



**The Leukemia &
Lymphoma Society®**

Fighting Blood Cancers



Treating Hematologic Malignancies: Barriers to Care

OUR FOCUS

LEUKEMIA

LYMPHOMA

MYELOMA

ABOUT

disease management and access to care

HELD IN CONJUNCTION WITH THE

**Oncology Nursing Society
31st Annual Congress**

East Ballroom | Boston Convention & Exhibition Center
Boston, Massachusetts

This program is sponsored by The Leukemia & Lymphoma Society

Breakfast Symposium

SATURDAY, MAY 6, 2006

6:15 AM – 8:15 AM

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**The Leukemia &
Lymphoma Society®**

Fighting Blood Cancers

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On behalf of The Leukemia & Lymphoma Society, I am pleased that you are joining us for ***Treating Hematologic Malignancies: Barriers to Care***, an educational Ancillary Symposium presented during the ONS 31st Annual Congress. The Society is honored to support this learning activity in full.

I would like to thank our esteemed speakers. Their purpose is to provide you with strategies to better educate and advocate for patients in today's cancer treatment paradigm.

This workbook will help guide you through the presentations. If you would like to receive 2.0 continuing education contact hours, please complete the Continuing Education/Activity Evaluation Form in this workbook and turn it in at the completion of this event.

Again, welcome. I hope that you find this program rewarding and informative.

Sincerely,

Carson J. Pattillo, MPH
Vice President, National Education Programs
The Leukemia & Lymphoma Society



6:15 AM

Welcome & Introductions

Carson Pattillo, MPH

Vice President

National Education Programs

The Leukemia & Lymphoma Society

6:30 AM

Medication Adherence for Patients

Patricia Jakel, RN, MN, AOCN

Clinical Nurse Specialist

Clinical Research Center

UCLA Medical Center

Los Angeles, California

7:10 AM

Treating Hematologic Malignancies: Overcoming Barriers to Care

Carolyn Blasdel, RN, MA, FNP, OCN

Clinical Research Nurse

Center for Hematologic Malignancies

Oregon Health & Science University Cancer Institute

Portland, Oregon

7:50 AM

Questions & Answers

Panel:

Patricia Jakel, RN, MN, AOCN

Carolyn Blasdel, RN, MA, FNP, OCN

8:15 AM

Adjournment



PROGRAM GOAL

Cancer therapies are available today that can save lives, and education and treatment adherence are critical for the best outcomes. Without access to information and optimal treatment management, an individual's quality of life and survival can be compromised. Barriers to education and care can be attributed to various factors, including communication challenges experienced by both the patient and health care professional.

In today's cancer treatment paradigm, many individuals are on oral therapy regimens, which limit counseling opportunities. When patients lack clarity and information, the nursing professional plays a critical role as the patient advocate and educator. This symposium addresses barriers to care and the best possible treatment outcomes and provides strategies for nurses to manage and educate patients. Issues surrounding treatment adherence will be addressed, as well as ways to improve patient outcomes through better communication methods.

PROGRAM OBJECTIVES

By the end of this program, participants will be able to:

1. Discuss medication adherence challenges with oral and targeted therapies in cancer treatment
 - oral therapy as a stand-alone cancer treatment and in combination therapies
 - barriers impacting adherence
2. Apply strategies to improve treatment adherence and communication
 - education and informed consent
 - tools to track treatment progress, medications, and side effects
 - counseling opportunities beyond the clinic
3. Identify the nursing professional's role as a patient advocate

CONTINUING EDUCATION INFORMATION *for Nurses and Health Care Professionals*

Approval for nurses has been obtained by The Society's National Office under provider number CEP 5832 to award 2.0 continuing education contact hours through the California Board of Registered Nurses.

The Leukemia & Lymphoma Society has been assigned meeting space to support an educational offering during the ONS 31st Annual Congress. The Oncology Nursing Society's assignment of meeting space does not imply product endorsement nor does the Oncology Nursing Society assume responsibility for the educational content.

FACULTY BIOGRAPHIES



Patricia Jakel, RN, MN, AOCN

■ *Clinical Nurse Specialist
Clinical Research Center
UCLA Medical Center
Los Angeles, California*

Patricia Jakel, RN, MN, AOCN, is Clinical Nurse Specialist at the Clinical Research Center, University of California, Los Angeles (UCLA), California, where she is responsible for supervising the nursing staff and overseeing the care of patients receiving research protocols, among other duties. She also coordinates outreach classes for chemotherapy verification and oncology core curriculum.

Ms. Jakel earned a master's degree in nursing in 1991 from UCLA and an undergraduate degree from Hartwick College in New York. She is certified as an Advanced Oncology Nurse by the Oncology Nursing Society, and received the Advanced Practice Nurse of the Year Award in 1997 from the Los Angeles Chapter.

Ms. Jakel is a member of several professional organizations, including the American Nurses Association, Oncology Nursing Society, and American Cancer Society. She has been a presenter on many occasions on topics such as symptom management in oncology; improving outcomes in patients with cancer, focusing on quality of life; and other topics important to oncology nursing.



Carolyn Blasdel
RN, MA, FNP, OCN

■ ***Clinical Research Nurse***
Center for Hematologic
Malignancies
Oregon Health & Science
University Cancer Institute
Portland, Oregon

Carolyn Blasdel, RN, MA, FNP, OCN, is Clinical Research Nurse at the Center for Hematologic Malignancies, Oregon Health & Science University Cancer Institute, in Portland. She has held this position for more than 7 years and works primarily with patients with chronic myelogenous leukemia. Ms. Blasdel is certified in oncology nursing and recently earned a post-master's certificate as a family nurse practitioner from Washington State University. She has worked on the clinical trials of Gleevec® since the original Phase I studies.

For 9 years, Ms. Blasdel was a clinical research nurse and study coordinator at the Don and Sybil Harrington Cancer Center in Amarillo, Texas. She also held positions in administration, teaching, and hospital nursing. Ms. Blasdel obtained a master of arts degree in psychosocial nursing from the University of Washington in Seattle and a bachelor of science degree in nursing from the University of Maryland in Baltimore.

Ms. Blasdel's work has been published in such journals as *Pharmacotherapy* and *Blood*. She presented at the 2003 Oncology Nursing Society Annual Congress and was the keynote speaker on side effect management for a telephone education program sponsored by The Leukemia & Lymphoma Society. She also has given various presentations on chronic myelogenous leukemia and on issues of adherence and oral cancer therapies to various oncology nursing groups.

FACULTY DISCLOSURE STATEMENT



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.

Carolyn Blasdel, RN, MA, FNP, OCN, has asked that we advise participants in this activity that she has an affiliation with Health Ed, Healthology, Robert Michael Communications, and Bristol-Myers Squibb (*Consultant*); Health Science Center for Continuing Medical Education (*Speaker's Bureau*); Novartis Oncology (*Speaker*); and McMahonMed for Oncology Special Edition (*Author*).

Patricia Jakel, RN, MN, AOCN, has asked that we advise participants in this activity that she has an affiliation with Merck, Amgen, GlaxoSmithKline, and MGI Pharma (*Speaker's Bureau*).

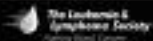
PRESENTATIONS




**Medication Adherence
for Patients**

Patricia Jakel, RN, MN, AOCN
Advance Practice Nurse
UCLA Medical Center
Associate Professor of Nursing
UCLA School of Nursing

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New Challenges for Nursing

National Cancer Treatment Expenditures, 1963-2004

Year	Cancer Treatment Spending (\$ Billion)	Total Personal Health Care Spending (\$ Billion)	Cancer Treatment Spending as Total (%)
1963	1.2	29.4	4.1
1972	3.9	76.3	5.1
1983	13.5	217.8	6.2
1985	18.1	376.4	4.8
1987	27.8	698.4	4.0
1995	41.2	879.3	4.7
2004	72.5	1640.1	4.4

1963-1995: Brown M., et al. *Annals Rev Public Health*. 2007;28:391-415.
2004: National Institutes of Health. *Cost of Cancer Report to the US Congress*. Bethesda, MD: National Institutes of Health; 2005.
National Health Care Statistics Perspectives: 1993-2012.
<http://www.cdc.gov/nchs/data/tables/tables/ncsreport/1002and2001.pdf>

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**Oral Therapies –
A Changing Paradigm**

- New anticancer oral agents since 2000
- New nursing challenges
 - Education time limited
- Beneficial for patients
 - Less time-consuming
 - No life-disrupting trips to clinics

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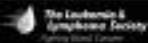
PRESENTATIONS




From Compliance to Adherence

- **Compliance:** as the extent to which the patient's behavior coincides with medical or health advice; this implies that patients are passive responders to clinicians' authoritative demands
- **Adherence:** recognizes patients' autonomy and requires their agreement with recommendations of the health care professional

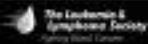
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**Cost of Non-Adherence –
Office of the Inspector General**

- It is estimated that only 50% of patients take their medications as prescribed
- 22% per year of ALL hospital admissions result from non-adherence and unintentional inappropriate use of medications; 28% of emergency department visits and 23% of admissions to skilled nursing facilities
- 125,000 deaths per year
- Studies have shown that 1 of every 6 adult patients has difficulty taking the prescribed medication during the first 2 weeks following hospital discharge

Toroni G, et al. Eur J Geriatric Res. 2006 Jan 18; [Epub ahead of print].

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Cost of Non-Adherence

- The cost of both direct and indirect non-adherence has been estimated at \$300 to \$400 million per year
- Considered "America's other drug problem"
- Taking medication is not just a pharmacological process; it is a psychological, interpersonal, and social process
- Medication will be deemed ineffective if the outcomes desired by the patient are not reached, even if the patient improves clinically

World Health Organization, Geneva, Switzerland, 2003.

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PRESENTATIONS



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Medication Adherence – Is It a Problem?

- Non-adherence rate of 43% in patients with breast cancer receiving oral chemotherapy¹
- Among patients 60 years and older, non-adherence rates range from 26% to 59%
- Average non-adherence rate is 24.8%

Lehertz AH, et al. Cancer. 1993;81:17-22.

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Key Questions in Novartis Study

- Are physicians prescribing Gleevec® properly?
- Are patients taking Gleevec® as indicated? (compliance)
- Are patients staying on therapy? (persistence)

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Fighting Blood Cancer

Customer Perspective

- Insight mining research shows that physicians, patients, and some nurses perceive that compliance and persistence are not an issue
- Authorization for Use data show that 96% of physicians think patients are compliant

Response	Percentage
Yes, Patients are Compliant	96%
Do Not Know & Disagree	4%

n = 86

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The Leukemia & Lymphoma Society
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Compliance and Persistency Analysis

- Part of a large compliance and persistency program initiated by the US Gleevec® Brand Team
- Patient level data provided by Verispan Inc.
- Analysis completed by Bayer Consulting
 - Wave 1- July 2004
 - Wave 2- March 2005
 - Wave 3- January 2006
 - Wave 4- November 2006
- Study designed to answer key questions about physicians who prescribe Gleevec® and patients who take Gleevec®

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Compliance Results – Wave 2

- Analysis by Bayer Consulting shows there are issues with compliance and persistency
- Average compliance rate is 75%

Compliance	Patients
0%	0
10%	281
20%	46
30%	16
40%	27
50%	40
60%	15
70%	127
80%	290
90%	241
100%	656
2004	2004

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Compliance Results (Excluding 531 Patients)

Average compliance rate of patients taking 2 or more scripts of Gleevec® is 86% (N = 3521)

Compliance	Patients
0%	0
10%	46
20%	16
30%	27
40%	40
50%	15
60%	127
70%	290
80%	241
90%	656
100%	2004

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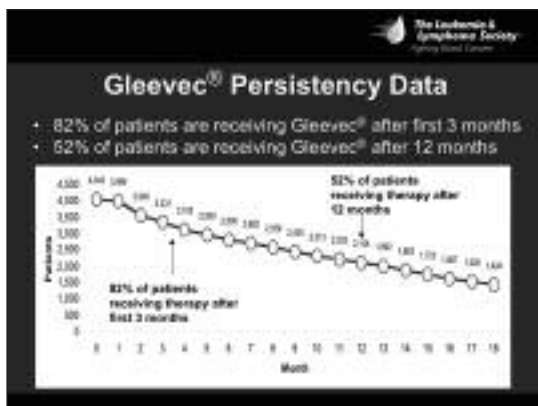
PRESENTATIONS



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PRESENTATIONS




CHARM* Trials (1)

- Patients with congestive heart failure (CHF) randomized to receive medication vs placebo (N = 7600)
- Method
 - 38-month follow-up
 - Adherence measured by clinicians' estimates and pill count
- Results
 - In patients with CHF, high adherence was associated with 35% lower mortality (including placebo) than low adherence
 - Outcome: decreased hospital admissions

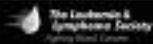
*CHARM = Congestive Heart Failure Assessment of Reduction in Mortality and Morbidity. Gaziano EA, et al. *Cancer*. 2005;34:2005-2011.

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CHARM Trials (2)

- Clinical trial adherence is unusually high
 - Frequent follow-up
 - Availability of drug free of charge
 - Free care
- High adherence to placebo is associated with improved survival
 - Healthier, feel better, higher compliance with medications
 - Belief that the therapy will work
 - Adherence to medication = adherence to lifestyle approaches – weight loss, exercise, seeking medical advice, and so on

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Study Looking at Discharge from Municipal Teaching Hospitals


- 27.9% of patients were able to list all their medications upon discharge
- 37.2% of patients were able to recount the purpose of their medications
- 14% of patients were able to state the common side effects of all their medications
- 41.9% of patients stated their diagnosis at the time of discharge

Wakayus AN, Friedman EA. *Mayo Clin Proc*. 2003;28:891-894.

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PRESENTATIONS

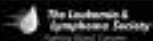



**National Quality Forum (NQF)
Report (1)**

- Goal is to improve medication adherence by creating standards to change how health care providers interact with patients
 - On average, physicians spend 23 seconds listening before they interrupt patients
- Develop performance measures that could examine medication refill rates and timelines and assess verbal counseling by nurses, pharmacists, and physicians
 - Research shows that medication counseling is cost-effective

Trugnor K. Am J Health-Syst Pharm. 2003;6:2449-2452.

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**National Quality Forum (NQF)
Report (2)**

- Prescribers have no idea if patients take medications; no access to pharmacy records
- Few health care providers receive formal education on how to monitor and improve patient adherence
- Recommendations of the report
 - Physicians and nurses need to evaluate adherence as a **VITAL SIGN**, every time they see the patient
 - ASK: Are you, how are you, and what dose

Trugnor K. Am J Health-Syst Pharm. 2003;6:2449-2452.

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**Are Medications Being Taken? Right Dose?
Right Time? Right Day? Right Way?**

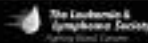
- Age-related barriers: visual, cognitive, memory, side effects, physical limitations, lack of social support
- Relationship with psychosocial characteristics and adherence
 - Complex regimen
 - Behavioral changes required
 - Convenience and efficiency of health care setting
 - Supervision and communication
 - Patient's health beliefs
 - Mental illness history
 - Social support



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PRESENTATIONS




Adherence Issues

- Fail to fill prescription
- Fill prescription but do not take medication
- Do not follow frequency or dose instructions
- Share or substitute medication

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Drug-Related Factors

- Administration regimens
- Number of drugs
- Adverse effects
- Packaging

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Patient-Related Factors

- Changing physiology
- Multiple morbidities
- Cognitive ability
- Health beliefs
- Psychosocial profile

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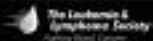
PRESENTATIONS




Other Factors

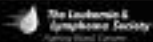
- Patient-prescriber relationship
- Access to medication
 - Insurance
 - Restrictive formularies
- Social support

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Results (1)

- Two critical parameters define patient compliance
 1. **Level of knowledge:** Sophistication of medical understanding and degree of information-seeking
 2. **Source of direction:** Self-reliance vs reliance on the physician in treatment decision-making
- Patients fall into 4 segments concerning compliance
 - Low knowledge/physician-directed; compliant
 - Low knowledge/self-directed; noncompliant
 - High knowledge/physician-directed; conditionally compliant
 - High knowledge/self-directed; conditionally compliant

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Results (2)

- Over time, patients move toward increased knowledge and self-direction
 - Patients learn about their disease over time and become increasingly knowledgeable about the disease, therapeutic options, and side effects
 - Patients become increasingly self-directed; concerns arise over time, no matter how smooth the initial therapeutic experience
- This movement leads patients to a place of conditional compliance

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PRESENTATIONS




Exploring the Meaning of Non-Adherence

- Conrad concluded that what may appear to be non-adherence is actually a form of patients asserting control over their medical condition
 - Patients are more likely to comply with orders when they
 - Feel susceptible to the disease
 - Believe the disease has potential serious consequences for health or daily function
 - Have no major obstacles to treatment such as adverse effects or cost

Conrad P. Soc Sci Med. 1985;28:29-37.

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Medication Adherence Between Younger and Older Patients

- Inconclusive
- Mallon et al. concluded that neither age nor gender seemed to be an important factor in the study of hypertension medication
- Younger persons seemed less regular in the timing
- Older persons were more likely to forget
- Fewer medications, poorer adherence? More medications, the more serious the illness

Mallon JM, et al. J Hypertens Suppl. 1998;16:S75-S79.
Shatenstein BA, Levy AR. Ann Pharmacother. 2002;36:1532-1533.

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Intervention Strategies: Simple and Complex

- Intervention requires a focus on individual patients and their needs
- Understand patient's beliefs about the illness and the medication
 - Patient's understanding
 - Acceptance
 - Level of personal control
 - Motivation
- RESPECT (Randomized Evaluation of Shared Prescribing for Elderly in the Community over Time)
 - N = 700, 20 general practices
 - Special training for pharmacists and physician
 - Pharmacists meet with patients in their homes or in private

Woeg L, et al. BMC Health Serv Res. 2004;4:11.

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PRESENTATIONS




Integrating Elders' Perceptions and Beliefs

- Cumulative losses
- Fatalism based on past experiences
- Neurosensory compromise
- Health care avoidance/physician domain
- Multiple and/or lay advisors
- Absence of targeted community-based programs and elder-specific teaching tools
- Cost concerns
– www.needymeds.com

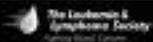
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Patient Resiliency

"If your time hasn't come yet, not even a doctor can kill you!!"
– Leigh Stocker



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"You don't have to see the whole staircase, just take the first step."
– Martin Luther King, Jr.



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PRESENTATIONS




The Leukemia & Lymphoma Society
Fighting Blood Cancer

Treating Hematologic Malignancies: Overcoming Barriers to Care

Carolyn Blasdel, RN, MA, FNP, OCN

Center for Hematologic Malignancies
Oregon Health & Science University
Portland, Oregon

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Fighting Blood Cancer

New Treatment Paradigm

- Some cancers are becoming chronic diseases that can be managed with long-term oral therapy
- Traditional cancer treatment has used mostly intravenous (IV) medications
- Nurses interacted with patients in the process of administering these IV medications

Chen L, et al. *Curr J Oncol Nurs*. 2004;8(Suppl 1):541-555.

2


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Oral Therapies

- With oral therapies the provider often gives the patient a prescription to fill with a brief explanation of the drug's action and side effects
- Oncology nurses are in a critical position to promote adherence, but in some practices patients may not see a nurse at all if not receiving IV therapy

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PRESENTATIONS




Oral Agents for Hematologic Malignancies

- Imatinib (Gleevec®) standard of care for chronic myelogenous leukemia (CML); approved in 2001
- Thalidomide (THALOMID®) in trials for multiple myeloma; off-label use in chronic monomyelocytic leukemia (CMML)
- Lenalidomide (REVLIMID®) for myelodysplastic syndrome (MDS) with deletion 5q; trials in myeloma
- Dasatinib for CML: applied for FDA approval

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Additional Oral Agents

- Hydroxyurea: used short term to reduce high counts at diagnosis; occasionally long term for salvage therapy; relatively inexpensive
- Busulfan: salvage therapy for CML
- Topotecan: trials in MDS and acute myelogenous leukemia (AML)
- Targeted oral agents: in trials

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Nurse as Patient Advocate

- Oral therapy shifts the responsibility for treatment administration from the chemotherapy nurse to the patient and caregiver
- Nurse as patient's advocate has a lead role in promoting adherence
- Establish procedure for oncology nurse to meet with patients on oral chemotherapy

Bodell CL. Clin J Onc Nurs. 2002;7(Suppl 1):5-9.

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PRESENTATIONS




Importance of Adherence

"Drugs don't work in patients who don't take them."

— C. Everett Koop, MD, former US Surgeon General

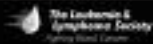
Deberberg L, Blaschke T. N Engl J Med. 2005;353-457-467.

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Communication is Key

- Communication is repeatedly emphasized in studies on adherence: listen to patients and respond to their specific concerns
- Provide time and atmosphere for patients to ask questions
- Multidisciplinary approach is ideal, but with today's medications commonly less expensive by mail order, many patients never interact with a pharmacist

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Communication

- Communication process is affected by
 - Accuracy of the information
 - Clarity of the instructions provided
 - Nature of the relationship

Murphy DA, et al. AIDS Patient Care STDS. 2000;14:47-58.

9

PRESENTATIONS





Trust

Trust between provider and patient is crucial; adherence to regimen depends on whether health care professional was viewed as an ally in cooperation with the patient

DiMatteo MR. *Med Care*. 2004;42:330-339.

10


Collaboration and Teamwork

- Promote trust by encouraging questions if the patient does not understand
- Ask about adherence at every visit and address concerns
- Involve the patient in the treatment decision-making process; encourage collaboration in treatment plans; work as a team

Worley DA, et al. *AIDS Patient Care STDS*. 2008;14:47-55.

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Communication

- Communication needs to be tailored to educational level, cultural beliefs, readiness for information
- Important to have patients recap their understanding of instructions
- Positive reinforcement for desired behaviors

Haynes RB, et al. *Cochrane Database Syst Rev*. 2005 Oct 19;(4):CD004071.

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PRESENTATIONS

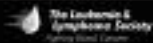



Address Beliefs

- Beliefs about medication have been found to be stronger predictors of adherence than clinical and socioeconomic factors
- Patients may believe oral therapy is less effective, ie, "not as strong"
- Strong concerns about side effects can result in lower adherence

Haynes RB, et al. Cochrane Database Syst Rev. 2005 Oct 19;(4):CD003811.

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Cultural Factors

To encourage adherence in people of other cultures, health care personnel are needed who are knowledgeable about the culture, are culturally sensitive, and speak the language

Murphy KH, et al. JAMA. 2004;291:2730-2738.

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Communication Follow-up


- Telephone or email follow-up can be essential
- Be proactive about contacting patients
- Patients do not remember much of what they are told at first visit
- Calling patients who miss appointments has been found to be critically important in keeping patients in care

Haynes RB, et al. Cochrane Database Syst Rev. 2005 Oct 19;(4):CD003811.

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PRESENTATIONS




Education (1)


- Basic components
 - Mechanism of action
 - When to take, relationship to food
 - Side effect management
 - Written instructions about
 - Proper storage
 - Whether medication can be crushed if needed
 - What to do if a dose is missed
 - Risks to other household members
 - Safe disposal

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Education (2)

- We are now relying on patients to take the drug, so it is important to explain the purpose of drug holidays and step-downs
- Explain why *not* to modify therapy on their own; patients may decrease dose due to side effects or increase dose hoping it will be more effective

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Risks of Non-Adherence

- Suboptimal dosing of imatinib is thought to encourage resistance
- Need to explain that normal blood counts do not mean the patient can stop therapy
- Almost all patients who stop imatinib have a relapse

Seidinger MM, et al. J Clin Oncol. 2005;23:1637-1647.
Duker BJ. Personal communication, 2006.

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PRESENTATIONS

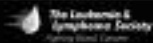



Keep It Simple


- Even complex multifaceted regimens to promote adherence are not always successful
- Key is to listen to patients and individualize to their needs

McDonald HF, et al. JAMA 2002;288:2868-2873

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Case Examples

- Patients have unique difficulties with taking their oral drugs
- Solution may be as simple as providing a different pill size (smaller easy to swallow vs dislike of taking a number of pills)



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Clinical Trials for Oral Therapies

- Latest oral therapies may be available only in a clinical trial, perhaps at another site
- Nurses as patient advocates are in a unique position to help patients participate
- Nurses may then work with the referral center to coordinate care and data collection

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PRESENTATIONS




Clinical Trials

- Patients may find clinical trials confusing and frightening; without true informed consent, patients are less likely to adhere to the regimen
- Provide a "study calendar" listing visits, labs, special tests required to improve adherence; usually has to be made by the institution
- Can set up template in Excel® and then just plug in starting date


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Clinical Trial Resources

- www.clinicaltrials.gov
 - Comprehensive, searchable database
 - Not all trials are listed



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Clinical Trial and Drug Information Resources

- www.centerwatch.com
 - Multiple resources on trials, drugs, informed consent
 - "Drugs in Clinical Trials Database" provides information on drugs in Phases I to III; more than 2,500 drugs with information on each, updated weekly

<http://www.centerwatch.com/professionals/cpcc/clinicaltrials.asp>

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PRESENTATIONS




The Leukemia & Lymphoma Society
Fighting Blood Cancer

Barriers to Clinical Trial Participation

- Minorities, women, and the elderly are underrepresented in trials
- Financial and travel barriers
- Lack of access to trials

Murphy, KJ, et al. JAMA. 2004;291:2720-2728

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Informed Consent Process

- Informed consent is a process, not just a form; a nurse can be vital part of this process
- Advantageous to have a designated clinical trial or "study" nurse who meets with patients

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Informed Consent Elements (1)

- Initially explained by the provider, but in many settings nurses help in the process by explaining
 - The overall experience
 - Benefits and risks that subjects may reasonably expect to encounter
 - Alternatives to participating in the research project
 - Extent to which patients' personally identifiable private information will be held in confidence

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Informed Consent Elements (2)

If research-related injury (ie, physical, psychological, social, financial, or otherwise) is possible, an explanation must be given of whatever voluntary compensation and treatment will be provided


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Informed Consent Elements (3)

Identify contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries

<http://www.lls.org/clinicaltrials/subjects/faq/faq030309.htm>

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Informed Consent

- Participation in clinical trials is voluntary, and subjects have the right to withdraw at any time
- Nurses can follow basics of informed consent in providing information even if patient is not on a clinical trial

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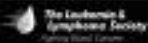
PRESENTATIONS




Thalidomide

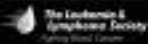
- Thalidomide for multiple myeloma
www.thalomid.com
- Restricted distribution to minimize risk of teratogenicity
- Program provides extensive education and informed consent
- Prescriber, pharmacy, and patient all must be part of System for Thalidomide Education and Prescribing Safety (STEPS)

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Lenalidomide

- RevAssist www.revlimid.com
- Lenalidomide also has a very high risk of birth defects
- Similar restricted access program
- Special education for patients
- Patients must register and agree to restrictions

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Connections (1)

- Connecting patients to resources
- Patients often need help navigating the health care system: it can be like a foreign country, complete with strange customs and a language the patient does not understand

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PRESENTATIONS




Connections (2)


- Some hematologic malignancies are relatively rare, so adherence can be helped by contact with other patients: The Leukemia & Lymphoma Society's First Connection program provides peer-to-peer support
- Classes or support groups at the cancer center or with The Leukemia & Lymphoma Society
- Be sure patients know who to call if they have problems (eg, special bright-pink card with cancer center contact numbers)

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Internet Resources

- Even regular Internet users often are unaware of pertinent websites
 - The Leukemia & Lymphoma Society at www.lls.org or Information Resource Center at (800) 955-4572
 - clinicaltrials.gov, cancer.gov, pubmed.gov
 - Pharmaceutical company websites often offer patient support programs
 - Patient-sponsored sites

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Tools to Promote Adherence (1)

- Patient diary/log, may be part of a clinical trial; if not, nurse can generate one
- Keep track of doses, start and stop dates for holds for low counts or other toxicities
- Nurse to review log at subsequent visits, by phone or email (get HIPAA compliant consent)
- Provide handouts listing common side effects of drugs and how to manage them (locally generated and pharmaceutical company-supplied materials)

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PRESENTATIONS

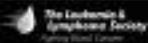


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Tools to Promote Adherence (2)

- Establish a routine for taking medication; link taking medication with a normal routine
- Have a backup supply (eg, at work)
- Suggest use of innovative new technologies (eg, Script Talk labels that read the information aloud)
- Keep track of blood counts and other tests that monitor progress; studies show that patients who monitor blood pressure are more compliant

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Tools to Promote Adherence (3)

- Pill organizers
- Talking pill boxes with verbal reminders
- Personal Digital Assistant (PDA) and other calendar reminders
- An ordinary calendar can be very helpful to keep track of doses and labs

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New Technology


- A Veterans Affairs study on depression recently used videoconferencing for informed consent of patients in isolated rural areas; also has potential in oncology
- Patients who are remotely located can email photographs of rashes, edema, and other side effects of concern

Doboska SK, et al. Telemedicine J E Health. 2005; 11:84-89.

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PRESENTATIONS




Other Barriers

- Other drugs can be barriers to effectiveness of oral agents; interactions are not always caught because patient may have different providers – nurse’s role can be critical to identify this
- Nurses should be familiar with drug interactions for imatinib, CYP3A4 inhibitors, and inducers of particular importance (eg, some antiseizure medications can greatly decrease imatinib to ineffective levels)

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Drug Interactions

Increase Imatinib Plasma Concentrations	Decrease Imatinib Plasma Concentrations	Altered by Imatinib Plasma Concentrations
<ul style="list-style-type: none">• Ketoconazole• Itraconazole• Erythromycin• Clarithromycin	<ul style="list-style-type: none">• Oxcarbazepine• Phenytoin• Carbamazepine• Rifampin• Phenobarbital• St. John’s Wort	<ul style="list-style-type: none">• Simevastatin• Cyclosporine• Piroxicam• Triazolobenzodiazepines• Dihydropyridine calcium channel blockers• Warfarin• Acetaminophen

Dasatinib® (imatinib mesylate) Prescribing Information. East Hanover, NJ: Novartis Oncology; November 2009.

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Other Medications as Barriers to Effectiveness

- Educate patients that herbal supplements may interact with oral agents
- Review medication list at every visit, including over-the-counter drugs and herbal supplements

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PRESENTATIONS



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Financial Barriers

- Multiple difficulties with reimbursement for expensive oral agents
- Patients with minimal insurance may be caught in a bind
- Medicare D now resulting in co-pays and deductibles for some patients who formerly got drugs at no cost through patient assistance programs
- Preauthorization for expensive oral drugs often required

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Financial Assistance

- Refer patient to social worker
- Assist patient in obtaining aid through appropriate State programs
- May be eligible for Medicare regardless of age if patient has a long-term disability
- The Leukemia & Lymphoma Society provides financial assistance for transportation, chemotherapy drugs, and so on; up to \$500/year

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PATRICIA JAKEL

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**The Leukemia & Lymphoma Society
1311 Mamaroneck Avenue
White Plains, NY 10605**

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