# BUILDING NURSING KNOWLEDGE THROUGH CASE STUDIES: clinical trials, genomics, and prognosis

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On behalf of The Leukemia & Lymphoma Society (LLS), thank you for joining us for Building Nursing Knowledge Through Case Studies: clinical trials, genomics, and prognosis, a continuing education activity originally presented in Anaheim, California.

We also thank our esteemed speakers for sharing their time and expertise. The significant role of patient-nurse communication related to testing, treatment, prognosis, ethical issues, diversity, clinical trials, as well as other challenges will be discussed. Our goal is to help you improve patient care using information presented and best practices shared in this activity.

If you would like to receive 1.5 continuing education contact hours, please complete the online learning assessment and evaluation. We hope this activity provides an informative and useful learning opportunity for you.

Thank you,

Lauren Berger, MPH  
Senior Director, Patient & Professional Education  
The Leukemia & Lymphoma Society
Welcome and Overview
Lauren Berger, MPH
The Leukemia & Lymphoma Society

Non-Hodgkin Lymphoma: The Nurse's Role and Experience in Providing Patients with Information on their Treatment Options
Amy Goodrich, ACNP-BC

Acute Myeloid Leukemia: Understanding the Basics, Treatment Options and how Nursing can Impact Better Patient Outcomes
Donelle Rizzuto, RN, OCN
Target Audience
This activity has been designed to meet the education needs of nurses involved in the care of patients living with hematologic cancers.

Program Goal
This activity will provide an opportunity for nurses to expand their knowledge about how clinical trials and genomics influence treatment and prognosis for patients with blood cancers.

Program Overview
Clinical trials are important in advancing treatment options for patients with blood cancers. Oncology nurses are key players in clinical trials, including identifying, implementing, educating, treating, monitoring and navigating patients throughout their cancer experience. Personalized nurse-patient communication can contribute to patient enrollment and promote optimal outcomes related to their treatment.

The rapidly evolving and expanding field of genomics is influencing oncology care. Nurses need to understand the practical applications of this emerging science, including prognosis, caring for patients, and other critical clinical issues.

The significant role of patient-nurse communication related to testing, treatment, prognosis, ethical issues, diversity, clinical trials, as well as other challenges will be discussed. Through interactive discussion of case studies, participants and panelists will build knowledge to impact and improve patient care.

Education Objectives
At the conclusion of this program, participants should be able to:

- Explain the role nurses play in helping patients to enroll in clinical trials and optimize their outcomes
- Describe how diversity issues impact enrollment and education about clinical trials
- Identify communication touch points for nurses in treating patients in clinical trials
- Explain how genomics research, including cytogenetics and other biomarkers, relates to treatment and prognosis for patients with blood cancer
- Describe communication strategies for nurses in educating patients about genomic information
- Describe strategies for addressing ethical issues nurses encounter in patient care
CE INFORMATION & DISCLOSURE

Nurses
Approval for nurses has been obtained by the national office of The Leukemia & Lymphoma Society under provider number CEP 5832 to award 1.5 continuing education contact hours through the California Board of Registered Nursing.

Fee Information
There is no fee for this education activity.

Faculty Disclosures
All faculty participating in continuing education activities by The Leukemia & Lymphoma Society are expected to disclose to the activity participants any significant financial interest or other relationships with the manufacturer(s) of any commercial product(s) discussed in their presentations. Faculty also are expected to disclose any unlabeled or investigational uses of products discussed in their presentations.

Amy Goodrich, ACNP-BC, has no affiliations with commercial interests to disclose.

Donelle Rizzuto, RN, OCN, has no affiliations with commercial interests to disclose.
Amy Goodrich, ACNP-BC, is a nurse practitioner in the hematologic malignancies program and research nursing manager at the Johns Hopkins Kimmel Cancer Center in Baltimore, Maryland. Ms. Goodrich manages patients with various types of hematologic malignancies, concentrating on the lymphomas. She also manages the cancer center’s research nurses and is extremely involved in research operations.

Ms. Goodrich earned her master’s degree in 2000 as an acute care nurse practitioner from the Johns Hopkins University and her undergraduate nursing degree from the University of Pittsburgh. She has published and presented extensively on various research topics, hematologic malignancies, new agents, symptom management, and other topics important to research and clinical professionals.
Donelle Rizzuto, RN, OCN, is a clinical nurse coordinator working with Dr. Eli Estey at the Seattle Cancer Care Alliance, where she has been employed for 9 years. She started her nursing career in community health in the Rainier Beach area of Seattle and worked there for over 8 years. During this time she also worked at Providence Mount St. Vincent, a nationally recognized long-term care center that was starting to care for hospice patients. While caring for hospice patients, Ms. Rizzuto felt that she may eventually want to work in the hospice field, so when the opportunity presented itself to work at Seattle Cancer Care Alliance, she jumped at it. Since then she has worked with a variety of hematology and hematology/oncology patients and providers. Ms. Rizzuto has worked with Dr. Estey and AML patients exclusively for the last three years which is a rare opportunity these days. Ms. Rizzuto is a proud survivor of triple negative breast cancer, which led her on a unique journey of living the life of a cancer patient. Originally from Wyoming, Ms. Rizzuto has lived in Seattle, home of the world champion Seattle Seahawks, for 24 years, and now resides with her husband Jerry in Edmonds, Washington.
Building Nursing Knowledge Through Case Studies: clinical trials, genomics, and prognosis

ONS DISCLAIMER

Meeting space has been assigned to provide a satellite symposium supported by The Leukemia & Lymphoma Society via an educational grant during the Oncology Nursing Society (ONS) 39th Annual Congress, May 1-4, 2014 in Anaheim, CA. The Oncology Nursing Society’s assignment of meeting space does not imply product endorsement nor does the Oncology Nursing Society assume any responsibility for the educational content of the symposium.
Non-Hodgkin Lymphoma: The Nurse’s Role and Experience in Providing Patients with Information on their Treatment Options

Amy Goodrich, ACNP-BC
Nurse Practitioner
Johns Hopkins Kimmel Cancer Center
Baltimore, Maryland

Non-Hodgkin Lymphoma Incidence

- NHL
  - A heterogeneous group of neoplasms with differing patterns of growth and response to treatment
- Cases:
  - 70,800 estimated new cases for 2014
  - 38,270 males and 32,530 females
  - NHL ranks 7th among men and 6th among women as the most frequent newly diagnosed cancer in the US
- Deaths:
  - NHL estimated to account for 18,990 deaths in 2014
    - NHL is the 9th leading cause of cancer deaths in men and 8th leading cause if cancer deaths in women
    - From 2000-2009, NHL annual death rates declined by 3%

**Risk Factors Associated with NHL**

- **Age**
- **Immunodeficiency**
  - AIDS, organ transplants, autoimmune disorders
- **Infectious agents**
  - HTLV-1: adult T-cell lymphoma
  - EBV: Burkitt’s lymphoma (Africa)
  - *Helicobacter pylori* (MALT lymphomas)
- **Environmental exposure**
  - Drugs, chemicals, occupational exposure

Ann Arbor Staging System

- Stage I
  - Single LN group
- Stage II
  - Multiple LNs on same side of diaphragm
- Stage III
  - Multiple LNs on both sides of the diaphragm
- Stage IV
  - Multiple extranodal sites or LNs and extranodal disease
- Substaging
  - Extramedullary extension (E)
  - Systemic symptoms (A/B)
  - Bulk > 10 cm (X)

What’s new in NHL?
**Ibrutinib**

- FDA approved in Nov, 2013 for use in relapsed/refractory mantle cell lymphoma (MCL)
- FDA approved in Feb, 2014 for use second line in chronic lymphocytic leukemia (CLL)
- First-in-class Bruton's tyrosine kinase (BTK) inhibitor
- Tyrosine kinases are enzymes that can transfer phosphate (phosphorylation) and function as cellular “on” or “off” switches
- Increased phosphorylation results in uncontrolled B-cell proliferation, differentiation and survival

**Ibrutinib Pivotal Trial in MCL**

- 111 patients studied at 18 sites
- Enrolled in 2 groups (48 patients ≥2 prior cycles of bortezomib and 63 patients < 2 cycles or no prior bortezomib)
- Median age = 66 years
- 86% had unfavorable risk disease
- Median of 3 prior therapies (30% post Hyper-CVAD; 11% post Stem-cell transplant)
- All patients received ibrutinib 560 mg daily by mouth until disease progression or unacceptable toxicity
Ibrutinib Pivotal Trial in MCL

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Grade 1-2</th>
<th>Grade 3-4 (%) (Definition)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td>2</td>
<td>16 (ANC &lt; 1000/mm³)</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>8</td>
<td>11 (Platelets &lt; 50,000/mm³)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>44</td>
<td>6 (increase of ≥ 7 stools/d over baseline)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>37</td>
<td>5 (Fatigue not relieved by rest; limits ADLs)</td>
</tr>
<tr>
<td>Nausea</td>
<td>30</td>
<td>0 (Inadequate intake; tube feeding/TPN)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>22</td>
<td>0 (≥ 6 episodes at least 5 minutes apart/day)</td>
</tr>
<tr>
<td>Peripheral edema</td>
<td>26</td>
<td>2 (&gt; 30% discrepancy in size; gross contour changes; limits ADLs)</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>23</td>
<td>4 (1 fatal; SOB at rest; limits ADLs)</td>
</tr>
<tr>
<td>Constipation</td>
<td>25</td>
<td>0 (Manual evacuation; limits ADLs)</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>23</td>
<td>0</td>
</tr>
</tbody>
</table>

- 8 patients (7%) discontinued due to toxicity
- 16 patients (14%) died during the trial; 12 of PD, 2 pneumonia, 1 sepsis, 1 cardiac arrest- unrelated
- No toxicity differences in the two groups
- Median follow up 15.3 months
- Response rate 68% (47% PR, 21% CR); responses improved over time with continued therapy
- Estimated median duration of response – 17.5 months
- Estimated overall survival at 18 months – 58%
Obinutuzumab

- FDA approved in Nov 2013 for use with chlorambucil in untreated CLL
- Type II glycoengineered, humanized anti-CD20 monoclonal antibody
- Compared to rituximab, induces increased Antibody-Dependent Cellular Cytotoxicity (ADCC), less Complement-Dependent Cytotoxicity (CDC) and superior direct cell death induction
- ?? Rituximab replacement ??

Obinutuzumab Pivotal Trial in CLL

- 781 patients enrolled in Europe
- Untreated CLL with indication for therapy AND coexisting medical conditions or reduced renal function
- Median age 73
- Randomized to 1:1:1
  - Arm A: Chlorambucil (0.5 mg/kg by mouth D1 & 15 q 28 days x 6 for all arms)
  - Arm B: Obinutuzumab + Chlorambucil
  - Arm C: Rituximab + Chlorambucil (R: 375 mg/m² D1 C1, then 500 mg/m² D1 C2-6)
### Obinutuzumab Pivotal Trial

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Overall Response Rate</th>
<th>Complete Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm A (C alone)</td>
<td>32%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Arm B (O + C)</td>
<td>78%</td>
<td>21%</td>
</tr>
<tr>
<td>Arm C (R + C)</td>
<td>65%</td>
<td>7%</td>
</tr>
</tbody>
</table>

### Obinutuzumab Pivotal Trial: O + C Arm Only

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grades 3-4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion related reactions</td>
<td>First infusion- 69</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Second 1000 mg infusion- 3</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>After second 1000 mg- &lt; 1</td>
<td>0</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>40</td>
<td>34</td>
</tr>
<tr>
<td>Infection</td>
<td>38</td>
<td>9</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Anemia</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Cough</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>
### Obinutuzumab Pivotal Trial in CLL

<table>
<thead>
<tr>
<th>Cycle Day</th>
<th>Dose</th>
<th>Infusion Rate</th>
<th>Premeds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 1 Day 1</td>
<td>100 mg</td>
<td>25 mg/hr over 4 hrs without rate escalation</td>
<td>Acetaminophen (650-1000 mg po)</td>
</tr>
<tr>
<td>Cycle 1 Day 2</td>
<td>500 mg</td>
<td>50 mg/hr escalated by 50 mg every 30 minutes to max 400 mg/hr</td>
<td>Acetaminophen (all doses)</td>
</tr>
<tr>
<td>Cycle 1 Day 8</td>
<td>1000 mg</td>
<td>100 mg/hr escalated by 100 mg every 30 minutes to max 400 mg/hr</td>
<td>• Cycle 1 Day 8 and beyond: if Grade 3 IR or with previous infusion, give antihistamine OR sympotms &gt; 214 prior to next dose, give IV glucocorticoid</td>
</tr>
<tr>
<td>Cycle 1 Day 15</td>
<td>1000 mg</td>
<td>Same as Cycle 1 Day 8</td>
<td>Same as above</td>
</tr>
<tr>
<td>Cycle 3 &amp; Day 1</td>
<td>1000 mg</td>
<td>Same as Cycle 1 Day 8</td>
<td>Same as above</td>
</tr>
</tbody>
</table>

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In your practice, how do a patient's age, race and ethnicity impact treatment decisions and your education style? How do those differ for patients receiving standard therapy vs. considering enrolling in a clinical trial?
Diffuse Large B-Cell Lymphoma

- Most commonly diagnosed NHL in the U.S.
- Accounts for 31% of NHL
- Unregulated and refractory differentiation and proliferation of lymphoid cells (cell clones)
- Multiple causal factors including genetic changes, chromosomal translocations, deletions, insertions of foreign genes into cells
  - BCL-2: t(14;18) in 20%–30% of cases (higher relapse)
  - BCL-6 (better prognosis)
- Lymphoma cells often mimic behavior of "normal cells" albeit at different rates

Common Phenotypic Variants of DLBCL With Different Prognosis

<table>
<thead>
<tr>
<th>Morphology</th>
<th>Molecular Marker Expression</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bcl2</td>
</tr>
<tr>
<td>Centroblastic (GCB)</td>
<td>Negative</td>
</tr>
<tr>
<td>Immunoblastic (non-GCB)</td>
<td>Positive</td>
</tr>
<tr>
<td>ABC most common</td>
<td></td>
</tr>
</tbody>
</table>

- Gene expression analysis has identified at least 2 main subtypes of DLBCL based on cell of origin
  - GCB (more favorable prognosis)
  - ABC
- 3-year OS rates of GCB subtypes have been observed to be superior to ABC subtypes (77% vs. 42%, respectively, \( p < 0.001 \)) with standard chemotherapy and with the addition of rituximab to standard chemotherapy (85% vs. 69%, \( p = 0.032 \))
- KIS7 independent predictor despite phenotype
Current Prognostic Approaches in Diffuse Large B-cell Lymphoma

- New NCCN IPI

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: &lt; 40</td>
<td>0</td>
</tr>
<tr>
<td>41-60</td>
<td>1</td>
</tr>
<tr>
<td>61-75</td>
<td>2</td>
</tr>
<tr>
<td>&gt; 75</td>
<td>3</td>
</tr>
<tr>
<td>LDH: Normal</td>
<td>0</td>
</tr>
<tr>
<td>1-3 x ULN</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 3 x ULN</td>
<td>2</td>
</tr>
<tr>
<td>ECOG PS &gt; 2</td>
<td>1</td>
</tr>
<tr>
<td>Ann Arbor stage III or IV</td>
<td>1</td>
</tr>
<tr>
<td>Extramedullary disease in BM, CNS, liver/GI tract or lung</td>
<td>1</td>
</tr>
</tbody>
</table>

NCCN-IPI

<table>
<thead>
<tr>
<th>Score</th>
<th>% of patients (n=1650)</th>
<th>5 year overall survival (old IPI)</th>
<th>5 year progression free survival (old IPI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low 0-1</td>
<td>19%</td>
<td>96% (90%)</td>
<td>91% (85%)</td>
</tr>
<tr>
<td>Low-Intermediate 2-3</td>
<td>42%</td>
<td>82% (77%)</td>
<td>74% (66%)</td>
</tr>
<tr>
<td>High-Intermediate 4-5</td>
<td>31%</td>
<td>64% (62%)</td>
<td>51% (52%)</td>
</tr>
<tr>
<td>High 5+</td>
<td>8%</td>
<td>33% (54%)</td>
<td>30% (30%)</td>
</tr>
</tbody>
</table>
**Survival: NCCN-IPI vs IPI**

**Indications to Treat: DLBCL**

- Confirmation of the tissue diagnosis and extent of disease is critical to treatment selection
- Once the diagnosis of DLBCL is confirmed, treatment should be initiated promptly
- The survival of patients with aggressive lymphoma may be measured only in weeks unless aggressive treatment is initiated promptly
### DLBCL Treatment

- **Initial therapy**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-II Nonbulky (&lt;10 cm)</td>
<td>RCHOP x 3 + XRT or RCHOP x 6 + XRT</td>
</tr>
<tr>
<td>I-II Bulky (≥10 cm)</td>
<td>RCHOP x 6 + XRT</td>
</tr>
<tr>
<td>III-IV</td>
<td>Clinical trial or RCHOP (21 or 14) or EPOCH + R</td>
</tr>
<tr>
<td></td>
<td>Consolidation: Autologous transplant in high risk disease</td>
</tr>
</tbody>
</table>

- Consider CNS prophylaxis in selected cases (sinus, testicular, breast, bone marrow, HIV, 2+ extranodal sites or elevated LDH) x 4-8 doses

### Case Study

- 39 yo Mr. A.
- Presents with rapidly increasing mass in left neck, no other symptoms
- Biopsy shows DLBCL
- LDH and other labs normal
- Staging reveals IIIA disease, non-bulky
- Supportive wife and 18 mo old daughter
- Came to the U.S. as a small child from Mexico
Case Study

- Variant info:
  - BCL6 positive/Centroblastic (GCB)
  - Estimated 85% overall survival at 3 years
  - Favorable prognosis
- Ki67 high
  - Unfavorable prognosis

Current Prognostic Approaches in Diffuse Large B-cell Lymphoma

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</table>
NCCN-IPI: Mr. A.

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<th>Score</th>
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<td>8%</td>
<td>33% (54%)</td>
<td>30% (39%)</td>
</tr>
</tbody>
</table>

Case Study

- Received RCHOP X 6
- Post therapy CT: residual mediastinal adenopathy
- Post therapy PET: negative but questionable increased FDG uptake in mediastinum
- 3 months later, repeat PET/CT: No change in size of nodes but more FDG uptake on PET
- 6 months later PET/CT: New and increasing FDG-avid nodes
Case Study

- Biopsy confirms DLBCL; primary refractory
- R-ICE x 4 with complete resolution of all FDG uptake except left supraclavicular/neck node
- Involved field radiation with excellent response on exam
- Consolidated with allogeneic transplant from a matched sibling donor
- 2 month post BMT CT scans show decreased neck adenopathy and otherwise normal

Case Study

- Develops GVHD of the skin requiring steroids
- 5 months post transplant, presents with diplopia (on steroids)
- Extensive work up negative
- Left eye becomes edematous and protruding
- PET: Soft tissue mass in orbital apex with other new areas of FDG uptake
Case Study

- Radiation and Rituximab
- Further progression, now at 9 months post transplant
- Started on lenalidomide and rituximab with some response
- Profound cytopenias, delays, progression
- Bone marrow negative for lymphoma
- Steroid pulse

Case Study

- Neuro symptoms
- Brain lesions on MRI
- Whole brain radiation, now nearing 1 year post BMT
- Further rapid progression
- Continued profound cytopenias
- Death 11 months post BMT; 29 months post diagnosis
**Mexican Cultural Implications**

- Strong reliance on family
- Father or oldest male holds greatest power
- May make health decisions for others in the family
- Machismo – defined sense of honor vital to Hispanic sense of self-esteem and manhood
- Women expected to be primary force holding family and home together, including primary caregiving

**Mexican Cultural Implications**

- Family involvement in health care common
- Strong faith and church ties
- Lay healing common
- Family often closely involved in caring for dying family member
- Low rate of hospice utilization
What successful strategies have you used or have you seen others use in managing challenging patients/families at the end of life, specifically surrounding whether to treat or focus on quality of life with hospice services?

Mr. A.

- Non-Hispanic wife
- Oldest male in family
- Significant distance from family
- Did not discuss prognosis with extended family
- Died at home without hospice
Key Take Aways

- Lots new and lots to come in NHL
- DLBCL prognostic tests/tools improving but not perfect
- Nursing understanding of prognostics critical (biggest challenge is keeping up!)
- It’s not always about the prognostic results
- Patient factors vary in many ways
Acute Myeloid Leukemia:
Understanding the Basics, Treatment Options and how Nursing can Impact Better Patient Outcomes

Donelle Rizzuto, RN, OCN
Clinical Nurse Coordinator
Seattle Cancer Care Alliance
Seattle, Washington

• AML is an aggressive form of blood cancer in which too many normal myeloid blood stem cells become abnormal leukemia cells
AML Incidence 2014

- It is estimated there will 18,860 new cases of AML diagnosed this year, majority will be in adults*
- It is estimated that there will be around 10,460 deaths from AML in 2014, majority will be in adults*

*R: American Cancer Society, Cancer Facts and Figures, 2014

Risk Factors

- Benzene exposure (cigarette smoke)
- Previous Chemotherapies - alkylating agents, platinum drugs, anthracyclines
- Radiation
- Certain blood cancers
  - MDS – Myelodysplastic Syndrome
  - Myeloproliferative Neoplasms
  - Polycythemia Vera
  - ET - Essential Thrombocytopenia
  - Myelofibrosis
- Some genetic syndromes: Down Syndrome, Fanconi's anemia, Shwachman syndrome, Diamond-Blackfan Anemia
Risk Factors

- Family history increases risk of AML only if close relative, such as parent or sibling. However even if close relative has AML, risk to family member is very low.
- People 60 years and older are more likely to develop AML.

The Role of Molecular and Cytogenetic Testing in Prognosis and Treatment

- Why is it that some patients are sent for stem cell transplant while others only receive chemotherapy with no plans for transplant unless relapse occurs?
- Determining treatment and prognosis is based on cytogenetics (karyotype) and molecular studies.
Cytogenetics

- Cytogenetics is the study of a patient's karyotype (chromosomes) – karyotyping in AML is looking at the chromosomes of the leukemia cell
- People with AML can have normal and abnormal chromosomes
- Older people are more likely to have abnormal chromosomes as well as people with prior blood disorders/cancers or prior chemotherapy

Molecular Studies

Molecular studies look for specific abnormal mutations in the leukemia cell;

Two most common:
- FLT3+: unfavorable, short remission and high relapse rate
- NPM1+: favorable in presence of no FLT3 mutation
Prognosis

- Once cytogenetic and molecular study results are known this allows practitioner to place the patient in one of three risk groups
  - Favorable
  - Intermediate
  - Poor

This risk refers to what happens with standard therapy and might not apply to newer therapies

Favorable” AML

- Inversion 16 – inv(16)
- Translocation of the 8 & 21 chromosome t(8;21)
- Normal cytogenetics with NPM1+ & FLT3-
- No Trial

- 80-90% of patients will achieve a CR
- 70% will achieve a cure with standard therapy (7+3), and without SCT
“Intermediate” AML

- Normal cytogenetics
- No NPM1+ and FLT3 negative
- Could choose trial or standard therapy

Overall survival rate at 2 years is 30% with standard therapy and 30-40% with standard therapy + SCT

“Poor” AML

- Abnormal Cytogenetics
- Trial Recommended
“Poor” AML

- Common poor prognosis abnormalities:
  - Trisomy 8; (+8) which is extra copy of the 8th chromosome
  - Monosomy 5 or 7: del(5), del(7) when a chromosome is missing from the 5th or 7th chromosome
- Overall survival is <5% with standard therapy and 10-20% with standard therapy + SCT

Clinical Trials: Talking With Patients
Nursing Role in Educating Patients

- Nurses can help patients understand that clinical trials give patients options to potentially achieve better results than standard therapy in potentially all risk groups.
- Many clinical trials drugs are approved for AML, however they are in different combinations.
- Some clinical trials for AML are focused on the older patient therefore are less toxic, with an emphasis on outpatient treatment.
- Although everyone reacts differently, a majority of patients on the less toxic trials are able to stay out of the hospital during their treatment.

Diversity in Educating Patients

- We typically think of diversity as people with different races or cultures, however nurses can also apply this to the different age groups we care for.
- My case study will be focusing on the older adult.
- Common reactions to participating in a clinical study for older population:
  - “I don’t want to be treated like a guinea pig”
  - “The drug company just wants to make money, they don’t care about me”
- What perceptions have you ran into regarding clinical trials and how did you address the issue?
Ethical Issues for Nurses

Case Study - Margo

Margo, 70 yo - normal cyto, NPM1+, FL13+

Clinical Trial: Started June, 2013 oral tadodostat (d1-35 days) + cytarabine d1-5 x 3 cycles

Bone Marrow: Morphologic remission after first cycle

Side effects: Moderate pruritic Rash, nausea, hospitalized 2 days

SCT: 11/6/2013

Tadodostat = serine peptidase inhibitor; causes amino acid deprivation with antitumoral response
Case Study - Wilma

Wilma 79 y.o. Normal cytogenetic, NPM1-, FLT3-, 1x MDS

Clinical Trial: Started Feb, 2013 oral losodosostat d1- 35 days + cytarabine d1-6 x 2 cycles

Bone Marrow: Morphologic remission after first cycle

Side Effects: Severe full body pruritic rash with burning/itching, arm swelling, resulting in patient declining further treatment after 2nd cycle

Supportive care: Put on prednisone due to bone pain, weakness, lack of appetite with great results of patient returning to baseline and function, stable on 40mg pred daily (started 9/2013)

Case Study - Wilma

- Supportive Care - RTC every 7-14 days for PRBC/hydration
- Peripheral blasts and CBC stable
- Pt “doing so well”, daughter wants her to consider another trial
- Pt received low dose ara-c sq 35mg and decitabine 35mg IV x 7 days 11/4/13
Case Study - Wilma

- Intermittent fevers x 2 weeks, pt declined to go to hospital taking high dose APAP at home
- Daughter overwhelmed with care of mom (dad at home with dementia as well)
- Discussed skilled nursing placement, palliative and hospice care options available
- Admitted 12/24 for fevers
- Inpatient issues – kidney failure, hospital induced dementia, respiratory failure → family decided comfort care
- Died Jan 10, 2014

Ethical Issues with AML

- Disagreement about treatment options, continuing or stopping
- Undue pressure on patient at critical point
- Cultural differences due to differences in gender, age or religious beliefs/spirituality
- Lack of understanding about outcome
- Need to communicate “bad news”

What other ethical issues you have encountered?
The Leukemia & Lymphoma Society Resources

You may find the following LLS FREE Materials by clicking on the following link: www.LLS.org/publications

- **Facts 2013** - is an update of current data available for blood cancers
- **Acute Myeloid Leukemia** - This booklet provides information about acute myeloid leukemia (AML) for patients and their families
- **Myeloproliferative Neoplasms Fact Sheets** - separate Facts Sheets for Myelofibrosis, Polycythemia Vera and Essential Thrombocythemia
- **Myelodysplastic Syndromes** - This booklet provides information about myelodysplastic syndromes (MDS) for patients and their families

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The Leukemia & Lymphoma Society (LLS) offers resources for your patients:

- **Live, Online Chat** - provide a friendly forum to share experiences and chat with others about anything from the initial phase of diagnosis to treatment and survivorship. Each chat is moderated by an oncology social worker and is password protected.
  - **WEBSITE:** www.LLS.org/chat
- **Co-Pay Assistance Program** - offers financial assistance to qualified cancer patients to help with treatment-related expenses and insurance premiums. Patients may apply online or over the phone with a Co-Pay Specialist.
  - **WEBSITE:** www.LLS.org/copay
  - **TOLL-FREE PHONE:** (877) 557-2072
- **For more information about blood cancers, other LLS programs and financial assistance, please contact an LLS Information Specialist.**
  - **TOLL-FREE PHONE:** (800) 995-4672
  - **EMAIL:** infocenter@LLS.org
REFERENCES


LLS Acute Myeloid Leukemia Booklet: www.LLS.org/publications.


