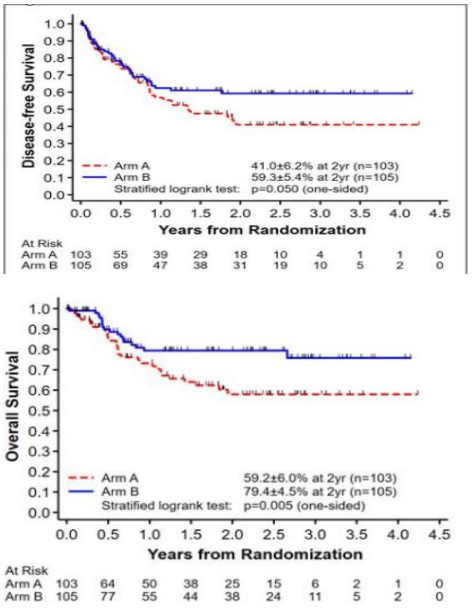
PHASE III STUDY OF BLINATUMOMAB IN PEDIATRIC RELAPSED B-ALL



Parameter	Blina	Chemo	p
%2-yr DFS	59	41	.05
%2-yr OS	79	59	.005
% SCT	73	49	<.001
% MRD clearance	79	21	<.001



Brown et al. *JAMA*. 2021

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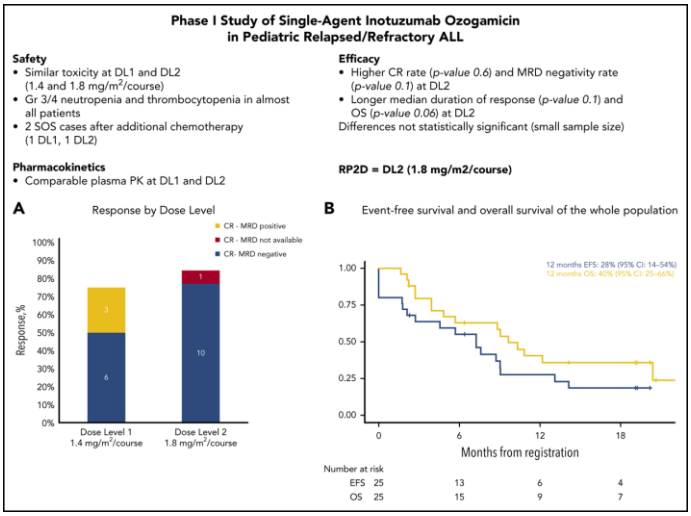
PHASE II STUDY OF INOTUZUMAB IN R-R PEDIATRIC ALL

- The recommended phase 2 dose established at 1.8 mg/m^2 per course
- 85% reached CR after 1 course, 100% of whom had MRD negativity



Brivio et al. Blood. 2021

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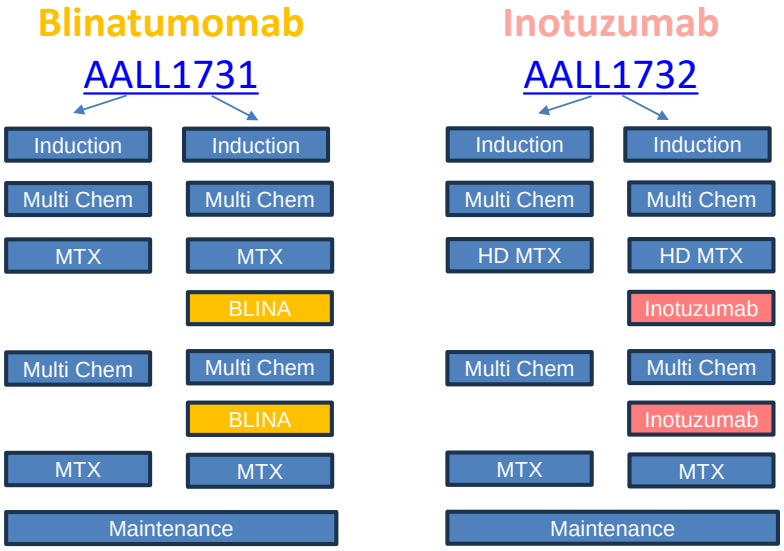
CHILDREN'S ONCOLOGY GROUP



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SEQUENTIAL IMMUNOTHERAPY

> Clin Lymphoma Myeloma Leuk. 2024 Apr;24(4):e168-e173. doi: 10.1016/j.clml.2023.12.016. Epub 2023 Dec 30.

Dose-Dense Mini-Hyper-CVD, Inotuzumab Ozogamicin and Blinatumomab Achieves Rapid MRD-Negativity in Philadelphia Chromosome-Negative B-cell Acute Lymphoblastic Leukemia

Nicholas J Short [1], Elias Jabbour [2], Trevor Jamison [2], Shilpa Paul [3], Branko Cuglievan [4], David McCall [4], Amber Gibson [4], Nitin Jain [2], Fadi G Haddad [2], Lewis F Nasr [2], Kayleigh R Marx [3], Caitlin Rausch [3], J Michael Savoy [3], Rebecca Garris [2], Farhad Ravandi [2], Hagop Kantarjian [2]

Affiliations + expand

PMID: 38212207 DOI: 10.1016/j.clml.2023.12.016

Mini-hyper CVD + CRIB (condensed rituximab, inotuzumab ozogamicin, and blinatumomab) for refractory pediatric B-acute lymphoblastic leukemia

David McCall [1], Elias Jabbour [2], Michael Roth [1], Cesar Nunez [1], Branko Cuglievan [1]

Affiliations + expand

PMID: 36031729 DOI: 10.1002/pbc.29939

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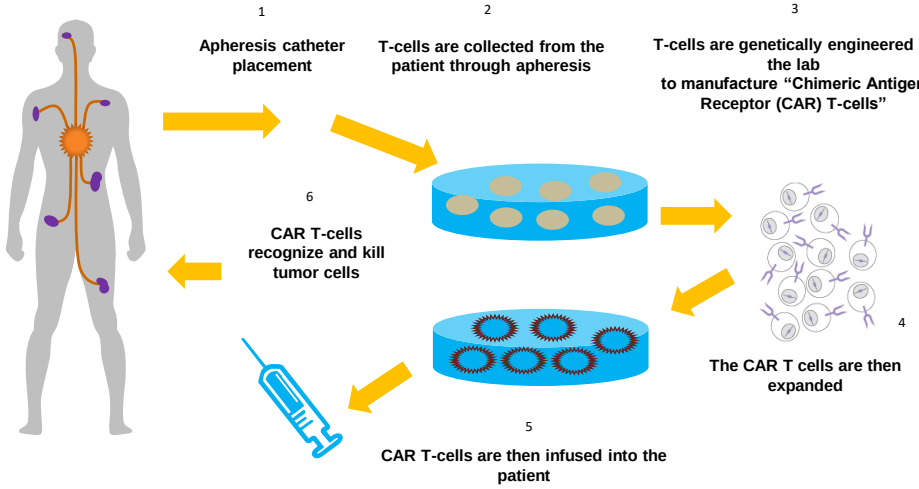
CHIMERIC ANTIGEN RECEPTOR T-CELL THERAPY: HOW IT WORKS



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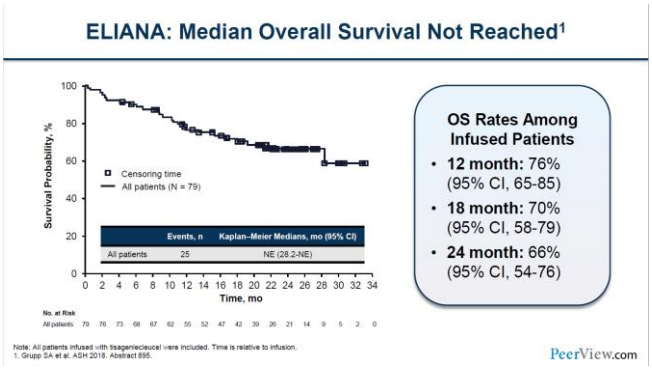
CAR T-CELL THERAPY IN ALL: PRESENT AND FUTURE CHALLENGES

- 75 patients
- 3-month remission rate of 81% and all MRD negative
- 6-month EFS: 73% OS: 90%
- 12-month EFS: 50% OS 76%
- CRS 73% and ICANS 40%



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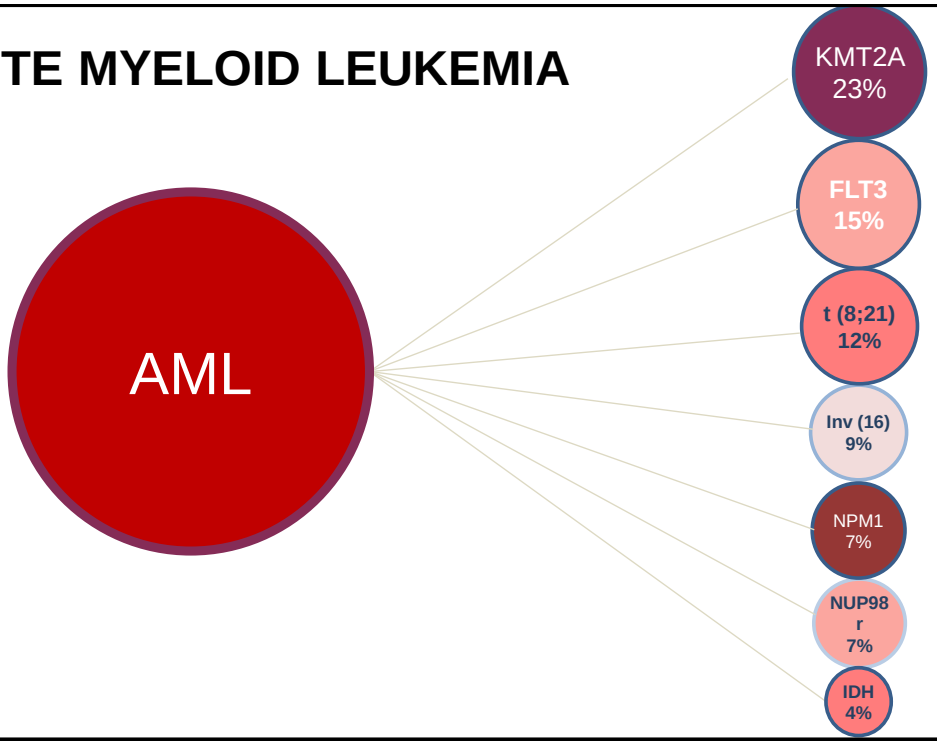
ACUTE MYELOID LEUKEMIA



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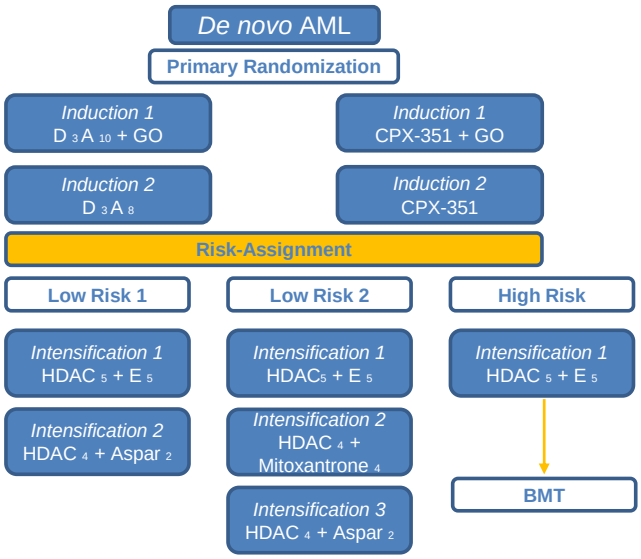
PEDI AML THERAPY IN US (COG)



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Gilteritinib if FLT3-ITD or activating mutations

Maintenance for 1 year

Adapted from COG AML1831.

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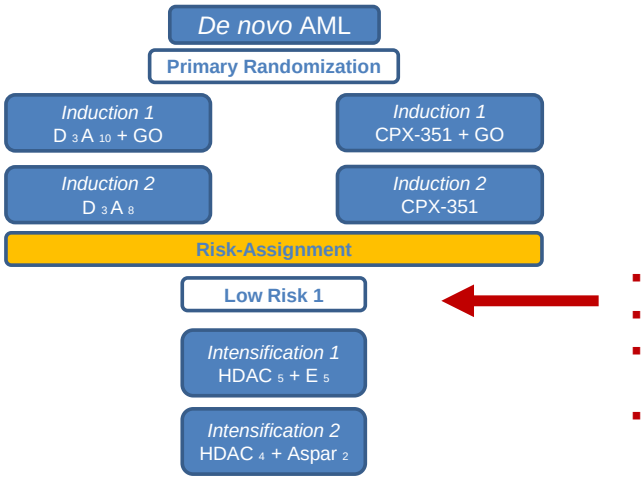
PEDI AML THERAPY IN US (COG)



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Gilteritinib if FLT3-ITD or activating mutations

Maintenance for 1 year

- Inv (16)
- t (8;21)
- CEBPA bZIP
- NPM1c

Adapted from COG AML1831.

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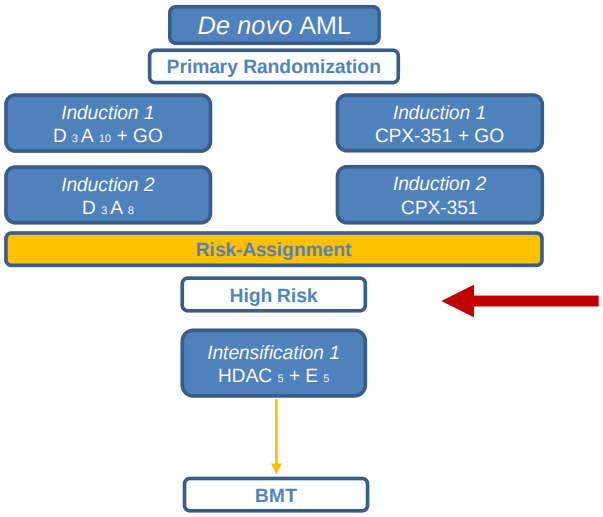
PEDI AML THERAPY IN US (COG)



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Gilteritinib if FLT3-ITD or activating mutations

Maintenance for 1 year

- KMT2Ar*
- NUP98r
- ETV6r or loss
- CBFA2T3-GLIS2
- Monosomy 5/Del (5q) or 7
- RAM phenotype
- MECOMr
- NPM1-MLF1
- DEK-NUP214
- KAT6A-CREBBP
- FUS-ERG

Adapted from COG AML1831.

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IMPORTANCE OF COMMUNICATION AND A PLAN

- Parents will instill a lot of trust with the medical team; therefore, it is of utmost importance to ensure a trusting and healing relationship not only with the patient, but also with the parents (when age appropriate).
- A lot of the anxiety of treatment comes from the unknown, taking the time to go over what side effects to expect at home and long-term effects will help ease a lot of this anxiety.
- Explain that once in survivorship, long-term follow-up is recommended to monitor for lifelong effects of chemotherapy (such as screening echocardiograms with anthracycline use).
- Reach out to Adolescent & Young Adult (AYA) groups to assist teens transitioning into adulthood and to provide college assistance.

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Short- and Long-term Side Effects

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QUIZ QUESTION!

Which of the following is the most common adverse effect of immunotherapies?

a) Urinary frequency

b) Alopecia

c) Infusion-related reactions

d) Altered mental status

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Which of the following is the most common adverse effect of immunotherapies?

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QUIZ QUESTION!

Which of the following is the typical recommended lifetime maximum anthracycline dosing?

a) 1 gm/m^2

b) 450 mg/m^2

c) 0.5 g/m^2

d) 100 mg/m^2

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d) 100 mg/m^2

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TRADITIONAL CHEMOTHERAPIES: METHOTREXATE

Adverse effects from methotrexate:

- Acute kidney injury
- Mucositis
- Methotrexate toxicity
- Lower blood counts (neutropenia risk!)
- Nausea/abdominal pain
- Watch for medication interactions

Long-term adverse effects from methotrexate:

- Decline in neurocognitive function
- Relatively normal renal function
- Relatively normal bone mineral density

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TRADITIONAL CHEMOTHERAPIES: VINCA ALKALOIDS

Vinca alkaloid side effects:

- Constipation
- Neuropathy
- Poor blink reflex
- Jaw pain
- Vinblastine typically has less neurotoxicity than Vincristine

Vinca alkaloid long-term side effects:

- Neuropathy, and neuropathic complaints, but reversible with time
- Motor function alterations
- Ocular and vocal cord palsies

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TRADITIONAL CHEMOTHERAPIES: ANTHRACYCLINES

Anthracyclines:

- Cardiac toxicity
- Nausea
- Skin changes or hair loss

Anthracycline long-term effects:

- Cardiomyopathies (lifetime dose max)!
- Coronary artery disease & atherosclerosis

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TRADITIONAL CHEMOTHERAPIES: CYCLOPHOSPHAMIDE

Side effects:

- Hemorrhagic cystitis
- Liver toxicity
- Kidney injury with or without hematuria
- Altered taste
- Nausea

Cyclophosphamide long-term effects:

- Increased risk of secondary malignancy
- Cardiotoxicities
- Fertility function
- Renal and liver dysfunction

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TRADITIONAL CHEMOTHERAPIES: ASPARAGINASE

Asparaginase:

- Risk of infusion reaction
- Pancreatitis
- Hyperglycemia
- Hyperlipidemia
- Coagulopathy

Long-term effects of asparaginase:

- Chronic pancreatitis
- Dysregulation of glucose
- Dysregulation of lipids
- Chronic abdominal pain
- Growth changes

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IMMUNOTHERAPY SIDE EFFECTS

Blinatumomab:

- Risk of infusion reaction
- Monitor for cytokine release syndrome
- Neurotoxicity can develop
- Encourage daily handwriting testing while admitted inpatient after initiating blina to evaluate for neurotoxicity.
- Neuro exams

Inotuzumab:

- Risk of infusion reaction
- Prolonged QT
- Alterations in liver function studies
- Ursodiol prophylaxis indicated
- Hepatic veno-occlusive disease

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LONG-TERM SIDE EFFECTS

- Vaccinations – Check titers and revaccinate per institution policy/CDC
- HEENT – Routine dental visits, and routine eye exams
- CNS – Developmental/Learning delays, seizures
- CV – Cardiomyopathies (secondary to anthracycline use, the ‘rubicin’ medications)
- Endocrine – Growth, diabetes, bone health/density, thyroid studies if radiated
- Pulm – Pulmonary function testing if received chest radiation or underwent stem cell transplant
- Secondary Malignancies – MDS, therapy-associated AML

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LONG-TERM SIDE EFFECTS

- Fertility concerns
- Psychosocial – Cancer and cancer treatment imparts lifelong trauma, ensure they are being followed with the appropriate mental health professionals for depression, PTSD, chronic pain, anxiety, etc.
  - Job prospects – Some jobs may discriminate against cancer survivors, survivorship clinics can assist with this
  - School & college – A lot of grants/scholarships available for cancer patients, additionally these may require learning accommodations due to treatment

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QUIZ QUESTION!

Which of the following is a common long-term adverse effect of prolonged steroid use?

a) Hearing changes

b) Mood changes

c) Allergic reactions

d) Glucose dysregulation

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Which of the following is a common long-term adverse effect of prolonged steroid use?

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Future

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LEUKEMIA & LYMPHOMA SOCIETY | DARETODREAM PROJECT

Transforming treatment and care for kids with blood cancer.

LLS PedAL

LLS PedAL: The First-of-its-Kind Global Master Clinical Trial for Pediatric Acute Leukemia

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CANCER CLINICAL TRIAL ELIGIBILITY CRITERIA: MINIMUM AGE CONSIDERATIONS FOR INCLUSION OF PEDIATRIC PATIENTS

Guidance for Industry and IRBs

Additional copies are available from:
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Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353;
Email: druginfo@fda.hhs.gov https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
and/or
Office of Communication, Outreach, and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, rm. 3128 Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010;
Email: ocod@fda.hhs.gov https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances

U.S. Department of Health and Human Services
Food and Drug Administration Oncology Center of Excellence
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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Kapil Bhalla, MD
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Clarence McQueen, BS

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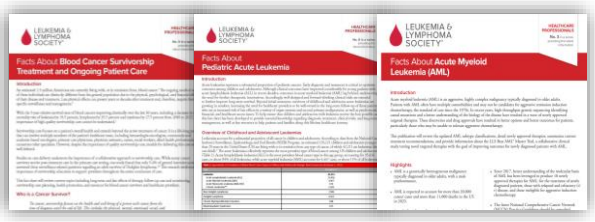
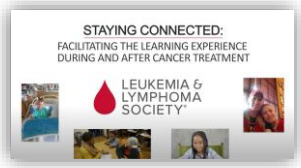
FREE LLS RESOURCES FOR HEALTHCARE PROVIDERS

- CME & CE courses: www.LLS.org/CE
  - Staying Connected: www.LLS.org/StayingConnected
- Fact Sheets for HCPs: www.LLS.org/HCPbooklets
- Videos for HCPs: www.LLS.org/HCPvideos
- Podcast series for HCPs: www.LLS.org/HCPpodcast
- LLS Research Grant Programs: www.LLS.org/Research or email researchprograms@LLS.org





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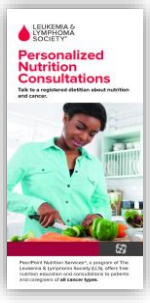
FREE LLS RESOURCES FOR PATIENTS

- **Information Specialists** (IRC) – Personalized assistance for managing treatment decisions, side effects, and dealing with financial and psychosocial challenges.
- **Clinical Trial Nurse Navigators** (CTSC) – provide personalized service for patients seeking treatment in a clinical trial, sift through and provide information to bring back to the HC team www.LLS.org/CTSC
- **Nutrition Education Services Center** (NESC) – one-on-one **free** nutrition education and consultations to patients of all cancer types with RDs who have expertise in oncology nutrition www.LLS.org/Nutrition
- **Reach out Monday–Friday, 9 am to 9 pm ET**
  - Phone: 800.955.4572
  - Live chat: www.LLS.org/IRC
  - Email: LLS.org/ContactUs
  - HCP Patient Referral Form: www.LLS.org/HCPreferral



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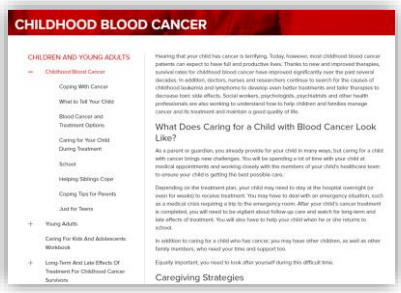
FREE LLS RESOURCES FOR PATIENTS AND CAREGIVERS

- **www.LLS.org/ChildhoodCancer**



- **Webcasts, Videos, Podcasts, booklets**:
  - www.LLS.org/Webcasts
  - www.LLS.org/EducationVideos
  - www.LLS.org/Podcast
  - www.LLS.org/Booklets

- **Support Resources**
  - Financial Assistance: www.LLS.org/Finances
    - Urgent Need
    - Patient Aid
    - Travel Assistance
  - Other Support: www.LLS.org/Support
    - LLS Regions
    - Online Weekly Chats Facilitated by Oncology SW
    - LLS Community Social Media Platform
    - First Connection Peer to Peer Program

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FREE LLS RESOURCES FOR YOUR PATIENTS AND CAREGIVERS

BOOKLETS AND FACT SHEETS

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

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Q & A

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