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## Friday, November 12

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A Blueprint for Success: Making Evidence-Based Practice Change a Reality
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**Mini-Institute**

Clinical Challenges in Infectious Disease Management
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**Mini-Institute**

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**Mini-Institute**

Mind Body Series
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## Saturday, November 13

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The following summarizes key information about the Oncology Nursing Society (ONS) 11th Annual Institutes of Learning (IOL). This information will be useful when following along during sessions and when evaluating the conference.

**Target Audience**
IOL is designed to meet the educational needs of oncology nurses involved in the delivery of quality cancer care.

**Conference Goal**
The ONS 11th Annual Institutes of Learning provides oncology nurses with educational experiences and networking opportunities that promote excellence in oncology nursing and quality cancer care.

**Conference Objectives**
At the end of the conference, participants will be able to:
1. Promote excellence in nursing practice by engaging in a variety of educational opportunities that address evidence-based quality cancer care.
2. Participate in collaborative learning through networking with fellow oncology nurses and associates.
3. Summarize issues and strategies affecting the oncology nurses contribution to leading the transformation of cancer care.
4. Apply new information related to major cancers.

**General Disclaimer**
ONS hereby disclaims responsibility and liability for any products, services, or information presented at the ONS 11th Annual IOL. ONS does not endorse any product or service exhibited, nor does it necessarily support the content contained in any educational session. Acceptance of advertising does not indicate or imply endorsement by ONS. Corporate support of official ONS sessions does not imply endorsement by the sponsoring company or responsibility for the educational content. Photographs will be taken during the conference, and registration implies a participant’s consent to be photographed. Photographs may be used in ONS publications, programs, and promotional materials.

**Syllabus Format**
Coordinators and speakers were invited to share key slides, references, and other learning tools to support your educational experience during their presentation. Every attempt was made to make this information as accurate as possible. Due to production timelines and our desire to have speakers deliver up-to-date information, we’re not able to provide the final presentations. Please contact the individual speaker if information is incomplete or additional information is desired.

**Continuing Nursing Education**
IOL attendees can earn a maximum of 12 contact hours of continuing nursing education (CNE) if all educational sessions are attended in their entirety and an evaluation is completed by midnight (Eastern Time) on Thursday, December 9, 2010.

ONS is accredited as a provider of CNE by the American Nurses Credentialing Center’s (ANCC’s) Commission on Accreditation.

ONS is accredited as a provider of continuing education by the California Board of Registered Nursing, Provider #2850.

Accreditation as an American Nurses Credentialing Center’s Commission provider refers only to its CNE activities and does not imply ANCC Commission on Accreditation endorsement of any commercial products.

The contact hours earned from this educational opportunity qualify for initial oncology nursing certification and renewal via ONC-PRO. Visit www.oncc.org for complete details on oncology nursing certification.

**Disclosure**
All Planning Team and faculty members participating in CNE programs provided by ONS are expected to disclose to the participants any significant financial interest or other relationships with the manufacturer(s) of any commercial products. A vested interest may be considered to exist if a faculty member is affiliated with or has a financial interest in commercial organizations that may have a direct or indirect interest in the subject matter. A “financial interest” may include, but is not limited to, being a shareholder in the organization; being an employee of the commercial organization; serving on an organization’s speakers’ bureau; or receiving research from the organization. An “affiliation” may be holding a position on an advisory board or some other role of benefit to the commercial organization. Unless noted otherwise, no significant financial relationships have been reported.
Disclosure (continued)

Faculty members are expected to disclose any unlabeled or investigational use of products discussed in their presentations. Faculty members who have disclosed discussion of these products are noted within the session information. Faculty members who have not disclosed evidence of a discussion related to unlabeled or investigational use of products do not plan on having such discussions during their presentation. All program materials and education content were reviewed for bias prior to publication.

Financial Support

Financial support for the ONS 11th Annual IOL has been negotiated independently from the planning of educational sessions. All program materials and education content were developed independently of commercial or non-commercial support. ONS gratefully acknowledges support from the following:

- Abraxis BioScience, Inc. and AstraZeneca LP
- Allos Therapeutics, Inc.
- Amgen
- Bristol-Myers Squibb
- Celgene Corporation
- Centocor Ortho Biotech Services LLC
- Eisai Inc.
- Genentech
- Genomic Health
- Millennium Pharmaceuticals, Inc.
- OSI Pharmaceuticals
- Otsuka America Pharmaceutical, Inc.
- Teva Pharmaceuticals
- Veridex LLC

Evaluation

Please use the Continuing Nursing Education Online Worksheet to track your evaluation scores and comments. Then, while from the comfort of your home or office, you can enter your evaluation data and comments. You’ll have until midnight (Eastern Time) on Thursday, December 9, 2010, to complete the evaluation. The evaluation center is available at http://evaluationcenter.ons.org.

Just a few reasons to use this quick and easy format:

- Get your conference CNE certificate immediately upon submitting your evaluation.
- Begin a transcript for all of your ONS-provided CNE programs.
- Print a list of your ONS-provided programs, making it extra convenient when reporting CNE data for licensure, certification, performance appraisals, etc.
- Reprint your certificate whenever you need it with just the click of a mouse.
- Have easy access to a personalized certificate (e.g., if you live in California) if required. The ONS Evaluation Center will generate one for you.

Attendees can earn up to 12 hours of continuing nursing education credit if all educational sessions are attended in their entirety and an evaluation is completed by the deadline. This credit amount applies only to the sessions within the conference. Satellite symposia and ancillary events are considered separate offerings and are not included in the conference evaluation.
Integrating Evidence Into Your Practice

Using the strongest available evidence in clinical practice contributes to quality patient care and better outcomes for patients. To help oncology nurses access and use this evidence, ONS has implemented several initiatives, including development of the ONS Putting Evidence Into Practice (PEP) cards, online resources, and guidelines for presenters.

Evidence-Based Practice (EBP)

EBP “defines care that integrates best scientific evidence with clinical expertise, knowledge of pathophysiology, knowledge of psychosocial issues, and decision making preferences of patients” (Rutledge & Grant, 2002). Evidence can include research, integrative reviews, practice guidelines, quality improvement data, and case studies. The strength of the available evidence is evaluated using a hierarchy of evidence (Table 1).

Expectations From Presenters

During this conference you will be listening to experts in many areas of oncology nursing. As a part of its commitment to EBP, ONS has asked these experts to share with you the current evidence related to their topics. You can expect these presenters to
- Make clear references to the current evidence in their topic areas
- Focus their presentation on the application of evidence to practice
- Clearly cite the evidence sources on slides, handouts, and reference lists so you may access them later.

Ideas for Integration Into Practice

As you listen to topics of interest, think about how you might integrate the evidence-based information into your practice setting. Some ideas for implementation might include
- Incorporating interventions into telephone triage, policies and procedures, standards of care, and order sets
- Developing or revising patient education materials
- Integrating information into orientation, educational programs, journal clubs, and grand rounds
- Developing performance-improvement activities
- Initiating discussions about current practice with nursing colleagues, physicians, and other healthcare professionals.

<table>
<thead>
<tr>
<th>Table 1. Hierarchy of Evidence Rating System</th>
<th>Strength of Evidence</th>
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</thead>
<tbody>
<tr>
<td>Level I Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs), or evidence-based clinical practice guidelines based on systematic reviews of RCTs</td>
<td>Strongest</td>
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<tr>
<td>Level II Evidence obtained from at least one well-designed RCT</td>
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<tr>
<td>Level III Evidence obtained from well-designed controlled trials without randomization</td>
<td></td>
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<tr>
<td>Level IV Evidence from well-designed case-control and cohort studies</td>
<td></td>
</tr>
<tr>
<td>Level V Evidence from systematic reviews of descriptive and qualitative studies</td>
<td></td>
</tr>
<tr>
<td>Level VI Evidence from a single descriptive or qualitative study</td>
<td></td>
</tr>
<tr>
<td>Level VII Evidence from the opinion of authorities and/or reports of expert committees</td>
<td>Weakest</td>
</tr>
</tbody>
</table>

Modified from Guyatt & Rennie, 2002; Harris et al., 2001
Evidence-Based Practice Guidelines

Resources
Resources available from ONS to further assist in integrating evidence into your practice include

- ONS PEP® cards (can be ordered from ONS or downloaded from www.ons.org)
- ONS Outcomes Resource Area (www.ons.org/outcomes)
- Evidence-Based Practice Resource Area (www.ons.org/evidence)
- Clinical Journal of Oncology Nursing series of articles on PEP.

Glossary of Terms

Evidence-Based Clinical Practice Guidelines
Practice recommendations from a group of experts based on a methodologically rigorous review of the best evidence on a specific topic. Note. Not all clinical practice guidelines are evidence based and may be developed partially or entirely by expert opinion. Thus, the method for development of clinical practice guidelines needs to be identified before determining the strength of evidence (Melnyk & Fineout-Overholt, 2005).

Descriptive Study
A type of nonexperimental research that collects descriptions of a particular phenomenon or situation. The purpose is to be able to better describe from a variety of perspectives or to take steps that will improve the situation (LoBiondo-Wood & Haber, 2002).

Meta-Analysis
A statistical blending of the findings of a number of research studies that have been conducted about a specific topic. It is a synthesis or bringing together of the analyses of separate studies (Powers & Knapp, 1995).

Qualitative Design
Variety of methodologies that involve description and interpretation of human experience or social interactions in ways that promote understanding and insight or challenge existing beliefs (Powers & Knapp, 1995). Examples: grounded theory, ethnography, and phenomenology.

Quantitative Research
Concerned with precise measurement, replication, prediction, and control. Usually has a hypothesize-test-rehypothesize sequence, emphasis on objective measuring procedures, extensive use of numbers to reflect the measurements and results, and an emphasis on cause and effect (Powers & Knapp, 1995). Examples: randomized clinical trial and intervention study.

Randomized Clinical Trial
Strongest research design to support cause and effect relationships. Subjects are randomly assigned to control and experimental groups to test the effect of an intervention or treatment (Melnyk & Fineout-Overholt, 2005).

Systematic Review
Summary of all the research evidence on a particular topic using a rigorous process for searching, retrieving, appraising, and synthesizing studies to answer a specific clinical question (Melnyk & Fineout-Overholt, 2005).

References
Lessons for Survival: How Cancer Changed My Life

Session Description: Every second, someone in America faces a life-threatening illness. Every three seconds an American is diagnosed with cancer. Bruce Feiler was in his prime—a 43-year-old bestselling author with a loving wife and twin daughters—when he learned he was facing one of the rarest, deadliest forms of cancer. In “Lessons for Survival” he tells the funny, touching, and ultimately deeply moving story of how he survived a “lost year” of treatment, relied on friends and family for support, and created a “Council of Dads.” Now cancer free, Feiler tells how he turned his harrowing journey into a source of inspiration and hope for millions around the world, through a best-selling book, a website for survivors and a prime-time documentary by Sanjay Gupta on CNN.

Continuing Nursing Education: Participants will receive 1.0 continuing nursing education credits for attendance and successful evaluation completion of this keynote session.

Target Audience: All healthcare professionals

Level of Content: Introductory

Content Area: General

Speaker: Bruce Feiler

Full Disclosure: Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this keynote session.

Objectives:
By the end of this presentation, participants will be able to:
1. Identify skills that patients use to persevere through life-threatening diseases and treatment.
2. List one idea that nurses could give to patients to help them survive this difficult time in their life.
**Session Description:** Implementation of evidence based practice remains a daunting task for many clinicians due to numerous constraints: inability to interpret research findings, time barriers, administrative nonsupport, and a dearth of strategies to hard-wire changes to achieve sustainability. The goal of this mini-institute is to provide a blueprint for groups seeking to make successful practice change (e.g., transforming research findings and highest level evidence into useful tools). Come prepared to participate.

**Target Audience:** Staff nurses and advanced practice nurses desiring to implement an evidence-based practice change

**Level of Content:** Intermediate

**Content Area:** Research

**Continuing Nursing Education:** Participants will receive 2.5 continuing nursing education credits for attendance and successful evaluation completion of this mini-institute.

**Coordinator/Speaker:**
Cynthia Smith Idell, RN, BA, MSN, AOCN®
Professional Practice Leader, Medical Oncology
City of Hope
Duarte, CA
cidell@coh.org

**Full Disclosure:**
Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

**Objectives:**
By the end of this presentation, participants will be able to:
1. Identify models for achieving evidence-based practice change.
2. Discuss barriers to practice change and strategies to overcome resistance to change.
3. Explore one practice change model, Promoting Action on Research Implementation in Health Services (PARiHS), and model components used to effect successful change (e.g., evidence, facilitation, and context).
4. Review and identify tools for practice change success: cohort teams, project plans, timeline, mentoring, and outcome evaluation processes (qualitative and quantitative).
5. Implement evidence-based practice change concepts into literature search, project planning and timeline development.

**Content Outline:**
**Session 1 Title: Everything You Always Wanted to Know About EBP But Were Afraid to Ask...in 40 Minutes**

I. Evidence-based practice (EBP) definition
   A. What it is
   B. Inter-relationships among QI, EBP, and research
   C. History of EBP and sample models

II. Five steps of EBP (Melnyk & Fineout-Overholt)
   A. PICO question
   B. Evidence collection and leveling
   C. Evidence appraisal
   D. Make change
   E. Evaluate change—outcomes measurement

III. Barriers to EBP
   A. Lack of organizational commitment
   B. Lack of individual commitment

IV. EBP barrier breakers
V. Group discussion and question and answer

Session II Title: Using the Promoting Action on Research Implementation in Health Services (PARiHS) Model to Implement Evidence-Based Practice (EBP)
I. Description of the PARiHS model
   A. Key variables and concepts
   B. Foundation and similar models
   C. Evidence
   D. Types of evidence
   E. Key dimensions
   F. Application
II. Context
   A. Definition and key concepts
   B. Dimensions of context
   C. Application
III. Facilitation
   A. Definition and key concepts
   B. The facilitation continuum
   C. Application
IV. Measurement
   A. Organizational readiness to change assessment (ORCA)
   B. Findings from the Institute for Evidence-Based Practice (IEBP)
   C. Measuring outcomes: The success of the intervention
V. Summary and to do
VI. Group discussion and question and answer

Session III Title: Finding the Best Evidence With Databases—A Case Study With Fatigue
I. Case study: Chemotherapy-induced fatigue in patients with prostate cancer on high-dose chemotherapy
II. The well-built clinical question
   A. The PICO model: patient, problem, intervention, comparison, and outcome
   B. Converting clinical scenarios into clinical questions
III. Finding best evidence with databases: What evidence do Web sites have to offer regarding fatigue?
IV. Question and answer session

Session IV Title: Processes and Tools to Facilitate EBP Change and Fatigue Case Study Application
I. Cohort teams—the value of teamwork with facilitators, sponsors, and targets
II. Expert consultants—the value of mentoring
   A. Components: Supervision, teaching, feedback, and emotional support
   B. Dispelling mentoring myths
   C. ONS mentor programs, including IEBP and research mentors
III. Project plan overview and application to fatigue case study
IV. Action plan overview and application to fatigue case study
V. Timelines and next steps and application to fatigue case study

Session V Title: Practice Change Using the PARiHS Model—The Fundamentals of Getting Started
I. Phases of project management
II. Initiation phase: Evidence, context, and facilitation activities
III. Planning phase: Facilitation, action plan, and measurement
IV. Execution phase: Critical and effective strategies

Bibliography:
improvement: The three-legged stool. AACN Advanced Critical Care, 17, 457–459.


### Evidence-based Practice Change Project Plan

<table>
<thead>
<tr>
<th>Project Phase</th>
<th>Tasks to be Completed / Questions to Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Initiation Phase</td>
<td>A. Establish the burning clinical question: In _<em>_</em>_<em>_</em>_<em>_</em>(population being studied), what is the effect of _<em>_</em>_<em>_</em>_<em>_</em>(intervention) on _<em>_</em>_<em>_</em>_<em>_</em>__ (what’s being measured) compared with_<em>_</em>_<em>_</em>_<em>_</em>_<em>_</em>__ (standard practice)?</td>
</tr>
<tr>
<td></td>
<td>1) Population:</td>
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<tr>
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<td>2) Intervention:</td>
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<td>3) Alternative Intervention / Usual Care:</td>
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<td></td>
<td>4) Outcomes:</td>
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<tr>
<td></td>
<td>B. Who do you need on your project team?</td>
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<tr>
<td></td>
<td>1) Key stakeholders from your institution</td>
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<td>2) Mentor</td>
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<td>C. Barriers and Strategies to overcome barriers</td>
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<tr>
<td></td>
<td>1) List any anticipated barriers</td>
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<td></td>
<td>2) Suggest one solution for each barrier</td>
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<td>D. Outline your project’s aim</td>
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<td></td>
<td>1) Purpose / Aim:</td>
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<td>2) Objectives:</td>
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<td>3) Supporting evidence and source:</td>
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<td>II. Planning Phase</td>
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<td>A. Complete Action Plan (Short form)</td>
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<td></td>
<td>1) Objectives to drive project plan:</td>
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<td></td>
<td>2) Timing of change: Sequence of events and next steps</td>
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</tbody>
</table>
### Friday, November 12

#### Oncology Nursing Society Institutes of Learning

**November 12–14, 2010**

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<table>
<thead>
<tr>
<th>III. Outcomes</th>
<th>Review (Phase Review)</th>
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<tbody>
<tr>
<td>A. How will ongoing project performance be measured / evaluated?</td>
<td></td>
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<tr>
<td>B. With what frequency will you evaluate?</td>
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<tr>
<td>C. How are project results shared? With whom?</td>
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<table>
<thead>
<tr>
<th>IV. Outcomes</th>
<th>B. Small Tests of Change / PDSA</th>
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<tbody>
<tr>
<td>1) Small test of change / pilot:</td>
<td></td>
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<tr>
<td>2) Plan:</td>
<td></td>
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<tr>
<td>3) Do:</td>
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<td>4) Study:</td>
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<td>5) Act:</td>
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<tr>
<th>IV. Outcomes</th>
<th>C. Sell your Message</th>
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<td>2)</td>
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<thead>
<tr>
<th>IV. Outcomes</th>
<th>D. Spreading the word</th>
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<tbody>
<tr>
<td>1) Communications to organization</td>
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<td>2)</td>
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<thead>
<tr>
<th>IV. Outcomes</th>
<th>E. Hard-wiring change strategies</th>
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<th>IV. Outcomes</th>
<th>E. Hard-wire change</th>
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<tr>
<th>IV. Outcomes</th>
<th>C. Customers and selling message</th>
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<th>C. Sell your message</th>
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<table>
<thead>
<tr>
<th>IV. Outcomes</th>
<th>B. Small Tests of Change / PDSA</th>
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</thead>
<tbody>
<tr>
<td>1) Small test of change / pilot:</td>
<td></td>
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<tr>
<td>2) Quality and Plan / Do / Study / Act</td>
<td></td>
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<tr>
<td>IV. More Initiation Phase</td>
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<td>--------------------------</td>
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<tr>
<td>A. Make the Business Case</td>
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<tr>
<td></td>
<td>A. Establish the “business case” for the project</td>
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<tr>
<td></td>
<td>1) Why is it needed?</td>
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<td>2) How does it fit with mission / goals?</td>
</tr>
<tr>
<td></td>
<td>3) Cost benefit analysis – cost effective?</td>
</tr>
<tr>
<td>B. Feasibility Study</td>
<td>B. Feasibility Study (practicality and ability to complete project)</td>
</tr>
<tr>
<td></td>
<td>1) Do I have needed resources / can I get them?</td>
</tr>
<tr>
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<td>2) Can I complete this project in one year?</td>
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<td>3) Does team have ability to do the project?</td>
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<td>4) Can I overcome barriers / constraints?</td>
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<tr>
<td>C. Risk Analysis</td>
<td>C. Risk Analysis</td>
</tr>
<tr>
<td></td>
<td>1) Legal risks</td>
</tr>
<tr>
<td></td>
<td>2) Strategies to monitor / manage risks</td>
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</tbody>
</table>

Key: 1) APN: Advanced Practice Nurse  
2) Champion: The APN of the project team cohort who serves to facilitate practice change  
3) Sponsor: The manager / director of the project team cohort who supports the change and provides necessary resources  
4) Target: The staff RN of the project team cohort in a front-line role to implement the practice change.  
5) WIIFM: What’s in it for me  
6) IEBPC: Institute for Evidence-based Practice Change  
7) ITS: Information Technology Services  
8) PDSA: Plan, Do, Study Act  
9) PI: Performance Improvement  
10) QI: Quality Improvement
<table>
<thead>
<tr>
<th>Objective (To Achieve Plan):</th>
<th>Actions:</th>
<th>Responsible Person</th>
<th>Target Completion Date</th>
<th>Comments</th>
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**Evidence-based Practice Change Action Plan**
### Evidence-based Practice Change Project Plan

<table>
<thead>
<tr>
<th>Project Phase</th>
<th>Tasks to be Completed / Questions to Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. Initiation Phase</strong>&lt;br&gt;A. Develop Burning Question (PICO)</td>
<td><strong>A. Establish the burning clinical question:</strong> In ___________(population being studied), what is the effect of _<strong><strong><strong><strong>(intervention) on _______ (what’s being measured) compared with</strong></strong></strong></strong> (standard practice)?&lt;br&gt;1) <strong>Population:</strong> Patients with prostate cancer who are receiving high-dose chemotherapy (Taxotere &gt; 80 mg /m2 and Gemzar) in the ambulatory setting who are experiencing Grade 3-4 NCI-CTC toxicity for fatigue&lt;br&gt;2) <strong>Intervention:</strong> Apply the ONS fatigue PEP card and/or NCCN interventions to teach patients strategies to recognize, to manage, and to report fatigue before becomes Grade 3-4 (e.g. fatigue ≥ 8 on 0-10 linear scale)&lt;br&gt;3) <strong>Alternative Intervention / Usual Care:</strong> Will compare groups who receive fatigue educational intervention to those who receive “usual care” e.g. no special educational fatigue intervention&lt;br&gt;4) <strong>Outcomes:</strong>&lt;br&gt;1. Tended fatigue scores of prostate cancer patients receiving Taxotere / Gemzar who receive special education on fatigue AND prostate cancer patients receiving Taxotere / Gemzar who do NOT get education&lt;br&gt;2. Chart audits looking at % fatigue education provided by staff as captured on patient education flowsheet&lt;br&gt;3. Number of received triage RN calls regarding fatigue complaints from prostate cancer patients on chemo&lt;br&gt;4. Patient satisfaction scores (measured by Press-Ganey) in the areas of symptom management education</td>
</tr>
<tr>
<td><strong>B. Key Stakeholders</strong></td>
<td><strong>B. Who do you need on your project team?</strong>&lt;br&gt;1) Champion (APN) Ambulatory Clinical Nurse Specialist for Medical Oncology&lt;br&gt;2) Sponsor (Manager) Ambulatory Clinical Manager for Medical Oncology&lt;br&gt;3) Target (RN) Ambulatory Clinical Staff Nurse in Medical Oncology&lt;br&gt;4) List other key stakeholders: Medical Oncologist, NP, PA; Unit Clerk; Scheduler, 2 Peers, Telephone triage RN</td>
</tr>
<tr>
<td><strong>C. Barriers &amp; Solutions</strong></td>
<td><strong>C. Barriers &amp; Strategies to overcome</strong> Barriers include: Lack of clinic time to teach; pressure to turn-over rooms; patient who are exhausted or pre-medicated for treatment. Solutions: Create hand-outs on fatigue based on ONS PEP card recommendations &amp; NCCN guidelines; review hand-outs with pt./care -givers. Have telephone triage RN log fatigue calls of prostate CA pt. Room posters to remind pt./RN to ask about fatigue. NP &amp; PA do intake fatigue assessment.</td>
</tr>
<tr>
<td><strong>D. Project Purpose / Aim, Objectives, &amp; Supporting Evidence</strong></td>
<td><strong>D. Outline your project’s aim, objectives and supporting evidence</strong>&lt;br&gt;1) <strong>Purpose / Aim:</strong> To devise and implement an education strategy built on best evidence to reduce fatigue in prostate cancer patients receiving high-dose chemotherapy with Taxotere and Gemzar.&lt;br&gt;2) <strong>Objectives:</strong> 1) To measure prostate CA pt. fatigue scores on high-dose chemotherapy (Taxotere &amp; Gemzar). 2) To review best evidence for managing fatigue (e.g. ONS PEP cards &amp; NCCN care guideline) &amp; select 2-3 education interventions to minimize fatigue (e.g. mild exercise, nutrition or activity priorities). 3) To monitor success S/P education intervention with pt. self-reported fatigue score, % RNs fatigue teach, triage RN C/O, pt. satisfaction scores.&lt;br&gt;3) <strong>Supporting Evidence:</strong> ONS Fatigue PEP card &amp; National Comprehensive Cancer Network fatigue guidelines</td>
</tr>
<tr>
<td><strong>II. Planning Phase</strong>&lt;br&gt;A. Action</td>
<td><strong>A. Overall Action Plan</strong>&lt;br&gt;1) <strong>Objectives to drive project plan:</strong> Reduce measurable fatigue scores for prostate cancer patients receiving chemotherapy by use of</td>
</tr>
</tbody>
</table>
Plan

1) Small test of change / pilot:
Once a team has set an aim, established its membership, and developed measures to determine whether a change leads to an improvement, the next step is to test a change in the real work setting.

Aim:
Reduce fatigue by applying specialized fatigue educational intervention during a 10 month pilot in Medical Oncology ambulatory setting to prostate cancer patients receiving high-dose chemotherapy.

2) Plan:
Finalize all aspects of this project plan, including timeline, milestones, cost-benefit analysis, risk management discussion, and planned outcome measurement at initial team meeting. Design chart audit to abstract patient fatigue scores to record in log books & to ascertain % RNs teaching re: fatigue.

3) Do:
Apply educational interventions on fatigue (derived from ONS PEP cards & NCCN). Document in project logbooks monthly patient fatigue scores during prostate cancer patient visits for high-dose chemotherapy with Taxotere & Gemzar. Also trend the number of triage calls from high-dose prostate cancer patients concerning patient fatigue complaints and fatigue scores >9 on 0-10 linear scale.

4) Study:
Observe results at 4 months & 10 months. Document in project logbooks earnings, and monthly patient fatigue scores (derived from ONS PEP cards & NCCN)."
### Evidence-based Practice Change Action Plan

#### Objective (To Achieve Plan): Pull together a team of stake-holders to review: project aims, objectives, interventions and outcomes to get buy-in and to prepare to solicit administrative support

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<tbody>
<tr>
<td>Invite MD, NP, PA, staff RNs, CNS, unit clerk, scheduler, triage RN, manager to 1&lt;sup&gt;st&lt;/sup&gt; team mtg.</td>
<td>Champion</td>
<td>12-20-09</td>
<td>Send invitation &amp; attachments 1 week early. Serve lunch!</td>
</tr>
</tbody>
</table>
### Friday, November 12

#### IOL

<table>
<thead>
<tr>
<th>Task</th>
<th>Responsible Person</th>
<th>Target Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare meeting outline – structured agenda, objectives, content, powerpoint</td>
<td>Champion</td>
<td>2-10-09</td>
</tr>
</tbody>
</table>
| Champion | 12-20-09

Considered more focused intervention / population:

- Present at December unit staff meeting & at January Shared Governance Councils

#### Target:
The staff nurse of the project team cohort group who serves as a front-line role to implement the practice change.

#### Sponsor:
The manager or director of the project team cohort group who supports change and provides necessary resources.

#### Objective (To Achieve Plan): Consider pilot logistics, e.g., timing, interventions, staff education, log-books (for fatigue scores and for RN triage complaints), who will record, design, chair audits/assign responsibilities for completing audits, feedback/suggestions.

- Request at December unit staff meeting at 1-15-10
- ONS PEP / NCCN guidelines: 12-20-09
- Considered more focused population

#### Champion:
The advanced practice nurse of the project team cohort group who serves as a front-line role to implement the practice change.

#### Facilitator:
The advanced practice nurse who serves as the project team cohort group facilitation.

#### Key: (1) APN: Advanced Practice Nurse
(2) Champion: The advanced practice nurse of the project team cohort group who serves as a front-line role to implement the practice change.
(3) Sponsor: The manager or director of the project team cohort group who supports change and provides necessary resources.
(4) Target: The staff nurse of the project team cohort group who serves as a front-line role to implement the practice change.
(5) WIIFM: What’s in it for me
(6) IEBPC: Institute for Evidence-based Practice Change
(7) ITSS: Information Technology Services
(8) PDSSA: Plan, Do, Study, Act

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Definition

- EBP is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

Integrating EBP Components

- Best clinical evidence from systematic review and critical appraisal that answers a "burning" clinical question
- Individual/Local clinical expertise (your team of reference)
- Patient's values and circumstances

Inter-relationships Between Quality Improvement, EBP & Research

- Research – systematic inquiry that uses disciplined methods to answer questions or solve problems. Goal = to generate new knowledge (Polit & Beck, 2006)
- Quality Improvement (QI) - AKA CQI or PI. Essentially an outcomes and improvement model. Evaluates work process in a cyclic fashion. Does not seek to generate new knowledge or test interventions (Hedges, 2006)
- Evidence-Based Practice (EBP) - the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (Melnyk & Fineout-Overholt, 2005)

History of EBP - Medicine

- Cochrane Collaboration - 1993
  - Founded by Dr. Archie Cochrane; British Epidemiologist
  - 1972 criticized medical profession for not providing rigorous reviews of evidence to justify healthcare decisions – RCTs strongest evidence
  - Cochrane Center 1992

Clinical Example

- PI – Monitoring rates of ventilator associated pneumonias (VAP) in ICU may show VAP rates have ↑ during the past few months
- EBP – Staff perform extensive review of literature or review national anti-VAP guidelines as a 1st step (EBP) which would yield multiple interventions ex. HOB ≥30°
- Research – If gaps in research exist (ex. Which oral care method is best for preventing VAP?), nurses would need to conduct a research study (to generate new knowledge)

IOWA Model of Research Practice

- Problem – focused “triggers”
- Clinicians search literature
- If no quality literature
- Conduct research OR find other evidence
- Develop EBP guidelines
- “Planned change”
- “Pilot” study & review
- Then, conduct larger study
- All levels participate: in job descriptions (time & resources provided to staff)
- Rewards
- Infrastructure to support research (high level to low level)

Model for EBP Change

- Dr. Mary Ann Rosswurm
  - West Virginia University
- Dr. June H. Larrabee
  - West Virginia University

- Based on theoretical and research literature related to:
  - EBP
  - Research utilization
  - Standardized language
  - Change theory
**ARCC Model**

Dr. Ellen Fineout-Overholt  
Arizona State University  
Dr. Bernadette Mazurek Melnyk  
Arizona State University

- Advancing Research and Clinical Practice through Close Collaboration (ARCC) Model (Melnyk & Fineout-Overholt, 2005)
- 1999 University of Rochester SON + Med School + Dental Faculty + Nursing Practice at Academic and Community Levels
- Primary purpose to integrate research and clinical practice throughout Rochester’s academic health center & community and to advance EBP locally as well as nationally

---

**5 Steps of EBP Change**

1. **PICO Question**
   - Establish your “Burning Clinical Question”
     - **P** = population
     - **I** = intervention
     - **C** = comparison intervention
     - **O** = outcome
     
     **EX.** In teenagers, how effective is Depo-provera versus oral contraceptives in the prevention of pregnancy? (Melnyk & Fineout-Overholt, 2005)

2. **Evidence Collection & Leveling**
   - Evidence (E) from a systematic review or meta-analysis of all RCTs or EBP clinical practice guidelines based on systematic reviews of RCTs
   - E from at least 1 well designed RCT
   - E from well-designed controlled trials w/o randomization
   - E from well-designed case-control or cohort studies
   - E from systematic reviews of descriptive and qualitative studies
   - E from a single descriptive or qualitative study
   - E from the opinion of authorities and/or reports of expert committees

**5 Steps of EBP Change – cont.**

3. **Evidence Appraisal**
   - What were the results of the study?
   - Are the results valid?
   - Will the results help me in caring for my pts?

4. **Make Change**

5. **Evaluate Change – Outcomes Measurement – Effectiveness of the Change**

(Melnyk & Fineout-Overholt, 2005)

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**Barriers: Lack of Organizational Commitment**

- Lack of Quantum/Transformational Leadership (Top Down Management)
- Failure to incorporate EBP time, $, and resources into the budget
- Lack of MD Support ("Cookbook" Medicine)

---

**Barriers: Lack of Individual Commitment**

- Lack of Interest/Professionalism ("We’ve always done it that way", 9-5 attitude)
- Lack of knowledge about research/EBP– attended school many years ago
- Lack of authority/autonomy to make change
- Overwhelming patient loads

---

**EBP Barrier Breakers**

"Brick walls are there to stop those that don’t really want something bad enough." (Pausch, R., 2007)
**Develop an EBP Strategic Plan of Attack:**
Implement EBP - PARIHS Framework

- Promoting Action on Research Implementation in Health Services
  - Evidence = codified + non-codified sources of knowledge
  - Requires teamwork
  - Requires conducive environments (context) ex. Transformational leaders
  - Facilitators and proper facilitation is required for successful implementation
  
  [Kibson et al., 2008]

**Select “The EBP Team”**

- Select EBP team members who can facilitate change
  - Visionary
  - Knowledgeable/Open to learn/Open to change
  - Skills
  - “Can-Do”
  - Passionate
  - Trusted

**Facility Assessment of Knowledge & Attitudes**

- Baseline facility assessment
- Conduct surveys or focus groups with healthcare providers initially to assess knowledge, attitudes, & behaviors related to EBP
- Also find out to what extent they think EBP will provide improved patient outcomes
- Assessments / focus group can raise interest
- Provides knowledge of misconceptions that need correction
  
  [Melnyk, B., & Fineout-Overholt, E., 2005]

**Find Other “Champions”**

Who has your back?

**Clarify Misperceptions - Educate “The Team”:**

- Education Plan
  - Assess knowledge via survey
  - Classes/Brown Bag Lunch Sessions
    - General EBP Overview
    - Formulating the “Burning Question” via PICO
    - Database Selection & The Search Strategy (Cochrane, CINAHL, PubMed)
    - Appraising the Evidence (Strength, Valid, Reliable, Credible, Applicable)
    - Applying the Evidence (Interventions, Outcomes, Hardwiring)

**Develop an EBP Strategic Plan of Attack – Start SMALL**

- Select a “pilot” unit
- Pick a practice change that can yield success (problem trigger, new evidence)
- Formulate your PICO question
- Seek the best evidence & plan the change
Develop an EBP Strategic Plan of Attack – Start SMALL

- Sell the practice change to your “target” population - nurses on the “pilot unit”
- Implement EBP change

“Educate the Masses”

- Snappy Logos/Titles
  - Give aways associated with project ex. Small Mag light
- Power Point presentations @ staff meetings
- Educational poster presentations
- Handouts
- Pocket Cards
- Order Sets

Remember 2 Things

1. EBP Success = P3 + P3
   - Patience
   - Perseverance
   - Patience
   - Perseverance
   - Patience
   - Perseverance

2. EBP: The Old & The New
   If Flo could do it, so can you!

PARiHS Model
Promoting Action on Research Implementation in Health Services

Success of Change = fx (Evidence + Context + Facilitation)

Evidence

- Types of Evidence
  - Research
    - Typical weight of evidence approach
  - Clinical/Professional Expertise
    - Testing against knowledge of peers and others
    - Knowledge from reflection on practice and “ways of knowing” concepts
  - Patient Experiences
- All types of evidence to be evaluated on a High-low continuum re its weight.
### Dimensions of Evidence

- **Research evidence**
  - Evidence is of sufficiently high quality
  - Evidence is valued
  - Evidence fits with personal understanding
  - Evidence is useful in thinking about the issue
  - There is consensus among colleagues about usefulness of the evidence
  - *The evidence used is of sufficiently high quality to support implementation of an approach or intervention*

### Context

- **Definition:** The environment or setting in which the proposed change is to be implemented.
  - Clearly defined boundaries
  - Decision making processes
  - Patterns of power and authority
  - Resources
  - Information and feedback systems
  - Management of competing forces
  - Systems that enable dynamic processes of change and continued development
  - Culture: prevailing values and beliefs

### Key Context Concepts

- The concept of a learning organization is key to a context that facilitates change
- Measurement importance
  - Process that generates evidence
  - Monitoring, feedback and evaluation
- High to low “weighting” should also be applied to the concept of context

### Facilitation Continuum

<table>
<thead>
<tr>
<th>Doing for others</th>
<th>Enabling Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Episodic contact</td>
<td>Sustained partnership</td>
</tr>
<tr>
<td>Practical technical help</td>
<td>Developmental</td>
</tr>
<tr>
<td>Didactic/traditional</td>
<td>Adult learning approach</td>
</tr>
<tr>
<td>Task orientation</td>
<td>Holistic/enabling</td>
</tr>
<tr>
<td>Technical skills</td>
<td>Co-counseling, critical reflection and giving meaning</td>
</tr>
<tr>
<td>Project management skills</td>
<td>Flexibility and situational role</td>
</tr>
<tr>
<td>Subject credibility</td>
<td>Authenticity</td>
</tr>
</tbody>
</table>

### Application

- **Evidence**
  - Select an area and evidence that is of high quality
  - Use PEP categories of evidence to select and discuss
  - Get the evidence in front of clinical and opinion leaders and create opportunities for consensus acceptance
  - Formal – use of committees, quality staff involvement etc.
  - Informal – personal contacts

- **Evidence continued...**
  - Enhance staff’s ability to connect the evidence with personal experience and values
  - Can you identify and discuss clinical examples and observations that relate to the intervention/project you are doing?
  - Can be formal or informal
  - Select an intervention that is likely to be accepted/valued by patients
  - Pilot test where you can
    - Confirms on a personal level
    - Where people directly involved, more committed and data is “believable”
  - Where hard evidence is not in the literature, get the evidence, collect the data
Application

- Context
  - Within the “micro-culture” involved in your project, how can you
    - Ensure adequate time and resources to accomplish goals
    - Demonstrate value of and reward innovation and activity that supports EBP
    - Create a shared vision that promotes the practice change you plan and the movement to EBP in general

Application

- Context continued......
  - Ensure that your team and staff have the authority to take what actions are needed
  - Make sure your action plan clearly states responsibilities and includes communication and feedback regarding progress in patient outcomes/project goals and objectives
  - Engage in team-building
  - Recognize and reward personal mastery and ongoing learning

Facilitation Strategies & Evidence of Effectiveness

- Titler – systematic reviews
  - Data feedback
  - Restrictive interventions
  - Auditing
  - Timely individual feedback

Experience with EBP

- Strategies
  - “Marketing” the project/action
  - Focusing and re-focusing efforts
  - Planning and revising the plan
  - Education
  - Visual cues and implementation tools
  - Deadlines
- Issues
  - Measurement
  - Sustaining improvements

Why Measure?

- How do you know that a change is needed?
- How do you know that a change has occurred?
- How do you know that a change has resulted in improvement?
- How does anyone know progress or effectiveness in a program/project?
- Feedback works
Summary

- General Dimensions of PARIHS model and high-low quality in each
  - Evidence
  - Context
  - Facilitation
- Similarity to other known models and theories of change, performance improvement, leadership
- Reviewed Evidence re Strategies that WORK
- Measurement Tips

Fatigue Case Study: A Clinical Scenario

- June 2009 – At an NCI-designated Comprehensive Cancer Center on the West Coast, nursing staff identify a patient care issue of excessive fatigue in prostate cancer patients receiving high-dose Taxotere (> 60 mg/m²), in the Medical Oncology ambulatory clinic and infusion settings, during a unit needs assessment.
- A root cause analysis done in July 2009 identifies contributing factors:
  1) Patient-related
  2) Provider-related
  3) System-related

The Well-built Clinical Question & Use of the PICO Model

- PICO Model (Melnyck & Fineout-Overholt, 2009)
  - P = Patient / Problem
  - I = Intervention
  - C = Comparison
  - O = Outcome
- Converting clinical scenarios into clinical questions to focus your literature search

PICO Exercise

1) In lung cancer patients with non-sustained fevers, what is the effect of turning every two hours compared to turning every four hours in the incidence of pressure ulcers?

<table>
<thead>
<tr>
<th>Population of Interest</th>
<th>Intervention of Interest</th>
<th>Comparison Intervention of Interest</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung cancer patients</td>
<td>Turning every 2 hours</td>
<td>Turning every 4 hours</td>
<td>Incidence of pressure ulcers</td>
</tr>
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</table>

Use the following scenario to develop a PICO question and fill in the table accordingly:

A 65-year-old man is brought to the ER by his wife with a 4-day history of nausea, vomiting, and headache. His medical history is positive for colon cancer and liver metastasis. He is taking acetaminophen 1 gram three times a day for his headache. His physical exam is benign. The laboratory results reveal nothing. The wife states “I have heard that Tylenol can cause their problems and I am wondering if he should continue to use the Tylenol for his headache considering the cancer in his liver.”

In __________________________ what is the effect of __________________________ on __________________________ compared with __________________________?

Applying PICO to Fatigue Case Study

Establish burning clinical question: In ________ (population being studied), what is the effect of ________ (intervention) on ________ (what’s being measured) compared with ________ (standard practice)?

Population: Patients with prostate cancer who are receiving high-dose chemotherapy (Taxotere > 60 mg/m² & Gemzar) in the ambulatory setting who are experiencing Grade 3-4 levels of fatigue (defined by NCI-CTC, 8 to 10 on 0-10 scale)

Intervention: Teach patients ONS PEP card or NCCN Fatigue strategies to identify, manage, & report fatigue before Grade 3-4 fatigue

Applying PICO to Fatigue Case Study – Alternative Intervention/Usual Care: Compare groups receiving fatigue education intervention to those who receive “usual care” e.g. no special fatigue education

Outcomes:
1. Tended fatigue scores of those who receive special education on fatigue AND those with no education
2. Chart audits looking at % fatigue education
3. # Triage RN call complaints by prostate cancer patients on high-dose chemo regarding fatigue
4. Press-Ganey Patient Satisfaction scores for symptom management education
Finding Evidence with Databases: What is the best fatigue intervention?

- ONS author website searches
- PEP website http://ons.org/Research/PEP
- AHRQ: www.guidelines.gov

Finding Evidence with Databases: What is the best fatigue intervention?

- TRIP database: www.tripdatabase.com
- UptoDate: www.utdol.com
- Cochrane: www.cochrane.org
- National Comprehensive Cancer Network
  - www.nccn.org

Cohort Teams: The Value of Teamwork

- Facilitator – Advanced Practice Nurse
- Sponsor – Manager or Director
- Target – Frontline Staff Nurse

Expert Consultants: The Value of Mentors

- Mentoring Components
  - Supervision
  - Teaching
  - Feedback
  - Emotional Support
- Dispelling Mentoring Myths
- ONS Mentor Programs & Practice Change

Timelines / Next Steps: Fatigue Case Study

- Problem Identification / Root cause analysis (7-09)
- Research Critique (8-09 to 9-09)
  - NCCN supportive care fatigue guidelines
  - Pt. teaching steps from Barriers study
  - Rehab exercise recommendations: KPS / Fatigue
- Transform knowledge into protocol (9-09 to 12-09)
  - Fatigue becomes part of performance criteria
  - Staff education: assessments, interventions, QOL
  - Built-in referral criteria to other disciplines
- Pilot & Evaluation (1-10 to 4-10)
  - Target population – 20 Prostate CA patients on high-dose Taxotere, Gemzar
  - Fatigue Score minimum 5 / KPS > 60

Outcome Evaluation Measures

Definition of Patient-Sensitive Outcomes: Measured in context of patient needs, given their diagnosis, treatment, and altered life expectancy. Includes:

- Health-related (QOL pt-focused outcome end points)
- Symptom management / Functional performance
- Social well-being
- Quality of death
- Coordination of care
- Patient satisfaction with care
- Compliance / Adherence / Knowledge
Friday, November 12

Outcome Evaluation: Nurse-Sensitive
1) Pt. outcomes amenable to nurse interventions
   (Given & Sherwood, 2005, Onc. Nurs. Forum, 32(4),773-744)
2) Nurses’ interventions with impact on pt. outcomes

Nurse-Sensitive Outcomes Processes
• Independent process
• Medical care process
• Interdependent intervention
• Prevention of injury or noscomial infection
• Symptom management
• Knowledge
• Functional status
• Psychological health status
• Economic

Outcome Measures: Fatigue Case Study
• Nurse sensitive outcome measures
  1) Education given on fatigue & exercise (% charted)
  2) Patient perception of education usefulness: Y or N
  3) Triage RN activities of patient distress re: fatigue
• Patient sensitive outcome measures
  1) Patient self-report of exercising to combat fatigue
  2) Decreased fatigue scores (on 0 to10 scale)
  3) Increased KPS (0 to100%) & ADL’s

Phases of Project Management

Initiation Planning Execution Closure
Assessment Planning Implementation Evaluation

Evidence
• Obtain, Summarize & Critique Evidence
  – Use the highest level/best evidence
  – Consensus around strength and applicability of evidence
  – Likely acceptance by patients

Initiation Phase: Context
• State how the project supports mission, goals of the organization
  – __________________________
  – __________________________
• Costs and benefits
• Are there any legal/other risks?

Initiation Phase: Context
• Who are the key stakeholders and how do you get them on board?
  – __________________________
  – __________________________
  – __________________________
• What are potential barriers?
  – __________________________
  – __________________________
Initiation Phase: Facilitation

- Project Team
  - Who do you need on the team?
    - Involving stakeholders
    - Authority to commit resources
- Identify focus
  - Goals, Objectives, Deliverables (Outcomes)
- Phase review: How will you review progress?
  - Measurement and Feedback
  - Leadership & Staff Engagement

Planning Phase: Facilitation

- Project Plan
  - Actions and sequence for Key Objectives
  - Set deadlines and times for review
  - Communications
  - Hardwiring
    - Visual cues and reminders
    - Tools
    - Maintaining attention: Strategies that WORK

Planning Phase: Facilitation

<table>
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<th>Responsible Person</th>
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Setting Up and Following “Measures of Success”

<table>
<thead>
<tr>
<th>Measure</th>
<th>Results</th>
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<tbody>
<tr>
<td>Time 1</td>
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<td>Time 2</td>
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<td>Time 3</td>
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<td>Time 4</td>
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Summary

- Working through project planning using PARIHS model concepts
- Importance of
  - Strength and acceptance of EVIDENCE
  - Assessing & planning for CONTEXT aspects
  - FACILITATION
    - COMMUNICATION
    - DEADLINES
    - MEASUREMENT
    - ACTION PLAN
IOWA Model of Research Practice

Model for EBP Change
Friday, November 12

Develop an EBP Strategic Plan of

And

Change

• If + hardwire the

Measure outcomes

• Attack – Measure results
Clinical Challenges in Infectious Disease Management

This session has been developed in collaboration with the Acute and Critical Care Special Interest Group.

Session Description: Nurses are intimately involved in assessment, reporting, and implementation of treatment for infectious complications. Speakers use case scenarios, expert panel discussions and your participation to address clinical scenarios involving management of infections in patients in surgical, radiation, inpatient, and outpatient oncology settings.

Target Audience: Oncology nurses in inpatient, ambulatory, and home care settings; also appropriate for staff and advanced practice nurses

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 2.5 continuing nursing education credits for attendance and successful evaluation completion of this mini-institute.

Estimated # of minutes of Pharmacology Content to be presented: 90

Coordinator/Speaker:
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Johns Hopkins Hospital
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Full Disclosure:
Amgen, Inc. Consultant for special educational offerings
Speaker has indicated that he/she intends to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

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Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she intends to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Speaker:
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Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she intends to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Objectives:
By the end of this presentation, participants will be able to:
1. Analyze clinical findings and management of complex infectious complications in cancer.
2. Translate key infectious disease management principles to the participant’s own clinical practice.
4. Identify challenging infectious disease controversies in the participant’s own clinical practice.
5. Outline key nursing interventions during administration of antimicrobial therapy.

Content Outline:
I. Overview of infectious disease concerns in oncology
II. Sources of best evidence common practice challenges and their benefits or problems for patients (e.g., ID approval processes, dosing for prophylaxis versus disease, innovative strategies)
III. Cases for discussion (each case presented is reinforced with slides reviewing evidence for decision advised by presenter)
A. Line infection—remove or treat through the infection?
B. Neutropenic fever in patients with multiple comorbidities—can they be managed outpatient?
C. Treatment of recurrent fungal infection in setting of prolonged marrow suppression
D. Community-acquired H1N1 influenza A or other timely infection in immunocompromised patient
E. Surgical wound infection in flap graft of patient with radical head and neck surgery or complex abdominal infection in patient with ovarian cancer
F. Necrotizing wound infection in patient with EGFR inhibitor rash and radiation dermatitis or another complex radiation-related infection
Bibliography:
The Problem: Infections in Patients with Cancer

- Estimates suggest 25%-44% of patients with solid tumors and nearly 70% of patients with hematologic malignancies experience an infection during their cancer trajectory.
- Approximately 60,000 patients are hospitalized annually for neutropenic fever, but this is felt to underestimate the problem.
- A oncology patient dies of infection every 2 hours.

Sources: Friese et al, 2010; Friese, 2007; Rolston et al, 2007; Segal et al, 2000; Shelton, 2000

The Problem: Infections in Patients with Cancer

- Infections in patients with cancer lead to increased hospitalizations, morbidity, mortality, therapy delays, and therapy dose reductions.
- Most infection control research has not been conducted in the oncology setting.
- In the past two decades, multi-drug resistant organisms have become an increasing problem. They can be the attributable cause to > 94,000 US cancer-related deaths per year.

Sources: Friese et al, 2010; Friese, 2007; Rolston et al, 2007; Segal et al, 2000; Shelton, 2000

Current Management Strategies

- Careful infection control practices and patient education.
- Prophylaxis with growth factors and antimicrobials in high risk groups.
- Utilization of neutropenia, infection and sepsis risk profiling instruments.
- Infection surveillance.
- Rapid, comprehensive infection management.
- Antibiotic stewardship.

Sources: Friese, 2007; Segal et al, 2000; Shelton, 2011; Viscoli et al, 2005; Zitella et al, 2006

Sources of Best Evidence

- Centers for Disease Control
  - Management of central line infections
  - Environmental infection control in healthcare facilities
- European Group for Blood and Marrow Transplantation (EBMT)
  - Infection prophylaxis
  - Infection treatment
- Infectious Disease Society of America (IDSA)
  - Hand hygiene and prevention of infection in healthcare settings
  - Use of antimicrobial agents in neutropenic patients with cancer
- National Comprehensive Cancer Center (NCCN)
  - Prevention and treatment of cancer-related infections
- Oncology Nursing Society
  - Putting evidence into practice (PEP) “Prevention of infection”

Infection Management Controversies Continue to Exist

- What preventive measures are most effective?
- What prophylactic strategies are most effective?
- Who has the greatest risk factors for infection?
- Can these risks be defined in probability measures?
- How can we ensure optimal safe practices in infection prevention and management?
- What specific interventions are necessary for defined infection sites or organisms?

Case Study #1

- CM is a 64 year old female diagnosed with Non-Hodgkins Lymphoma. Received R-CHOP, via a dual lumen portacath, 10 days ago followed by Neulasta. CM admitted to the oncology unit febrile with neutropenia.
- CM states she developed a fever and chills yesterday but felt too ill to call. She now complains of tenderness at her portacath site, generalized weakness, achiness, and dizziness.
Physical Assessment

Temp 38.7℃  BP 90/54  P120  R24  
O₂ sat 88% RA, 94% on 2L O₂ nasal cannula

Significant Labs:

- WBC 500/mm³  ANC 400
- HGB/HCT 8.0g/dl and 23.0%
- Plts 19,000/mm³
- Glucose 210mg/dl

• Cultures were drawn both peripherally and from the portacath.
• A urinanalysis with culture and sensitivity, if indicated, was sent.
• The patient was started on Cefepime 2 grams IV q 8 hours within the first hour of admission to the hospital.

Considerations

• Do we remove or retain the portacath?
• What additional cultures or tests are warranted?
• Is the antibiotic coverage evidence-based and acceptable?
• What are the most common bacterial or fungal causes of catheter-related blood stream infections?

• When would you consider drawing additional cultures?
• If the patient remains febrile, what then?
• If the patient does not have good peripheral access, what next?
• What is the duration of therapy?

Case Study #2: Neutropenic Fever

• KA is a 66 year old female who is Day 16 of reinduction for first relapse of her acute myeloid leukemia (AML) arising from myelodysplastic syndrome (MDS).
• PMH: Type II Diabetes Mellitus, hypertension, mild renal insufficiency
• Her reinduction course has been uncomplicated and she is discharged to clinic for count checks and transfusions.

• KA arrives to clinic on Day 18.
• She complains of feeling fatigued today.
• Vitals on arrival:
  – Temp: 38.5℃, HR: 108 bpm, BP: 104/62, O₂: 94% on room air
  – Labs: ANC < 50/mm³, platelets: 18K/mm³, SCR: 1.5mg/dl
How should KA be treated for neutropenic fever?

- A. Admitted for intravenous antibiotics.
- B. Given first dose of intravenous antibiotics in clinic and observed.
- C. Sent home on oral antibiotics.
- D. Not sure. Need more information regarding the patient.

How should KA be treated for neutropenic fever?

Case Study #3: Refractory Fungal Infection

- JB is a 42 year old male Day 45 status post nonmyeloablative transplant for a follicular Non-Hodgkin’s Lymphoma. He has engrafted. His course has been complicated by ongoing Grade 2 skin and gut GVHD requiring corticosteroids.
- JB has been receiving prophylactic antibiotics including valacyclovir, fluconazole, and trimethoprim-sulfamethoxazole.
- 2 weeks ago, JB presented with a new cough and right-sided pleuritic chest pain.
- The chest CT gave evidence of multiple small nodules. The impression was new fungal pneumonia.
- The team changed JB to voriconazole for treatment of a presumed fungal pneumonia.

What should JB receive for treatment of his progressive fungal infection?

- A. Continue voriconazole.
- B. Change to lipid formulation of amphotericin B.
- C. Change back to posaconazole.
- D. Continue voriconazole and add micafungin.

Today, JB presents to clinic with shortness of breath and new complaints of chest pain.

Another chest CT is performed and shows interval increases in his pneumonia.

What should JB receive for treatment of his progressive fungal infection?
Case Study #4: Complex Wound Infection

- MR is a 30 year old male who presents after resection of a mandibular lymph node showing inflammation with contiguous adherence to a mass biopsy positive for squamous cell carcinoma.
- CT scan shows a 2 X 3 cm mass in the posterior oropharynx, base of the tongue, and is classified as Stage III/locally invasive tumor.
- Tumor cytogenetics show that the mass is EGFR wild-type +, HPV - , PS3 - .
- It is decided that optimal treatment would be neoadjuvant chemo-radiotherapy followed by surgical excision, aiming for total resection.

Case Study #4: Treatment Plan

- Chemotherapy:
  - Cisplatin 50 mg/m² day 1 and 8 repeated every 3 weeks with hydration and antiemetics appropriate to a moderately emetogenic regimen.
  - Granulocyte colony stimulating factor 24 hours after the last dose of cisplatin in each cycle.
  - Cetuximab 500 mg/m² before initial radiation treatment followed by weekly cetuximab infusion 250 mg/m². Appropriate premedications are prescribed and skin cleansing advised. The lymph node excisional biopsy site is closed and approximated.
- Radiotherapy:
  - Intensity Modulated Radiotherapy (IMRT) 66-70 Gy in 33-35 divided doses delivered Monday through Friday over 6-7 weeks.

Case Study #4: 2 weeks into treatment

- MR reports to the radiation clinic after a weekend off with a grade 1-2 erythematous, indurated global skin appearance with a mild, diffuse maculopapular rash. The biopsy remains clean and approximated but with skin reaction overlapping.
- Skin cleansing is reinforced and radiation acceptable emollients are provided with a prescription for diphenhydramine 50 mg q6 hr as needed for itching.

Case Study #4: Three days later... (17 days after start of therapy)

- The radiation technician asks the nurse to see MR’s increasing skin irritation.
- The radiation dermatitis and EGFR maculopapular rash are now indistinguishable, diffuse, with pustular areas. The nurse classifies this as a grade 2-3 toxicity.
- The medical oncologist suggests corticosteroid cream 2% to be soap and water washed 2 hours before RT, and oral minocycline 100 mg bid.
- Laboratory measures are normalized and the next every 3 week chemotherapy is planned for on-time administration in 4 days.

Case Study #4: Cycle #2 Chemotherapy Day

- MR comes to medical oncology on his planned chemotherapy day complaining of fatigue and listlessness.
- Vital signs: T- 37.4, HR- 92, R- 28, BP- 110/60, O₂ saturation- 91%.
- Rash is still a grade 2 but with less pustular lesions. Clear exudate is oozing from some of the lesions. The previous biopsy site is tender to touch but still approximated.

Case Study #4: Decision time...

- How should we proceed with MR’s treatment plan?
  - A. Give chemotherapy and radiotherapy as planned.
  - B. Administer cisplatin, but take a one week break from cetuximab, continue radiotherapy.
  - C. Give chemotherapy, but take a one week radiotherapy break.
  - D. Break from all therapy for one week.
  - E. Continue all anti-cancer therapy, but change antimicrobial treatment plan.
How to Plan, Implement, and Sustain an Effective Survivorship Program

Session Description: The goal of this mini-institute is to introduce you to a framework for developing a sustainable survivorship program. Speakers will review cancer survivorship in the United States and discuss the fundamentals of program planning, business essentials, metrics for success, and basic elements and lessons learned from programs at the George Washington University Medical Center in Washington, DC; Breslin Cancer Center in Lansing, MI; and Sanford Cancer Center in Sioux Falls, SD.

Target Audience: Oncology nurses interested in developing a survivorship program

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 2.5 continuing nursing education credits for attendance and successful evaluation completion of this mini-institute.

Coordinator/Speaker:
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George Washington Cancer Institute
Washington, DC
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Full Disclosure: Nothing to Disclose

Speaker:
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Full Disclosure: Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Objectives:
By the end of this presentation, participants will be able to:
1. Explain the context of cancer survivorship today and the need for survivorship programs.
2. Identify the basic components of sustainable program development.
3. Apply best practices learned from survivorship programs in different stages of development.
4. Identify metrics for a successful survivorship program.
5. Generate a basic business plan mock-up.

Content Outline:
I. Defining cancer survivorship
   A. Needs of survivors
   B. National direction for cancer survivorship initiatives (IOM, CDC, etc.)
   C. Essential components of survivorship care

II. Program planning basics
   A. Needs assessment
   B. Assessing capacity
   C. Business planning components
   D. Goals and metrics for program success
   E. Resources for program development

III. Case studies of three survivorship programs in Washington, DC; Lansing, MI; and Sioux Falls, SD

IV. Question and answer

V. Workshop with participants
   A. Assessing needs, readiness, and capacity
   B. Goal setting

Bibliography:

**Web Sites:**
Overview of SWOT analysis. www.quickmba.com/strategy/swot/
Overview of the value chain: www.quickmba.com/strategy/value-chain/
U.S. Small Business Administration’s business plan writing tool: www.sba.gov/smallbusinessplanner/plan/writebusinessplan/SERV_ESSENTIAL.html
Defining Survivorship

Adapted from presentation developed by Mary McCabe, M.A., R.N.
Director, Cancer Survivorship Program
Memorial Sloan-Kettering Cancer Center
Used with Permission.

Current Focus on Survivorship

- Rapidly growing population of survivors due to advances in diagnosis and treatment
  - approximately 12 million cancer survivors nationally
  - 20 million globally
  - Predictions of 20 million by 2020
  - 62% of adults diagnosed with cancer today can expect to be alive in five years
  - 75% of pediatric survivors alive after 10 years
- Greater emphasis on patient-centered issues by the medical community - quantity AND quantity of life
- Increasing expectations by patients for good quality of life

Quality of Life Model Applied to Cancer Survivors

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<tr>
<td>Functional Activities</td>
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<td>Cognition / Attention</td>
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<td>Pain</td>
<td>Diagnoses of Diagnosis and Control of Treatment</td>
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</tbody>
</table>

Spiritual Well Being

- Meaning of Illness
- Religious Beliefs
- Transcendence
- Hope
- Uncertainty
- Inner Strength

Survivorship Challenges

- Increasing expectations for good quality of life after cancer
- Increasing identification of life challenges
  - Late effects
  - Occur after treatment has been completed
  - Long term effects
  - Effects that persist after completion of treatment

Long-Term Follow-up Programs Rationale

- A need to figure out how to care for the large number of individuals in follow-up
- Greater understanding of the consequences of cancer and its treatment
- Focus on the application of interventions to eliminate/reduce sequelae
- Follow-up care setting can be a platform for research
- Begin to focus on survivorship education and training

Survivorship Care Usual Practice

- Follow-up by oncologists is routine
- Patients find it reassuring
- Duration of follow-up is variable
- Follow-up guidelines are limited and recent
- Follow-up care focused on surveillance for recurrence
- Limited transfer of knowledge and information to primary care provider
Institute of Medicine Report  
11/05

- Implement survivorship care plan
- Build bridges between oncology and primary care
- Develop and test models of care
- Develop national guidelines, institute quality assurance, strengthen professional education
- Make better use of psychosocial and community support services
- Address employment and insurance issues
- Invest in survivorship research


Models of Care Essential Components

- Surveillance for recurrence
- Screening for new cancers
- Identification and interventions for consequences of cancer and its treatment
- Health promotion strategies
- Coordination between oncology specialists and primary care providers

Institute of Medicine Report  
11/05

Running Cancer Survivorship Like a Business

- What are the gaps in your care for cancer survivors? What are national / local directives for survivorship care?
- What are survivors telling you?
- What is staff telling you?
- SWOT / Capacity Analysis

Executive Training on Navigation & Survivorship: Finding Your Patient Focus  
www.gwumc.edu/casnp

Budgeting

- What is a budget?
- Why do you need a budget?

Business Plan Fundamentals

- Every business needs a business plan
- They are works in progress and need continual updating and revision
- Allows a deep understanding of who you are and what you do

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Adapted from presentation developed by Leonard H. Friedman, PhD, MPH
The GW Department of Health Services Management and Leadership  
Used with Permission

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Models of Care Essential Components

- Surveillance for recurrence
- Screening for new cancers
- Identification and interventions for consequences of cancer and its treatment
- Health promotion strategies
- Coordination between oncology specialists and primary care providers

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Assessment

- What are the gaps in your care for cancer survivors? What are national / local directives for survivorship care?
- What are survivors telling you?
- What is staff telling you?
- SWOT / Capacity Analysis

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Running Cancer Survivorship Like a Business

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Budgeting

- What is a budget?
- Why do you need a budget?

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Budgeting

- What is a budget?
- Why do you need a budget?
Business Plan Structure
- Executive summary
- Market Analysis
- Company Description
- Organization and Management
- Marketing Management
- Service Line
- Funding Request
- Financials

Goal Setting for Program Success
Developed by
Mandi Pratt Chapman, MA
GW Cancer Institute’s Center for the Advancement of Cancer Survivorship, Navigation, and Policy
www.gwumc.edu/casnp

Why are Goals Important?
- Articulate what you intend to do to leadership, your client base and possible funders
- Provide a means of measuring program success
- Mechanism for breaking tasks down into manageable pieces

Creating SMART objectives
- Specific
- Measurable
- Action-Oriented
- Realistic
- Time-Bound
Examples:
- Provide survivorship care plans to 100 cancer patients transitioning out of active treatment within one year.
- Decrease patient no-show rates from 30% to 10% within two years.

Align Program Goals with Institutional Priorities
- Align program goals with institution’s strategic goals
  - Begin with short-term goals to demonstrate success
  - Create long-term goals that will contribute to realization of the larger organization’s strategic plan
- What is your organization’s mission? What does leadership value? Create goals that will foster institutional investment.
  - Profit? © Demonstrate return on investment
  - Patient outcomes? © Demonstrate impact on survival/prognosis/QOL
  - Patient retention? © Demonstrate patient satisfaction
  - Staff retention? © Demonstrate staff satisfaction, opportunities for growth

Logic Model
- Clarifies what you plan to do, why, how, and when (short-, intermediate-, and long-term objectives)
- Provides a methodical way to capture, document and disseminate program results
- Enables process improvements
- Provides a tool to keep you focused on your program goals
- Demonstrates program success, outcomes and impact to improve institutional investment in your program / sustain funding from grants
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Case Study: Sanford Cancer Center
Program Goals
• Improve the patient experience by expanding survivorship services (NCCCP initiative)
• Provide a multi-disciplinary approach to supporting survivorship at all points of the patient experience (diagnosis, treatment, surveillance)
• Empower patients by providing tools that will help them to maintain their optimal level of health for survivorship (body, mind, and spirit)
• Engage oncology caregivers in Survivorship initiative through education and certification opportunities

Assessment of Need
• Visit to City of Hope
• Patient focus groups
• NCCCP participation
Market analysis:
• Regional Cancer Center serving adult patients from region encompassing South Dakota, Minnesota, Iowa, and Nebraska
• Initiating survivorship care at Cancer Center with goal to partner with regional resources to support survivorship plan

Organizational Description
• Organizational Mission: Dedicated to the work of Health and Healing
• 100 % conceptual support of cancer care and survivorship
• Cancer Center of Excellence
• Largest rural care system in the United States with international reach

Capacity Analysis
• Creative allocation of existing resources, both fiscal and FTEs
• Collaboration of medical center and cancer center to maximize resources
• Growth of program with existing staff
• Patient vocalization of need for expanded survivorship services

Service
• Current Program: Provide post-treatment visit with nurse practitioner for assessment, support, and resource referrals
• Physician or patient self-referral
• Primary disease focus of breast cancer
• A Time To Heal, ABC support group, Bosom Buddies
• Journey of Healing
• Exercise Program, Dietician support, Genetic Counselor, reproductive counseling, financial, social, and emotional resources
Service

- **Future Program**: Promote survivorship from time of diagnosis. Needs assessment and deliberate focus to increase referrals to support services.
- Treatment summary and Survivorship plan
- Support services structured for patient benefit at all points of journey to survivorship
- Embrace, Treehouse Organization, Journey of Healing
- Expand survivorship focus to all cancer types

Budget

- Explore options covered by third party payers
- Volunteer opportunities
- Explore grant opportunities and scholarship funds
- Organizational commitment/support

SMART Objectives

- Provide post treatment assessment and survivorship care plans to a minimum of 50 cancer patients within first year of revised survivorship program format
- Measure success of revised format through patient surveys, physician input, and supportive resource referral volumes

Program Success

- **Development phase**: Staffing structure, cancer exercise certification, EMR assessment tool development, metrics and report development
- **Successes experienced since GWU executive training**: Renewed focus on survivorship program growth, deliberate efforts towards revising approach and expanding services
- **Measuring Success**: data mining, metrics, patient feedback

Lessons Learned

**Barriers to success:**
- Time
- Funding

**Strengths contributing to success:**
- Organizational support and growth
- Passion and desire to make it happen

Best Practices

- Embrace (Roger Maris Cancer Center)
- NCCCP/NCI
- City of Hope
- A Time to Heal (Nebraska Methodist Health System)
Change Management

- Creative use of existing resources
- Promoting the benefits for patients, physicians and the organization to grow support and resources
- Collaborate with existing resources to develop new ones
- Be willing to regroup, re-evaluate, and reorganize to achieve success

Sustainability

- Optimize services that are covered by third party payers
- Promote survivorship involvement with regional facilities
- Incorporate patient navigators into survivorship initiative
- NCCC participation
- Explore additional grant opportunities for programming

Impact of caSNP

- Renewed focus on expansion and revising Survivorship program
- Networking opportunities
- Knowledge and tools of others that may be further along in development of Survivorship programs

Case Study: Breslin Cancer Center Program Goals

- Develop cancer treatment summary care plan utilizing ASCO resources
- Develop workflow to incorporate Journey Forward initiation with each new treatment patient
- Document cancer treatment summary

Assessment of Need

- July 2008 - Participated in City of Hope Survivorship Education for Quality Cancer Care
  - Support needed from Administration/Physician/Staff
  - Developed reachable goals to begin looking at what are patient population needed
  - Patient survey led to developing Breast Cancer Survivorship Clinic, supported by Susan G Komen Grant

Market Analysis

- Breast Cancer population
  - Breast cancer specialist had no room for new patients
  - Brought in mid-level for assistance with long term follow up
  - Breslin has the only Breast cancer specialist in the area
  - Is helping to focus on survivorship in all populations
Friday, November 12

Organizational Description

- Academic Clinic
- Research driven
- Survivorship high on list of Chief of the division
- Interest from nursing staff - education
- Administrative support

Capacity Analysis

- Breast Cancer Survivorship Clinic
  - Funded by Susan G Komen Grant
  - Supports nursing, social worker, physician
  - Team approach-similar to Interdisciplinary clinic
  - Nurses sent to Survivorship education course

Service

- Survivorship clinic plus educational seminars
  - Clinics: 1/month, 4 patients who have received multi-modality treatment
  - Seminars: 3/year-
    - Lymphedema
    - Healthy lifestyles
    - Sexuality

Budget

- Program is entirely funded by grant
- Small portion coming from donation funds
- Local ONS chapter helped to sponsor one speaker

Program Success

- Clinic has been running for 1 year
- Each patient has received Journey Forward summary
- Each PCP has received ASCO breast cancer treatment summary
- Patients have loved it - mini support group
- Staff directly involved in clinic are sharing more information with other patients
- Surveys are completed at the end of clinic, 3 months and 6 months after clinic to measure impact of education

Lessons Learned

- Treatment summaries take time to complete-about 2 hours per patient
- Would not be able to have clinic without grant support
- Unrealistic to have multiple site specific clinics at this time
- Had buy in of administration and champion physician prior to initiation of clinic
- Staffing is challenging. Needed support staff for clinic navigation, development of flyers and mailings. Nursing role is shared by 2 nurses - each has their own way of doing things, some conflict resolution needed to get work done
Best Practices

- Do not reinvent the wheel - Use the resources readily available (i.e., ASCO and Journey Forward)
- We found that the program had to be flexible - ever changing
  - Incorporated suggestions from clinic surveys prior to next clinic
  - Updated education powerpoint to reflect on patient needs – Included more on sexuality and hot flashes

Change Management

- First survivorship specific clinic in the area
  - Led to sharing at ONS meetings
  - Other cancer center looking at survivorship needs
  - TIME is a barrier - treatment summaries take time and physician support
  - Patients are very pleased with being part of the clinic
  - Seminars were open to the community - even helped with increasing enrollment in other community programs
  - Need to have people passionate in survivorship and willing to go above their current role to get change started

Sustainability

- Have reapplied for grant for second year, looking at specific clinic for metastatic breast and those receiving AI
- Truthfully - if grant not received, clinic will be cancelled
- Training at GW assisted with vision - not to be discouraged by making both the high reaching goals and the obtainable ones

Impact of caSNP

- Prior to attending caSNP - Clinic was looking at another site specific survivorship clinic - head/neck or lymphoma
- Reality check due to staffing changes helped refocus goals to what can the clinic realistically do
- Still have that high reaching goal of providing community survivorship programs but also looked at who would support me and what we really could accomplish
Mind Body Series

The creams used during this session have been donated by Udderly Smooth®. Redex Industries manufactures Udderly Smooth® and is an exhibitor at this conference. The speakers have indicated that they have no financial relationships to disclose.

Session Description: During this mini-institute, speakers will provide an overview of the biology of stress, history of mind-body approach, and elements of selected mind-body techniques. Discussion will also address breathing, chakras, guided meditation, movement, and progressive muscle relaxation.

Target Audience: Oncology nurses and other healthcare professionals

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 2.5 continuing nursing education credits for attendance and successful evaluation completion of this mini-institute.

Coordinator/Speaker:
Geronima Cortese-Jimenez, MPH, RN, OCN®
Oncology Nurse Education Coordinator
Life with Cancer—Inova Fairfax Hospital
Falls Church, VA
threejimenez@msn.com

Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Speaker:
Drucilla Brethwaite, MSW, LCSW, OSW-C
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Life With Cancer—Inova Health System
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Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Speaker:
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Oncology Counselor
Life With Cancer—Inova Health System
Fairfax, VA
Micheline.toussaint@inova.org

Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Objectives:
By the end of this presentation, participants will be able to:
1. Describe the history, theory, and research of mind body techniques.
2. Name several mind body techniques.
3. Integrate mind body techniques in practice.
4. Identify mind body resources.
5. List and explain seven major chakras.

Content Outline:
I. Stress response
   A. Biology of stress
   B. Biofeedback
   C. Autogenic training
   D. Breath
   E. Progressive muscle relaxation
   F. Body scan

II. Guided imagery
   A. Fundamentals
   B. Client capacity
   C. Scripts
   D. Affirmations

III. Meditation and mindfulness
   A. Eating
   B. Movement
   C. Smelling
   D. Sound
   E. Mandalas
Bibliography:

Web Sites:
Developing true freedom...together. What meditation is not: www.healthandyoga.com/html/meditation/meditation_not.html
**Mind-Body Series Agenda**

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<td>Body Scan</td>
<td>Imagination</td>
<td>Imagination</td>
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**Complementary Medicine:** is used together with conventional medicine

**Alternative Medicine:** is used in place of conventional medicine

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**ONS Position**

- Evaluate personal values
- Assess patients for use
- Seek proper training
- Working knowledge of cost, liability, ethical and legal issues
- Establish EVP in use
- Support research

The Use of Complementary, Alternative, and Integrative Therapies in Cancer Care, ONS, [http://www.ons.org/Publications/Positions/CAM](http://www.ons.org/Publications/Positions/CAM)

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**Mind-Body connection is...**

- Our thoughts, feelings, beliefs and attitudes can positively or negatively affect our biological functioning
- And the reverse: what we do with our physical body can impact our mental state in a positive or negative way

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**Mind-Body Approaches**

- Breathing
- Guided Imagery/Visualization
- Meditation
- Autogenic Training
- Biofeedback
- Progressive Muscle Relaxation
- Movement (Yoga, Tai Chi, Feldenkrais)
- Hypnosis/Hypnotherapy
- Aromatherapy
- Music
- Expressive Arts

[http://www.chuc.edu/health/whatiscam/#mindbody](http://www.chuc.edu/health/whatiscam/#mindbody)

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**Mind-Body Benefits**

- Reduce cancer related symptomatology
- Non-invasive and no identifiable side-effects
- Self-select
- Actively participate in care
- Contribute to increased quality of life
- Parasympathetic state
- Enhance self-awareness
- Improve immune function
Factoids

- 640-850 muscles
- Busiest muscle are the eyes (blink about 100,000/day)
- 13 muscles to smile; 50 muscles to frown
- Largest muscle is the buttock

Progressive Muscle Relaxation (PMR)

Is a systematic technique for reducing overall body tension by tensing and relaxing different muscle groups in your body.

Two Levels of Tensing

- Tensing muscle as tightly as you can without hurting yourself
- Tensing muscle slightly, just enough so you notice the tension

PMR Technique

1. Quiet place, music (preference)
2. Sit or lie down, eyes closed (preference)
3. Deep breathing (about 2 minutes)
4. Tense a single muscle group
5. Hold for count of 8 breath normally (muscle may shake)
6. Quickly exhale, letting the muscle go limp
7. Add a cue i.e. “Let it go” “Relax” “Calm and rested”
8. Remain still for 15 seconds; continue with each group
9. Focus on the feeling of relaxed muscle (5 minutes)
10. Get up slowly

Biofeedback

Use of auditory and/or visual physiologic information to modify physiologic functions such as heart rate, respiration and skin temperature.

Thermal Biofeedback

Circulation is drawn away from the periphery and the gut and redirected to large muscles, heart and brain.
**Mind is a Powerful Force**

- **Anxious thoughts or images**: Increase tension
- **Positive thoughts or images**: Sense of well-being

**Common Visualizations**

- Daydreams (What images are most pleasing?)
- Memories (Think of a time when you felt happy and safe.)
- Imagination (What kinds of things make you feel relaxed, safe?)
- Random images (sounds, scents, tastes)

**Eye Palming**

- Rub palms together, place over closed eyes, fingertips on forehead, palms on cheeks
- Block out light
- No pressure on eyelids
- Mindful of breath
- Focus on color black
- May notice other colors but bring attention back to black
- Associate black color with an image (black fur, black object)
- After few minutes, open eyes, remove hands from eyes, notice any feelings of warmth in eyes

**Power Animal Imagery**

- Introspection
- Solitude
- Transformation
- Expert swimmer through emotional waters
- Ability to navigate along the Earth’s magnetic lines
- Finding one’s way back from the brink
- Ability to find sustenance in barren landscapes
- Strength in the face of adversity
- Navigate a hostile environment
- Creature of dreams, shamans, mystics and visionaries
- Defense and revenge

**Inner Guide**

- Close eyes, relax, mindful of breath
- Imagine in detail an animal or being that possesses great wisdom and compassion
- Dialogue with your inner guide
- Your inner guide can clarify what is causing you stress, remind you of your strengths, instruct you how to relax
- Wait for answers
- Open eyes, notice any feelings of warmth and relaxation

**Safe/Special Place**

- Close eyes, relax, mindful of breath
- Create an image of a sanctuary where you feel calm, peaceful, protected
- Allow for only a private entry
- Stay as long as you like
- Open eyes, notice any feelings of warmth and relaxation
Container

- Construct a container large enough to hold everything that is causing you distress
- Needs to be a strong container, perhaps made of concrete or steel
- Can be above or below ground, maybe in the side of a mountain
- Place two valves on the container (1 on the side, the other on the top)
- The valve on the side is tightly closed

Breathing serves two main physical purposes:

1. Helps transport oxygen to various parts of the body
2. Helps in elimination of waste products

- Insufficient oxygen often results in:
  --lack of overall energy
  --mental sluggishness
  --lack of focus
  --depression, anxiety

- The brain requires the most amount of oxygen
- As we age, arteries often get clogged, reducing the supply of blood and oxygen to the brain—a factor in senility, slowed thinking, forgetfulness

- Different types of relaxation breathing:
  --4-7-8 Breath (Inhale 4, Hold 7, Exhale 8)
  --Alternate Nostril Breath (Nadi Suddhi)

- In addition to relaxing the nervous system, breathing can relax the mind, giving the mind a focal point, an anchor
- In Relaxation Breathing, we are simply observing the breath mindfully
What are Chakras?

*Chakra* is a Sanskrit word which means *wheel* or *disk*

Chakras are first mentioned in the Vedas, ancient Hindu texts of knowledge.

Chakras

- There are seven major chakras in the body.

- The state of each chakra reflects the health of a particular area of your body; psychologically, emotionally and spiritually.

First Chakra

- Earth element, sense of smell
- Our foundation
- Reminds us of our connection to the earth
- Family roots

Second Chakra

- Water element, sense of taste
- The chakra of the “self”, storehouse of unconscious mind
- Governs impulses and desires

Finger, A.

Kabat-Zinn, J.

Chakras and Endocrine System

- Chakras are not physical
- They interact with the physical body through endocrine and nervous system
- Each one of the seven chakras are associated with one of the seven endocrine glands, and also with a group of nerves called the plexus.

Friday, November 12

Mindfulness means paying attention in a particular way:

- on purpose
- in the present moment,
- non-judgementally

Mind

Body

Oncology Nursing Society Institutes of Learning
November 12–14, 2010
### Third Chakra
- Fire element, sense is sight
- Personal Power
- Furthers the development of self-esteem and personality, separate from your tribal identity

### Fourth Chakra
- Air element, touch sense
- Forgiveness and compassion
- Unconditional love

### Fifth Chakra
- Space element, sense is sound
- Will Power
- Chakra of purification
- Communication between individual spirit and spirit of universe

### Sixth Chakra
- Command center of the elements
- Full self-realization
- Referred to as “third eye”

### Seventh Chakra
- Spiritual Power
- Reminder of our connection to the divine

### Mindful Meditation Overview
- What is mindful meditation?
- A practice of finding ways to tune out mental chatter
- An exercise in sustained concentration used to calm the body and quiet the mind
- A practice that helps to develop and maintain basic positive qualities such as kindness and patience
Benefits to Meditation

- Improved breathing and decreased heart rate
- Reduction in anxiety and depression
- Improved health and healing
- Helps to alleviate acute, chronic or post-surgical pain
- Acceptance
- Improved ability to manage anger and frustration

Getting Started and Common Elements during Practice

- Begin with 5-10 minutes early 6 days a week for two weeks
- Splash water on your face/rinse out your mouth
- Choose a quiet, uncluttered area
- Choose a comfortable position: seated on a cushion or lying down
- Focus your attention: it may be on your breath, an object or a mantra (a chosen word or set of words)
- Practice the gentle return back to your focus when your mind wanders

Goals of Touch and Why it is Important

- To make connections
- Helps to create a supportive environment
- To decrease anxiety and fear
- Improve mood
- Be aware of why you are using touch
- Be intentional
- Center yourself prior to entering the patients room to be more present
- Couple it with warm dialogue

How Touch Enhances the Mind/Body Connection

- Expectation of touch (imagination)
- Ritual (meaning)
- Nontactile communication (voice)
- Ambient factors (music, aroma, light levels)
- Light or deep touch
- Location of touch

Hand Massage

- Instructional Hand Massage Video
- Break into pairs to practice
- Guide guests through a hand massage while they are practicing on one another
- Notice the changes you may be feeling during and after the massage
Aromatherapy 101: The Healing Properties of Essentials Oils

Session Description: Don’t miss this overview of the art and science of aromatherapy. It’s your chance to see firsthand the many benefits of essential oils.

Target Audience: All healthcare professionals

Level of Content: Introductory

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Coordinator/Speaker:
Michelle Willis-Styles, RN
Staff Nurse
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Atlanta, GA
michellemotivates@yahoo.com

Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Speaker:
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Shift Nurse Manager
Emory University Hospital
Atlanta, GA
bowenbarbara@att.net

Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Discuss the history of aromatherapy and its evolution.
2. Describe five healing properties of essential oils and five methods of application.
3. List five safety/precaution measures to take when using essential oils.

Content Outline:
I. What is aromatherapy?
   A. Definition and history of aromatherapy
      1. What are essential oils?
   B. The chemistry of essential oils
      a. Methods of use and application
II. Healing properties of essential oils (antifungal, antibacterial, etc.)
   A. Review of select oils
   B. Review of basic essential oil first aid kit
      1. Safety and precautions

Bibliography:

Web Sites:
American Holistic Nurses Association: www.ahna.org
Aroma Apothecary Healing Arts Academy: www.aromaapothecary.com
Clinical Trials: www.Clinicaltrials.gov
National Cancer Institute: www.cancer.gov
NCCAM: nccam.nih.gov
ONS: wwwCONS.org
“The way to health is to have an aromatic bath and a scented massage everyday”

Hippocrates

Aroma History

Ancient Cultures to Modern Times

Modern day Aromatherapy Pioneers

Aroma History

Popular text site that aromatic or essential oils have been used for thousands of years, noting use in ancient times and cultures. Listing their use in sacred texts as the bible and others. Citing use in ancient Egypt, Africa, Asia, India, Greece, Rome, Central America, Europe and the Middle East.

Pioneers

Robert Tisserand
Jean Valnet
Marguerite Maury
Shirley Price
Jane Buckle
Gabriel Mojay

What is Aromatherapy?

Aromatherapy is the use of plant substances that have been extracted to promote, enhance, or restore physical, mental and emotional health and well being.
What are Essential Oils?

Essential Oils are highly concentrated extracts taken from the bark, leaves, petals, resins, rinds, roots, seeds, stalks, or stems from certain aromatic plants, herbs or trees.

Methods of Extraction

- Steam Distillation
- Expression
- Solvent Extraction
- Enfleurage
- Carbon Dioxide Extraction

The Science behind Essential Oils

The basics: Carbon, hydrogen and oxygen are the building blocks of all life and are contained in all essential oils.

When combined essential oils form molecular structures that can be grouped into families of chemicals.

The Chemistry of Essential Oils

- Terpenes
- Alcohol
- Aldehydes
- Esters
- Ketones
- Oxides
- Phenols

Mode of Action

How do they work?

- Inhalation
- Topical Application
- Internal Application

Healing Properties

- Antibacterial
- Anti-inflammatory
- Antiviral
- Antispasmodic
- Antifungal
- Insect repellent
Healing Properties

Antiemetic
Aphrodisiac
Cleans the mind, helpful with mental fatigue
Hormone balancing

These are just a few examples.

Methods of use

Diffusion
Massage
Body Oil
Bath
Direct Inhalation
Neat
Chest Rub

Methods of Use

Shower
Foot Bath
Compress
Sauna
Perfume
Meditation
Mist
Add to Cosmetic Products

Top 10 Essential Oils

Peppermint (mentha piperita)
Eucalyptus (eucalyptus globulus)
Ylang Ylang (cananga odorata)
Geranium (pelargonium graveolens)
Lavender (lavandula angustifolia)

Top 10 Essential Oils

Lemon (citrus limon)
Clary Sage (salvia sclarea)
Tea Tree (melaleuca alternifolia)
Roman Chamomile (chamaemulum nobile)
Rosemary (rosmarinus officianalis)

Aromatherapy First Aid Kit

Top three essential oils to have at home

Lavender – analgesic, anti-inflammatory, antiseptic, insecticide, sedative

Tea Tree- antibiotic, antifungal, antiseptic, antibacterial, antiviral
### Aromatherapy First Aid Kit

- **Eucalyptus**: anti-inflammatory, antiseptic, antibacterial, antiviral

### Everyday Aromatherapy

#### Anxiety
- Clary Sage, Lavender, Ylang Ylang

#### Nausea
- Peppermint, Ginger

#### Muscular Aches
- Lavender, Marjoram, Peppermint

#### Insomnia
- Chamomile, Lavender, Vetiver, Rose

### Everyday Aromatherapy

#### Migraine
- Peppermint, Lavender, Blue Chamomile

#### Colds
- Eucalyptus, Peppermint, Lavender, Tea Tree, Cajeput

#### Fatigue
- Rosemary, Geranium, Grapefruit, Peppermint

### Everyday Aromatherapy

#### Acne
- Blue Chamomile, Lavender, Tea Tree, Thyme, Geranium, Lemon

#### Inflammation
- Helichrysum, Blue Chamomile, Yarrow, Rosemary, Spikenard

#### Menstrual/PMS
- Hormone Balancers: Geranium, Rose, Ylang Ylang, Clary Sage

### Everyday Aromatherapy

#### Menopause
- Geranium, Clary Sage, Rose, Yarrow, Ylang Ylang, Spikenard, Sweet Orange

#### Stress
- Lavender, Chamomile, Ylang Ylang, Neroli, Frankincense, Clary Sage, Sweet Orange

### Safety and Contraindications

Essential Oils are very potent safety and care should always be considered when using any oil.

1. Use sparingly.
2. Use a reliable reference guide
3. Never ingest
4. Avoid contact with eyes
5. Keep out of reach of children
Safety

6. Do not apply directly to the skin. Always use a carrier oil.
7. Consult primary physician or healthcare provider before use.
8. Caution is to be used in pregnancy, diabetes, epilepsy, high blood pressure, low blood pressure, kidney disease, allergies, estrogen dependent cancer.

Safety

9. Caution with certain medication
10. Certain oils are phototoxic
11. Certain oils are extremely toxic and are to be avoided completely
12. Certain oils cause irritation

Research

Show me the evidence?

Research in the field of Aromatherapy is on going. Below is a list of current clinical trials and or completed studies:

- Does Massage with or without aromatherapy reduce infant’s distress.

Research

- Effects of Aromatherapy on Childbirth
- The effects of smell on mood and physical response
- A Randomized trial of the effectiveness of Aromatherapy on Chemotherapy induced Nausea and Vomiting

Research

- Effects of aroma hand massage on pain, state anxiety and depression in hospice patients with terminal cancer
- Neuropharmacology of the essential oil bergamot.
- Holistic foundations of aromatherapy in nursing

Research

- Anxiolytic effect of aromatherapy massage in patients with breast cancer
- The science and art of aromatherapy
- Using topical aromatherapy for the management of fungating wounds in a palliative care unit
Research

U.S. National Library of Medicine
National Institute of Health
PubMed

http://ncbi.nlm.nih.gov/pubmed
www.clinicaltrials.gov

Complementary, Alternative and Integrative Medicine Use

According to the 2007 Study conducted by the National Center for Complementary and Alternative medicine (NCCAM);

Americans spent $33.9 billion out-of-pocket on complementary and alternative medicine (CAM).

CAM Use

CAM products, classes and materials, non vitamin, non mineral products such as fish oil, glucosamine and Echinacea.

CAM practitioner visits for acupuncture, massage and chiropractic care

ONS

ONS has a position statement in regard to “The Use of Complementary, Alternative, and Integrative Therapies in Cancer Care.”

www.ons.org

Aromatherapy and Cancer Care

• Hospital
• Outpatient
• Palliative Care
• Hospice

Standards of Training

Currently no licensure exist in the U.S. There are National and International organizations that have established education and practice guidelines. The National Association for Holistic Aromatherapy (NAHA) has established educational guidelines dividing a curriculum of study for Level 1 and Level 2.
### Standards of Training

**NAHA**- Level 1 requires 30 hours of Aromatherapy Foundation.
Level 2 requires 200 hours of training. Course of study includes:
- Intro to History & Development
- Intro to Aroma chemistry
- Profiles of Essential Oils
- Anatomy & Physiology
- Bending

### Standards of Training

- Botany
- Safety, Precautions, Contraindications
- Legal & Ethical Issues
- Research
- Case Studies

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**Smell is a potent wizard that transports you across thousands of miles and all the years you have lived.**

-Helen Keller
Comparative Effectiveness Research: What Every Oncology Nurse Needs to Know

**Session Description:** Comparative effectiveness research (CER) evaluates drugs, technologies, healthcare delivery, and treatment options through decision analyses methodologies. It is an important element of the health reform plan. Oncology nurses must become involved with and understand how to conduct, review, and interpret CER, as it directly impacts nursing practice and health policy. Due to soaring costs and quality issues, there has been increased demand for evidence-based assessments on the value of healthcare. CER uses evidence-based tools to assist in decision making about what is best for the patient.

**Target Audience:** Oncology nurses, research nurses, advanced practice nurses, health policy decision makers, and other healthcare professionals

**Level of Content:** Intermediate

**Content Area:** Research

**Continuing Nursing Education:** Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

**Coordinator/Speaker:**
Deborah Braccia, RN, MPA, OCN
Regional Account Scientific Director
Novartis Oncology
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**Full Disclosure:**
Novartis. Employee—however this speaker does not intend to discuss any Novartis compounds.

*Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.*

**Speaker:**
Anita Nirenberg, DNSC, RN, MSN, AOCNP
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**Full Disclosure:**
Nothing to Disclose

*Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.*

**Objectives:**
By the end of this presentation, participants will be able to:
1. Define comparative effectiveness research (CER).
2. Explain the importance and impact of CER on health policy.
3. Interpret CER evaluations and incorporate into clinical decision making.

**Content Outline:**
I. Definitions
II. Background and importance—health policy
III. Health reform
IV. Cost and quality of care in the US
V. Importance and opportunities for oncology nursing
VI. Incorporation of CER in clinical decision making

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from a population-based national sample. Journal of the National
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President Obama on Health Care Reform

“The greatest threat to America’s fiscal health is not Social Security, though that’s a significant challenge; it’s not the investments that we’ve made to rescue our economy during this crisis. By a wide margin, the biggest threat to our nation’s balance sheet is the skyrocketing cost of health care…. This time, the call for reform is coming from the bottom up and from all across the spectrum -- from doctors, from nurses, from patients; from unions, from businesses; from hospitals, health care providers, community groups…”

White House Forum on Health Reform, March 5, 2009

What’s the Problem?

- 18,000+ RCTs published annually
- Tens of thousands of other clinical studies
- Systematic reviews consistently conclude that evidence is insufficient
- Problem will not be solved by doing more of the same

“Comparative effectiveness research can improve care for all Americans and is an important element of President Obama’s health reform plan”

HHS Spokeswoman Jenny Backus

CER Hypotheses

- Gaps in evidence reflect insufficient engagement of decision makers (patients, clinicians, payers) in selecting research questions and designing studies

-Sean Tunis, MD, MSc

“Comparative effectiveness research can improve care for all Americans and is an important element of President Obama’s health reform plan”

HHS Spokeswoman Jenny Backus

History of CER in Health Policy

- 2003
  - The Effective Health Care Program is created from the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.
  - Section 1013 of that MMA authorizes the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research with a focus on comparing the outcomes and effectiveness of different treatments and clinical approaches, as well as communicate its findings widely to a variety of audiences.
  - The research is driven by the needs of Medicare, Medicaid, and the State Children’s Health Insurance Program.

History of CER in Health Policy

- 2005
  - First appropriation of $15 million to AHRQ
  - The program releases its first comparative effectiveness report on treatment alternatives for gastric reflux disease.

- 2008
  - Congress doubles AHRQ’s Effective Health Care Program budget to $30 million.
**American Recovery and Investment Act of 2009**

- 1.1 billion in funding allocated to CER
  - $400 million to the Office of the Secretary in the US Department of Health and Human Services (HHS)
  - $400 million to the National Institutes of Health
  - $300 million to the HHS Agency for Healthcare Research and Quality (AHRQ)

- Established Federal Coordinating Council for CER
  - Responsible for setting national priorities for comparative studies on the relative effectiveness of different medical treatments for the same or similar conditions
  - 15 members
    - 1 nurse
    - 1 social worker
    - 1 economist
    - 1 statistician
    - 1 lawyer
    - 10 MDs

**AHRQ $300 Million to Support CER Projects**

- $148 million for evidence generation
- $48 million for national patient registries
- $29.5 million translation and dissemination grants
- $20 million to support training and career development in CER
- $9.5 million to establish an infrastructure to identify new and/or emerging issues for comparative effectiveness review investments
- $10 million for a Citizen's Forum
- $1 million to support other grants
- $50 million and enhancing existing contracts for evidence synthesis
- $24 million for evidence generation
- $5 million for translation and dissemination
- $3 million for salary and benefits for ARRA related full-time equivalent positions


**Assessing and Improving Value in Cancer Care – IOM Workshop Summary, November 4, 2009**

- Challenges to value in cancer care
- Cancer – Patient communication and influence on value
- Generating Evidence on effectiveness and value
- Value in the Oncology Market
- Ethical issues and value in oncology
- Solutions for value in cancer care


"This report lays the foundation for an ongoing enterprise to provide the evidence that healthcare providers need to make better decisions and achieve better results"

Sheldon Greenfield, MD, IOM Report Co-Chair
Saturday, November 13

NCCN Oncology Summit on Comparative Effectiveness
- Held December 7, 2009
- NCCN Comparative Therapeutic Index
- White paper under development

Agency for Healthcare Research and Quality (AHRQ)
- Cancer Consortium
  - Brigham and Women’s Hospital and Dana Farber
  - University of North Carolina
- Cancer DEcIDE Network Stakeholder Meeting
  - Jan 2010
  - Develop research protocol concepts for the highest impact areas to be addressed in cancer CER

CER and Patient Protection and Affordable Care Act (PPACA)
- Enacted March 2010
- Establishment of CER entity, Non-profit Patient Centered Outcomes Research Institute (PCORI)

PCORI
- Objectives:
  - Set research priorities and a research agenda
  - Conduct or support CER
  - Develop research methodologies
  - Develop data resources
  - Obtain and use data from the Federal government
  - Establish advisory panels to advise on research priorities.

PCORI
- 21 member board
  - Federal and state agency representatives
- Financed through Patient Centered Outcomes Research Fund
  - 2010 - $10 million
  - 2011 - $50 million
  - 2012 - $150 million
  - 2013 - $150 million plus fees from health insurance and self insured plans
  - 2019+ funding eliminated

What is Comparative Effectiveness Research?

Patient-Centered Outcomes Research Provisions Summary March 2010, AAMC
Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

Council Definition (con’t)

- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and subgroups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

Council’s Vision

1. Establishment of a process for CER priority-setting that maximizes the value of Federal investments in CER through responsiveness to patient and other stakeholder needs, transparency, and effective coordination.
2. Development of a robust, foundational infrastructure for CER.
3. Implementation of a strategy to support rapid, systematic dissemination of CER results to empower patients, clinicians, and other stakeholders to make more informed decisions and increase the quality of care.

Council Activity Recommendations

- Research
- Human and Scientific Capital
- Data infrastructure
- Dissemination and translation of findings
Saturday, November 13

Types of CER

- Clinical Trials
- Observational studies and modeling
- Secondary data analysis using registries and linked databases

Differences between Comparative Effectiveness Research and Efficacy Studies

- **CER**
  - Applicable to real world needs and decisions faced by patients, clinicians, and other decision makers
  - Head to head trials
  - Observational studies
  - Syntheses and modeling

- **Efficacy**
  - Typically placebo controlled clinical trials
  - Rigorous
  - Limited population

Examples of CER Summaries of Evidence

- **Agency for Healthcare Research and Quality**

Examples of CER Summaries of Evidence

- **AHRQ Prostate Cancer Consumer Guide**

http://cancercontrol.cancer.gov/cer/overview.html
Web Sites for Additional Information

- Oncology Nursing Society www.ons.org
- AcademyHealth http://www.academyhealth.org/
- Society for Medical Decision Making www.smdm.org
- International Society for Pharmacoeconomics and Outcomes Research www.ispor.org
- Agency for Healthcare Research and Quality www.ahrq.gov
- The White House- Health Care Reform http://www.whitehouse.gov/issues/health_care
- HealthReform.gov http://www.healthreform.gov/
- RAND www.rand.org
- Kaiser Family Foundation http://www.kff.org/
- Center for Medical Technology Policy www.cmtpnet.org
Cutaneous T-Cell Lymphoma: Novel Therapeutic Options and Challenges in Symptom Management

Session Description: Cutaneous t-cell lymphoma (CTCL) represents a group of rare lymphoproliferative disorders. The two most common include mycosis fungoides and Sezary syndrome. Speakers will address pathophysiology, treatment options, symptom management, and the psychological impact of disfigurement and social isolation associated with these disorders.

Target Audience: Oncology nurses and nurse practitioners

Level of Content: Introductory

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Estimated # minutes of Pharmacology Content to be presented: 30

Coordinator/Speaker:
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Full Disclosure:
Celgene. Non-CE speakers bureau
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Speaker:
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Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Name two clinical manifestations of CTCL.
2. List two FDA-approved systemic therapeutic options for treatment CTCL.
3. Identify two symptoms associated with CTCL and nursing interventions for each symptom.

Content Outline:
I. Cutaneous T-cell lymphoma (focus on mycosis fungoides and Sezary syndrome)
   A. Epidemiology
   B. Etiology and pathophysiology
   C. Clinical manifestations
   D. Staging—National Cancer Institute; updated International Society of Cutaneous Lymphoma/European Organization of Research and Treatment of Cancer
   E. Diagnostic tests

II. Review of treatment options, nursing considerations, and side-effect management
   A. Brief review of topical and light therapies
   B. Approved systemic agents
      1. Bexarotene
      2. Denileukin
      3. Diflotoxic
      4. Vorinostat
      5. Romidepsin
   C. Other systemic agents
      1. Chemotherapy
      2. Alemtuzumab
      3. Agents in phase III clinical trials

Bibliography:


Introduction

- A rare group of Non-Hodgkin’s lymphomas characterized by malignant T-lymphocytes that manifest primarily in the skin
- Malignancy of a single clone of CD4+ T-cells
- Vary in clinical presentation, histology, immunophenotype and prognosis
- Disease progression often involves lymph nodes, viscera and peripheral blood cells

Introduction

- Most common variants are Mycosis fungoides (MF) and Sezary syndrome (SzS)
- Often difficult to diagnose
- No effective cure exists except in early stage disease
- Often requires chronic management
- Profound effect on quality of life
- Causes significant psychological stress

Epidemiology

- MF and SzS represent approximately 55% of all cutaneous T-cell lymphomas
- Incidence steadily increasing over the past three decades
- Currently 16,000-20,000 estimated cases in U.S.
- Approximately 1200 new cases diagnosed annually
- Median age of onset is 50-60 years
- 2 x more common in men and African Americans
- More aggressive in African Americans

Etiology

- Etiology remains unknown
  - Theories include:
    - Chemicals
    - Environmental/occupational exposure
    - Smoking
    - Viral infections – HTLV-1, HHV-8, CMV
    - Bacterial infections
    - Cytokines
    - Genetic predisposition
    - Chronic exposure to antigens

Pathophysiology

- Malignancy of the immune system
- Preprogrammed skin homing T-cells infiltrate the skin → expand clonally → remain in activated state → fail to exit the skin
- Cells proliferate and over time causing visible skin changes and can accumulate in lymph nodes and viscera
- SzS is a more aggressive form with diffuse skin involvement and circulating malignant T-cells in peripheral blood

Mycosis fungoides

- MF is the most common form of CTCL
- First described by Jean-Louis Alibert in 1806
- Indolent clinical course with slow progression
- Often presents as a rash in bathing suit distribution
- Classic stages:
  - Premycotic
  - Patch
  - Plaque
  - Tumor
  - Erythroderma
WHO-EORTC Classification

- Mycosis fungoides
- Mycosis fungoides variants and subtypes
  - Multicentric reticulosis
  - Expansive reticulosis
  - Extranodal T-cell lymphoma
- Lymphomatoid papulosis
- Premycotic MF
  - Primary cutaneous CD4+ lymphoproliferative disorder
    - Primary cutaneous angioimmunoblastic T-cell lymphoma
    - Lymphomatoid angiocentric lymphoma
  - Primary cutaneous CD4+ small/medium-sized pleomorphic T-cell lymphoma
    (provisional)

Premycotic Stage

- Nonspecific, slight scaly rash present for months to decades prior to diagnosis of MF
- Biopsies often non-diagnostic
- Mimics nonspecific dermatitis — psoriasis, eczema, allergic dermatitis
- Lesions may resolve with/without treatment with topical corticosteroids
- Characterized by waxing and waning
- May never progress to definitive diagnosis of MF

Patch Stage

- Erythematous, flat macules with or without scaling
- Often occur in sun-protected areas
- Often hypo or hyperpigmented in dark-skinned individuals
- May be pruritic
- Vary in size, shape and color
- Most patches are large often > 5cm
- May be associated with alopecia or follicular involvement

Plaque Stage

- Increased T-cell infiltration produces dusky-reddish palpable lesions
- More generalized distribution
- Pruritis worsens and can involve both lesional and non-lesional skin
- Vary in shape — round, oval, acriform or serpiginous patterns

Tumor Stage

- Characterized by large, mushroom-like nodules
- May arise from previous sites of patches/plaques plaques or unaffected skin
- Vary in size
- Typically more painful, less pruritic
- Tumors often ulcerative and prone to infection
- Clinically more aggressive with worse prognosis

Erythroderma Stage

- Represents more advanced disease
- May be accompanied by patches, plaques and/or tumors
- >80% BSA reddened skin
- Affected areas may consist of patches or plaques and/or tumors
- Intense, debilitating pruritis with scaling
- More commonly observed in those with SzS
Sezary syndrome

- Leukemic form of MF
- More aggressive with poor survival
- “Red man syndrome”
- Triad of symptoms:
  - Erythroderma with > 80% BSA
  - Lymphadenopathy
  - Circulating cerebriform lymphocytes (Sezary cells) in peripheral blood
    - Absolute count > 1000 Sezary cells/cubic mm

Sezary syndrome

- Other clinical features include:
  - Intense pruritis
  - Exfoliative dermatitis with thickening of skin
  - Thickening of palms and soles
  - Ectropion
  - Alopecia
  - Immunocompromised

Diagnostic Workup

- Complete H&P
  - Assessment of entire skin including:
    - Type of skin lesion and extent of involvement
    - Assess for lymphadenopathy and/or organomegaly
- Lab studies
  - CBC
  - Peripheral blood smear
  - Basic metabolic panel
  - LDH
  - Albumin
  - Uric acid
  - Flow cytometry
    - CD4/CD8
    - Immunogenotyping

Diagnostic Workup

- Skin biopsy
  - Biopsy of most indurated skin lesion
  - Immunophenotyping
- Lymph node biopsy
  - Excisional biopsy of largest node
  - Histopathology, flow cytometry, T-cell receptor gene rearrangement
- Imaging
  - Chest x-ray
  - CT scan or PET/CT

Diagnostic Workup

- Skin biopsy
  - Multiple biopsies often required
- Lymph node biopsy
- Bone marrow biopsy
  - Should be considered depending on clinical presentation and staging
- Imaging
  - Chest x-ray
  - CT scan or PET/CT

TNMB Classification

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<tr>
<th>Stage</th>
<th>Definition</th>
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<td>T1</td>
<td>Limited patches, &lt; 10% of skin involved</td>
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<tr>
<td>T2</td>
<td>Patchy or plaque involving 10-99% of skin</td>
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<tr>
<td>T3</td>
<td>Generalized eruption involving &gt; 90% of skin</td>
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<tr>
<td>T4</td>
<td>Erythroderma involving &gt; 90% of body surface</td>
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<td>1-3 lymph nodes involved</td>
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<td>2</td>
<td>&gt; 4 lymph nodes involved</td>
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<table>
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<tr>
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</thead>
<tbody>
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<td>No bone marrow involvement</td>
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<tr>
<td>1</td>
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</table>

<table>
<thead>
<tr>
<th>B</th>
<th>Pathologic stage</th>
</tr>
</thead>
</table>
Saturday, November 13

**Topical and Light Therapies**
- Front line, early stage: “skin-focused” topical interventions.
  - Nitrogen Mustard
  - Carmustine
  - Topical retinoid X receptor selective retinoid
  - Total skin electron beam irradiation
  - Phototherapy
  - Corticosteroids

**Treatment Algorithm**

**Topical Therapy**
- Nitrogen Mustard (mechlorethamine)
  - Effective response rate: 70-80% CR in patch disease, skin clearance medium time 6-8 mo
    - Kim et al. (2003).
  - Hypersensitivity
  - Allergic contact dermatitis
- Carmustine (BCNU)
  - Similar response to Nitrogen Mustard
  - Less contact dermatitis
  - Mild leukopenia

**Topical Therapy**
- Corticosteroids
  - Ease of use
  - Reduced carcinogenicity
  - Known side effect protocol
- Topical Retinoid Bexarotene Gel
  - Non-immunosuppressive
  - Mild local irritation and rash

**Phototherapy**
- PUVA- psoralens with ultraviolet light A
- PUVB- narrow band ultraviolet light B
  - Well-established, safe and effective for early stage disease: 71% total clinical remission
    - Ramsay et al. (1992)
  - More advanced: 54% CR, 29%PR
    - Gathers et al. (2002)
  - Total skin electron beam radiation for extensive disease MF
    - Alopecia
    - Desquamation
    - Permanent telangiectasia

**Systemic Therapy**
- Usually under care of Dermatologist initially
- Interferon alpha: stages Ia to IVa 64% had objective response
  - Used in combined modality
- Retinoids
- Chemotherapy
  - Methotrexate
  - Others
- Antineoplastic Agents
  - Denileukin Diftux
  - Vorinostat
  - Romidepsin

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*With permission from: Greer JP, Foester J, Rodgers GM et al. eds. Wintrobe’s Clinical Hematology, 12th ed.*
Saturday, November 13

Denilekin difitox

- Brand name: Ontak®
- MOA: fusion protein which selectively delivers the cytotoxic activity of diphtheria toxin to targeted cells.
- Use: persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD 25 component of the IL2 receptor.

Denileukin Diftox

- Dose: 9 or 18 mcg/kg/day days 1-5 every 21 days for 8 cycles
- Phase III trial advanced stage ORR 30% Olsen et al. (2001)
- Premedication: Antihistamine and acetaminophen prior to each infusion.
- Withhold treatment if serum albumin <3 g/dl
- Infuse over 30-60 minutes

Denileukin Diftox

- Black Box Warnings:
  - Capillary Leak Syndrome: monitor weight, edema, blood pressure and serum albumin prior to and during treatment. May be delayed, occurring up to 2 weeks post infusion.
  - Infusion Reactions: usually occur within 24 hours of infusion and result within 48 hrs. Reported lower incidence in cycle 3 and 4

Denileukin Diftox

- Other Adverse Reactions:
  - CNS: fever, headache
  - Dermatologic: rash
  - GI: nausea/vomiting, diarrhea
  - Hematologic: lymphopenia

Vorinostat

- Brand Name: Zolinza®
- MOA: Inhibition of histone deacetylase enzymes which catalyze acetyl group removal from protein lysine residues. This causes termination of cell growth leading to cell death.
- Phase II trial: demonstrated activity in heavily pretreated patients (> 5 therapies) Ducic et al. (2007)

Vorinostat

- Oral capsule: 400 mg daily, continue until disease progression or unacceptable toxicity
- Dosing: adjustment for toxicity: Intolerance: reduce dose to 300 mg once daily
- Administer with food
## Adverse Reactions

- **CV:** peripheral edema, QT prolongation
- **CNS:** Fatigue, headache
- **GI:** Diarrhea, nausea
- **Heme:** Thrombocytopenia, anemia
- **Renal:** Proteinuria
- **Risk of DVT**

## Bexarotene

- **Brand Name:** Targretin® capsules & topical gel
- **MOA:** Exact mechanism unknown. Binds and activates retinoid X receptor subtypes. These receptors regulate the expression of genes which control cellular differentiation and proliferation.
  - 56 pts with advanced disease (IIB-IVB) 55% responded w/13%CR. Medium duration 299d

---

## Bexarotene

- **Oral** 300-400 mg/m^2/day taken as single daily dose. Take after fat-containing meal

---

## Bexarotene

### Topical:
- Apply to lesions once every day for first week, then increase on weekly basis to daily, 2 times/day, 3 times/day and finally 4 times/day as tolerated. Allow gel to dry before covering with clothing. Do not cover with occlusive dressing.

---

## Romidepsin

- **Brand Name:** Istodax®
- **MOA:** Histone deacetylase inhibitor resulting in modulation of gene expression. It causes the accumulation of acetylated histone and induces cell cycle arrest and apoptosis
  - Phase II trial of 71 pts heavily pretreated and advanced stage showed CR in 4 pts, PR 20 pts and ORR of 34%. Med duration response 13.7 mos. Piekarz et al. (2009).

---

## Romidepsin

- **Dose:** 14 mg/m^2 IV over 4 hours on day 1, 8, and 15 of a 28 day cycle. Continue treatment until progression of disease or intolerant to toxicities
- **No special tubing, no premeds for hypersensitivity needed**
Saturday, November 13

Romidepsin

- Adverse Reactions:
  - CV: QT prolongation
  - GI: nausea and vomiting, diarrhea, anorexia
  - Heme: Thrombocytopenia, leukopenia
  - Fatigue

Other Systemic Therapy

- Photopheresis
- Combining Modalities
- Newer Investigational agents
  - Alemtuzumab
  - Dendritic cell based vaccines
  - Transimmunization
  - Temozolomide
  - CD30 targeted therapy
  - Arsenic trioxide
  - Tazarotene
  - Allogeneic Stem cell transplant

Symptom Management: Pruritis

- Frequent, severe and often difficult to treat
- Pathophysiology:
  - Cutaneous free nerve endings
  - Cerebral Cortex
  - Neuropeptides release pruritic mediators

Assessment and Staging

- Cutaneous T-cell lymphoma may mimic common skin disorders such as eczema, psoriasis or contact dermatitis.
- Histological findings and molecular evidence of T-cell receptor clonality to confirm diagnosis

Treatment of Pruritis

- Underlying cause
- Early Stage: high potency topical steroids
- Oral Steroids
- Phototherapy
- Combination therapy

Skin Care Management

- Goal is to relieve skin discomfort such as dryness, cracking, flaking, heat sensitivity and pruritis
  - Oatmeal baths
  - Bathing/showering with lukewarm water
  - Rinse skin completely and pat dry
  - Use of moisturizers/emollients
  - Use of mild laundry detergent
  - Wear loose-fitting clothing
  - Sun protection
Other Physical Considerations

- High risk for local or systemic infection
  - #1 cause of death
- Alopecia
- Electrolyte imbalances
- Anemia
- Hypoalbuminemia
- Poor temperature control
- Pain
- Difficulty performing ADLs and ambulation
- Increased fatigue/inability to sleep

Psychological Impact

- Psychological impact of disfigurement and social isolation
  - Cancer diagnosis
  - Embarrassment
  - Loneliness
  - Fearful
  - Anger
  - Depression
  - Family dynamics

Summary

- MF is the most common form of CTCL followed by SzS.
- Incidence appears to be increasing
- Cause remains unknown
- MF difficult to diagnose
- No cure with exception of very early disease
- Treatment options are expanding
- Prognosis and treatment depend upon stage of disease.
- Causes profound effect on quality of life
**Saturday, November 13**

**Open Session • 9:15–10:45 am • W230 BC**

**Drug and Lab Values: Applications to Practice**

**Session Description:** In this session, speakers will discuss clinical assessment and evaluation of laboratory tests related to general individualized care and specific to oncology care. Discussion also includes examples of electrolyte, renal, and liver abnormalities related to medications specific to oncology, and commonly prescribed medications.

**Target Audience:** Clinical staff nurses and advanced practitioners

**Level of Content:** Intermediate

**Content Area:** Clinical Practice

**Continuing Nursing Education:** Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

**Estimated # minutes of Pharmacology Content to be presented:** 60

**Coordinator/Speaker:**
Cynthia Chernecky, RN, PhD, AOCN®, FAAN
Professor
Medical College of Georgia
Augusta, GA
cchernecky@mcg.edu

**Full Disclosure:**
Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

**Speaker:**
Deborah Walker, DNP, FNP-BC, AOCN®
Assistant Professor/Clinical Nurse Practitioner
University of Alabama at Birmingham
Birmingham, AL
dkirk2332@hotmail.com

**Full Disclosure:**
Celgene. Speakers bureau
Eisai. Speakers bureau

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

**Objectives:**
By the end of this presentation, participants will be able to:
1. Evaluate laboratory values and their association to medications including pharmacology and pharmacokinetics.
2. Decide implementation strategies based on laboratory values.
3. Generate assessment and evaluation criteria based on prescribed therapy.

**Content Outline:**
I. Generalized care
   A. Medication interferences
   B. Assessment and evaluation
      1. Glucose
      2. Liver function tests
         a. AST
         b. ALT
      3. Other affected labs
II. Cancer specific care
   A. Chemotherapy and other modalities (e.g., monoclonal antibodies)
      1. Electrolytes
      2. Serum blood values
      3. Renal function
      4. Liver function
      5. Pharmacology and pharmacokinetics
      6. Case studies

**Bibliography:**
Saturday, November 13


OsI Pharmaceuticals, Inc. (2010). Tarceva® (erlotinib) prescribing information.


More than just cancer:
- Diabetes
- Heart disease
- Renal impairment
- Liver disease/dysfunction
- Thyroid disease
- Bleeding

Facts
- > 40,000 known drug effects on lab tests.
- Up to 38% drugs cause significant lab test effects.
- Alert programs: **CDS** (clinical decision support), **AHFS** (American hospital formulary service) drug information, **PDF** drug-lab interactions.

**Dilantin**
- Decreased neutrophils, pancytopenia, Lupus E.
- Stevens-Johnson = cutaneous rash oral, eyes, lips, vagina, fever.
- Effectiveness decreased by ETOH, antihistamines, antacids, rifampin, folic acid.
- Increases serum glucose.
- Brands vary so may need to change brands to get desired effect.

**Phenobarbital**
- Side effects: Stevens-Johnson, thrombophlebitis, angioedema.
- Corticosteroids decrease effectiveness of phenobarb.
- Phenobarb (like antibiotics) decreases effectiveness of birth control pill.

**Furosemide (Lasix)**
- Side effects: loss of hearing at high doses, pancytopenia, Stevens-Johnson.
- Increases ototoxicity with DDP (Cisplatin) chemotherapy and/or vancomycin.

**MSO4 = Morphine**
- Increases amylase lab value, orthostatic hypotension.
- Rifampin (anti-TB) decreases morphine’s action.
### Famotidine (Pepcid)
- Decreases platelets.
- Decreases RBC.
- Dysrhythmias.

### Gabapentin (Neurontin)
- Taper off drug or seizures may occur.
- Decreases WBC
- Dry mouth – use candy.

### Paroxetine (Paxil)
- Increases serum glucose.
- Increases warfarin, bleeding.

### Quetiapine fumerate (Seroquel)
- For psychosis, may induce fainting with strenuous exercise.
- Causes tachycardia and palpitations as antagonist of brain neurotransmitters (5-HT, dopamine, adrenergic).

### Sertraline (Zoloft)
- Inhibits serotonin reuptake in CNS.
- Increases effects of warfarin, bleeding.
- Do NOT use with St. John’s Wort.

### Trazadone HCl
- Increase serum glucose.
- Side effects agranulocytosis, thrombocytopenia, leukopenia, eosinophilia.
Fluoxetine (Prozac)

- Increased thrombophlebitis, brady/tachycardia, MI.
- Increases digoxin toxicity and warfarin toxicity.
- Increases blood glucose.
- Do NOT use with St. John’s Wort.

Chinese Herbs; Chan Su or Dan Shen

Bufadienolides that block vasodilation and increases vasoconstriction and BP.

Do NOT use with digoxin = dysrhythmias, death.

Evening primrose oil (PMS, DM neuropathy, ADD)

- Decreases phenobarbital and dilantin serum levels causing increased seizures.

Warfarin - ↑ bleeding from Herbals

- Angelica root
- Capsicum
- Feverfew
- Garlic
- Ginseng
- Ginko
- Horse chestnut
- Licorice root
- Siberian ginseng
- Chinese dong qui (PMS, cramps)

Licorice

- Increases BP.
- Hypokalemia (inhibits conversion of cortisol to cortisone)

KAVA-KAVA

- ↑ LFT’s, can induce hepatitis.
- Note: often transient LFTs from many drugs can be counteracted by eating spinach 3x/week for 2 weeks prior to treatment. Spinach is high in fiber and zinc (not iron- Popeye wrong) helps enzymes work better to breakdown substances and decrease oxidative damage.

- Confusion, lethargy if used with CNS depressants like alprazolam (Xanax) or cimetadine (Tagamet) due to inhibits CP-450.
Kelp (Seaweed)

- Produces abnormal thyroid profile, affects hyperthyroidism significantly.
- ↑ T4 and T3
- ↓ Thyrotropin (TRH or TRF – releasing factor)

REMEmber: Sometimes life can be confusing

Common Drug Interactions

<table>
<thead>
<tr>
<th>↑ Bleeding Warfarin</th>
<th>Steven's Johnson</th>
<th>Cardiac</th>
<th>↓ CBC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine</td>
<td>Diltiazem</td>
<td>Chan Su</td>
<td>Ciprofloxacin</td>
</tr>
<tr>
<td>Ginseng</td>
<td>Furosemide</td>
<td>Dan Shen</td>
<td>Diltiazem</td>
</tr>
<tr>
<td>Ginseng</td>
<td>Phenobarbital</td>
<td>Fluoxetine</td>
<td>Furosemide</td>
</tr>
<tr>
<td>Licorice</td>
<td>Licorice (↑K+)</td>
<td>Farnatidine</td>
<td></td>
</tr>
<tr>
<td>Paroxetine</td>
<td>Quetiapine</td>
<td>Gabapentin</td>
<td></td>
</tr>
<tr>
<td>Sertraline</td>
<td>“pril” (↑K+)</td>
<td>Trazadone</td>
<td></td>
</tr>
</tbody>
</table>

↑ Birth Control Pill | LFTs | Thyroid | ↑ Glucose
| Antibiotics | Ciprofloxacin | Kelp | Fluoxetine |
| Phenobarbital | Kava Kava | Lidocaine |
| Morphin      | Paroxetine | Dextroedone | Risental |
| “pril” for BP | Trazadone, minor |

Cisplatin

- ↑ BUN/Cr, AST, bili, uric acid, amylase
- ↓ CBC, Na, K, Ca, Mg, Phos
  - Coombs positive hemolytic anemia has been reported
  - SIADH has also been reported

- Monitor:
  - Weekly CBC, CMP, electrolytes, periodic LFTs
  - Ototoxicity – much higher incidence (31%)
  - Neurologic exam – peripheral neuropathy
  - ↓ Anticonvulsant agents therapeutic levels (phenytoin)

Dexamethasone

- ↑ Na, H₂O retention, glucose, LFTs
- ↓ K, Ca, I uptake and protein bound iodine conc

- Monitor:
  - ↑ Blood pressure, risk for CHF in susceptible patients
  - Drug induced secondary adrenocortical insufficiency
  - PT/INR if on warfarin
  - Cyclophotase levels – increased activity of both when used together – convulsions have been reported
  - May increase K loss when combined with amphotericin B or K depleting diuretics
  - May increase the risk of tendon rupture when used with fluoroquinolones

Cytarabine

- Ara-C or cytosine arabinoside
  - ↑ LFTs, BUN/Cr, uric acid with TLS
  - ↓ CBC, digoxin levels, efficacy of gentamicin

- Monitor:
  - Lab – CBC, CMP, uric acid
  - High doses may cause pulmonary edema and cerebellar toxicity
  - stomatitis, liver injury and conjunctivitis

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Lenalidomide

- Revlimid® (Celgene Corporation, Summit, NJ)
  - ↑ risk for coagulopathy, digoxin levels
  - ↓ CBC, K, Mg, acquired hypothyroidism

- Monitor:
  - CBC frequently
  - Electrolytes
  - Thyroid tests if indicated
  - For hypercoagulable state

Erlotinib

- Tarceva® (Schwarz Pharma Manufacturing, Seymour, IN)
  - ↑ PT/INR, LFTs, bili, alk phos, BUN/Cr
  - ↓ Platelets

- Monitor:
  - For pulmonary toxicities
  - Check PT/INR if on warfarin
  - Routine CBC, LFT, bili, alk phos and BUN/Cr

- Cigarette smoking has been shown to reduce erlotinib AUC

Imatinib mesylate

- Gleevec® (Novartis Pharmaceuticals Corporation, East Hanover, NJ)
  - ↑ LFT, bili, BUN/Cr
  - ↓ CBC, thyroid levels, LVEF dysfunction
  - RARE: ↑ CPK, LDH, amylase, Ca, uric acid

- ↓ Mg, Na, K

- Monitor:
  - CBC weekly x one month, then biweekly for month 2, then periodically
  - CMP/Electrolytes
  - Thyroid studies
  - Cardiac function

Nilotinib

- Tasigna® (Novartis Pharma AG, Stein, Switzerland)
  - ↑ QT prolongation, lipase, AST/ALT, bili, alk phos, glucose
  - ↓ CBC, phos, Ca, Na, Mg, K (↓ ↑)

- Monitor:
  - CBC every 2 weeks x 2 months, then monthly
  - ECG baseline, then in 7 days after initiation, then periodically
  - Chemistry and Hepatic testing periodically
  - Monitor and correct electrolytes initially and then periodically

Dasatinib

- Sprycel® (BMS, Princeton, NJ)
  - ↑ AST/ALT, bili, QT prolongation
  - ↓ CBC, phos, K, Ca
    - Causes platelet dysfunction

- Monitor:
  - CBC weekly x 2 months, then monthly
  - Fluid retention/pleural effusions
  - ECG in patients at risk for QT prolongation

TYROSINE KINASE INHIBITORS (TKI)
**Everolimus**

- **Afinitor®** (Novartis Pharma Stein AG, Stein, Switzerland)
  - ↑ Creatinine, blood glucose, lipids, triglycerides, AST, ALT, bilirubin
  - ↓ CBC, phosphate
  - Monitor: renal function, blood glucose, lipids and hematologic parameters before initiation of therapy and periodically thereafter.

  

**Sorafenib**

- **Nexavar®** (Bayer Healthcare Pharmaceuticals Inc., Wayne, NJ)
  - ↑ PT/INR, lipase, amylase, AST/ALT, BUN/Cr
  - ↓ CBC, Phos, albumin
  - Monitor:
    - CBC, CMP, amylase, lipase, phos, PT/INR frequently
    - Blood pressure

**Sunitinib malate**

- **Sutent®** (Pfizer Labs, New York, NY)
  - ↑ AST/ALT, bili, coagulopathy, BUN/Cr, QT prolongation, lipase, amylase, alk phos, uric acid
  - ↓ LVEF, CBC, Hypothyroid dysfunction
  - ↑↓ Phos, K, Na, Ca
  - Monitor:
    - CBC, CMP, phos, bili before initiation of treatment and with each cycle
    - Thyroid studies if indicated
    - Coagulation panel, lipase, amylase if indicated
    - ECG, MUGA or ECHO if indicated

**Temsirolimus**

- **Torisel®** (Wyeth Pharmaceuticals Inc., Philadelphia, PA)
  - ↑ AST, glucose, cholesterol, triglycerides, alk phos, Cr, bili
  - ↓ CBC, phos, K
  - Monitor:
    - CBC, CMP, electrolytes, lipid panel at baseline and periodically throughout treatment

**Alemtuzumab**

- **Campath®** (Millennium and ILEX Partners, LP, Cambridge, MA)
  - ↑ thyroid test, bili, LFT, alk phos
  - ↓ CBC (esp. lymphocytes), albumin, Na, haptoglobin
    - severe, sometimes prolonged myelosuppression
  - ↓ ↑ K, glucose
  - Monitor:
    - CBC weekly, more frequently if needed
    - CD4+ counts should be assessed after treatment until recovery to >/=200 cells/µL.
    - Frequently for infections

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**MONOCLONAL ANTIBODIES**

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**Saturday, November 13**

### Megestrol acetate

<table>
<thead>
<tr>
<th><strong>Medication</strong></th>
<th><strong>Actions</strong></th>
<th><strong>Notes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Megace</strong> (BMS, Princeton, NJ)</td>
<td>↑ glucose, LDH</td>
<td>Monitor: Glucose, leukopenia. Use with caution in those with hx of thromboembolic disease.</td>
</tr>
</tbody>
</table>


### Cetuximab

<table>
<thead>
<tr>
<th><strong>Medication</strong></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Erbitux</strong> (ImClone Systems Incorporated, Branchburg, NJ)</td>
<td>↓ Mg (50%), Ca, K, WBC, H/H</td>
<td>Monitor: CBC, electrolytes routinely, Pulmonary toxicity.</td>
</tr>
</tbody>
</table>


### Panitumumab

<table>
<thead>
<tr>
<th><strong>Medication</strong></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Vectibix</strong> (Amgen Inc., Thousand Oaks, CA)</td>
<td>↓ Mg (occurred 6 weeks or longer after the initiation of treatment), Ca</td>
<td>Monitor: Monitor electrolytes periodically and for 8 weeks after the completion of therapy.</td>
</tr>
</tbody>
</table>


### Arsenic trioxide

<table>
<thead>
<tr>
<th><strong>Medication</strong></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Trisenox</strong> (Cell Therapeutics, Inc., Seattle, WA)</td>
<td>↑ WBC (Hyperleukocytosis), QT prolongation, glucose, AST, ALT, K</td>
<td>↓ K, Mg, Ca, H/H, Plt, glucose. Monitor: For APL Differentiation Syndrome, ECG weekly, more frequently if indicated. Monitor electrolytes, hematologic and coagulation (DIC) profiles should be monitored at least twice weekly during induction and at least weekly in consolidation.</td>
</tr>
</tbody>
</table>


### Asparaginase

<table>
<thead>
<tr>
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</tr>
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<tbody>
<tr>
<td><strong>Elspar</strong> (Merck &amp; Co, Inc., West Point, PA)</td>
<td>↑ AST/ALT, alk phos, bili, amylase, glucose, ammonia levels, proteinuria, BUN</td>
<td>↓ CBC, Thyroid function tests, fibrinogen, clotting factors V and VIII and minor Factors VII and IX, albumin, cholesterol, Ca. Increased and decreased in total lipids have occurred.</td>
</tr>
</tbody>
</table>

- Monitor: CBC, CMP, amylase, coagulation studies, lipids, thyroid test. |

**Methotrexate**

- ↑ LFT, BUN/Cr, uric acid, protein in urine
- ↓ CBC, albumin, the clearance of theophylline levels

- Monitor:
  - Baseline – CBC, CMP, CXR, PFT may be needed
  - BUN/Cr – if elevated, can cause toxicity
  - TLS
  - Theophylline levels
  - Folate deficiency increases MTX toxicity
  - NSAIDS can increase blood concentration of MTX


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**RETINOIDS**

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**Bexarotene**

- Targretin® (R.P. Scherer, St. Petersburg, FL)
  - ↑ CA125 assay values in patients with ovarian; triglycerides, cholesterol, LDL, AST/ALT, bil, PT/INR, LDH
  - ↓ HDL, hypothyroidism, WBC, hypoglycemia

- Monitor:
  - Fasting Lipid panel weekly for about 2-4 weeks, and at 8 week intervals
  - Initial LFTs then 1,2,4 weeks then every 8 weeks if stable
  - Baseline Thyroid studies and CBC - then throughout treatment
  - Acute pancreatitis - from elevated triglycerides

*R.P. Scherer (2009). Targretin® (Bexarotene) prescribing information.*

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**Tretinoin**

- Vesanoid® (Roche Laboratories, Inc., Nutley, NJ)
  - ↑ leukocytosis, cholesterol, triglycerides, LFT

- Monitor:
  - Differentiation syndrome
  - CBC, coagulation profile, LFT, lipid panel should be monitored frequently


---

**Abbreviations**

- ↑ - increase
- ↓ - decrease
- CBC – complete blood count
- WBC – white blood cell
- Hgb/Hct, H/H – Hemoglobin/Hematocrit
- PFT – pulmonary function tests
- LFT – liver function tests
- AST – aspartate aminotransferase
- ALT – alanine aminotransferase
- ALK Phos – alkaline phosphatase
- Na, K, Ca, Mg, pico, i – Sodium, potassium, Calcium, Magnesium, Phosphorus, iodine
- BUN/Cr – blood urea nitrogen/creatinine
- PT/INR – prothrombin time
- PTT – partial thromboplastin time
- LDL – low density lipoproteins
- HDL – high density lipoproteins
- PFTs – pulmonary function tests
- CXR – chest xray
- CMP – complete metabolic panel
- SIAH – syndrome of inappropriate antidiuretic hormone
- ECG – electrocardiogram
- ECHO – echocardiogram
- MUGA – Multiple gated Acquisition scan
- AUC – area under the curve
- TLS – tumor lysis syndrome
- LVEF – left ventricular ejection fraction
- CPK – creatine phosphokinase
- LDH – lactate dehydrogenase
Where’s the Line? Ethical Economics and Health Care

This session has been planned in collaboration with the Ethics Special Interest Group.

Session Description: In these changing and shifting economic times, it is incumbent for the oncology nurse and other healthcare providers to be familiar with prevailing economic theories. This session will address the nuances of healthcare costs, the role of advocacy, and how this information applies to oncology nursing.

Target Audience: Healthcare providers, oncology nurses, and oncology advanced practice nurses

Level of Content: Intermediate

Content Area: General Content

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Coordinator/Speaker:
Gabriela Kaplan, RN, MSN, AOCN®
Clinical Nurse Specialist, Oncology Care Alternatives Hospice
Cranford, NJ
gabiaocn@gmail.com

Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Speaker:
Laura Beamer, DNP, NP, AOCNS®, AOCNP®
Doctoral Nurse Fellow
City of Hope National Medical Center
Duarte, CA
labeamer@gmail.com

Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Define selected economic theories.
2. Identify ethical principles involved in healthcare decision making.
3. Apply ethical principles in environment of economic famine.

Content Outline:
I. Economic theory review (selected)
   A. Capitalist
   B. Socialist
   C. Supply side
II. Review of ethical principles
   A. Care ethics
   B. Principle-based ethics
III. Case studies

Bibliography:
**ECONOMIC THEORIES**

**Capitalism**
- An economic system in which the means of production and distribution are privately or corporately owned.
- A theory or system in which property and investment in business are owned and controlled by individuals directly, or through ownership of shares in companies

www.refdesk.com

**Socialism**
- A theory or system of social organization that advocates the vesting of ownership and control of the means of production and distribution (capital, land, etc.) in the community as a whole
- Common ownership and cooperative management of the means of production and allocation of resources

www.dictionary.com

**Economic Theories**
- Capitalist concepts
- Socialist concepts
- Supply – side concepts

**The Health Care Connection**
- One is not entitled to what can’t be paid for
- Profit margins are needed to survive (stay open for business)
- Health care is NOT a right ..it is to be bought
- “Throwback” to the Puritan ethic: If you can’t afford health care, you don’t deserve it

**The Health Care Connection**
- Medical care is a right, not a privilege
- The government (centralized) owns and operates both the financing of health care and its delivery
- Recognition that health care delivery is a human service, not a manufacturer of material goods
- How do we explain Medicare, the VA system?
Supply – Side Economics

- An economic theory which holds that reducing tax rates, especially for businesses and wealthy individuals, stimulates savings and investment for the benefit of everyone
- Also called “Trickle – Down Economics”
- Economic growth can be stimulated by lowering barriers for people to produce goods and services

www.InvestorWords.com

The Health Care Connection

- Insured consumers pay a different price than the price paid to the deliverers of the medical service (price charged vs. price paid)
- Demand-side cost sharing
  - Patients pay more in co-pays or deductibles
- Supply-side cost sharing
  - Alters the incentives of health care workers to provide the service

Some Literary / Historical Discussion Points

- “From each according to his ability, to each according to his need.” Ayn Rand, Atlas Shrugged
- “When morality comes up against profit, it is seldom that profit loses.” Shirley Chisolm
- “Money has no fatherland, financiers are without patriotism and without decency, their sole object is gain.” Napoleon Bonaparte

ETHICAL PRINCIPLES

Principle – Based Ethics

- Beneficence / Non-maleficence
- Autonomy
- Fidelity / Veracity
- Justice

Distributive Justice

- To each person:
  - an equal share
  - according to need
  - according to effort
  - according to contribution
  - according to merit
  - according to free-market exchanges

Beauchamp & Childress, 2009, p. 243
Saturday, November 13

Allocation of Healthcare
- Partitioning the comprehensive social budget
- Allocating within the health budget
- Allocating within the health care budget
- Allocating scarce treatments for patients

Prioritization of Healthcare
- How to decide?
  - Cost-effectiveness analysis (CEA)
  - Cost-utility analysis (CUA)
  - Quality adjusted life-years (QALYs)
  - Public preference
  - Majority "rules"

Rationing of Health Care
- Types of Rationing
  - Wealth determines
  - Government determines allotments & sets limits
  - A certain amount of health care is distributed equally & those who can afford more are allowed to purchase it

Rationing Scarce Health Resources
- Constituency
- Progress of science
- Prospect of success
- Medical utility
- Lotteries
- Social utility
- Triage

GENETIC TESTING 101

BRCA1/2 Full Sequencing
- Accounts for ~80-85% of mutations in the BRCA genes
- Standard of care for appropriate cases
- Cost $3,340.00
BART (Large Rearrangement/Duplication)

- Accounts for 10% of mutations in the BRCA genes.
- Experimental vs standard of care
- Cost $700.00

Testing to Help the Patient vs Family

- Medicare
  - Patient must be affected
- Medicaid
  - Varies from state to state
- Private Insurance
  - Will often pay if considered standard of care
    - Deductable (e.g., $500, $1000 annually)
    - Co-pay (e.g., insurance pays 80%, patients pays 20%)
    - In network, HMO authorizations, etc.

COSTING OUT CARE & PREVENTION OPTIONS

Comparing the Costs

- Screening:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammogram (annual)</td>
<td></td>
</tr>
<tr>
<td>Breast MRI (annual)</td>
<td></td>
</tr>
<tr>
<td>Clinical breast exam (q 6 months)</td>
<td></td>
</tr>
<tr>
<td>Transvaginal Ultrasound</td>
<td></td>
</tr>
</tbody>
</table>

Comparing the Costs

- Genetic Testing:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full sequencing</td>
<td></td>
</tr>
<tr>
<td>BART</td>
<td></td>
</tr>
<tr>
<td>Single site</td>
<td></td>
</tr>
<tr>
<td>&quot;AJ&quot; panel</td>
<td></td>
</tr>
</tbody>
</table>

Comparing the Costs

- Treatment

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mastectomy w/reconstruction (curative intent)</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy</td>
<td></td>
</tr>
<tr>
<td>Radiation therapy</td>
<td></td>
</tr>
<tr>
<td>TAH/BSO, omentectomy, LND, peritoneal washings</td>
<td></td>
</tr>
</tbody>
</table>
Comparing the Costs

- **Prevention**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral mastectomy w/reconstruction (prophylactic [RRMI])</td>
<td></td>
</tr>
<tr>
<td>BSO (prophylactic)</td>
<td></td>
</tr>
</tbody>
</table>

**CASE STUDY 1: Economics & Ethics of Who to Test**

- Who is the best person in this family to test for a mutation?
- What can be done if the “best person” does not have health insurance?
- Can testing be done on a dead family member?

**CASE STUDY 2: Rationing Genetic Testing**

- Which genetic tests are needed in this family?
- Can we advocate for more than one genetic test at a time?
- How many genetic tests does one individual deserve?

**CASE STUDY 3: Medication Madness**

- Non-insured patient requires long-acting pain medication
- After jumping through hoops, patient’s pain is well controlled
- State changes Medicaid providers

**Case Study 4: Decisions, Decisions...**

- Resources are costly and scarce
- Who decides?
- On what basis?
- Shall we be “equal” or shall we be “just?” (and who decides?)
- Is there another paradigm?
**Session Description:** Explore the various surgical options that are available to those who have been diagnosed with lung cancer, including lung resection VATS procedure, prior adjuvant therapy, surgical resection biopsies such as an open lung biopsy, mediastinoscopy, and bronchoscopy, as well as malignant pleural effusions management. Speakers will also address chest tube and pain management care. Be prepared to learn from case studies and discuss preventive care, lung cancer screening, and long-term follow-up care.

**Target Audience:** Acute or adult nurse practitioners

**Level of Content:** Intermediate

**Content Area:** Clinical Practice

**Continuing Nursing Education:** Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

**Estimated # minutes of Pharmacology Content to be presented:** 15

**Coordinator/Speaker:**
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**Full Disclosure:**
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

**Speaker:**
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**Full Disclosure:**
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

**Objectives:**
By the end of this presentation, participants will be able to:
1. Identify the signs and symptoms of lung cancer and how it is diagnosed.
2. Identify the common surgical procedures that are performed for a person with lung cancer as it relates to the stage of disease.
3. Explain the various stages of the clinical pathway for a lung cancer patient including chest tube management, pain management and long-term care.

**Content Outline:**
I. Lung cancer
   A. Signs and symptoms
   B. Risks
   C. Type of lung cancer
      1. Diagnosis
      2. Stage of disease
      3. Cell type
         a. Adenocarcinoma
         b. Squamous cell
   D. Peripheral care
II. Surgeries performed
   A. “Goal standard of care”—pulmonary resection
   B. Video-assisted thoracoscopic surgery procedure (video)
   C. Diagnostic care
   D. Adjuvant care, then surgery
   E. Palliative care surgery
III. Clinical care pathway
   A. Chest tube management
   B. Pain management
IV. Long-term care timeline
V. Preventive

**Bibliography:**
Atrium Medical Corporation. (2008). “Oasis dry suction” and “Heimlich valve” and “Pneumostat.”
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Lung Cancer Facts

- Lung cancer is the #1 cancer killer
- Estimated 222,520 will be diagnosed and 157,300 will die (ACS, 2010)
- 2000 new “daily” smokers under 18 each day
- 70% of diagnoses are late stage, thereby unresectable
- Five year survival is 15%

Additional facts

- Lung cancer is the leading cause of death among men and women
- 2 out 3 people diagnosed with lung cancer are older than 65; <3% are younger than 45 and the average age of diagnosis is 71
- Risk of getting lung cancer:
  - 1 out of 13 men
  - 1 out of 16 women

Lung Cancer Facts

- Dry cough, early common symptom in 50-80% of the patients.
- Hemoptysis
- Dyspnea
- Fatigue
- New onset wheezing
- Hoarseness
- Fever, chills and/or night sweats

What causes lung cancer?

- Cigarettes - 90% cancer in men; 78% in women
- Dose dependent - duration and number of cigarettes
- Risk of lung cancer from cigar, less than cigarettes - 5 cigars = 1 pack of cigarettes

More causes........

- Secondhand smoke - same chemicals as cigarettes, but in lower concentrations
- Radiation - occupational exposure, such as nickel, coal, mustard gas, arsenic and iron
- Asbestos not only lung cancer, but mesothelioma (cancer of pleural surface)
- Age - <1% under 30 years, increases markedly after each decade
- Prior lung cancer; risk is 20 - 30%
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Types of Lung Cancer

- Non-small cell lung cancer - most common; 80% of lung cancers. Adenocarcinoma, squamous cell or large cell carcinoma.
- Small cell lung cancer – about 20% of lung cancers. Cancers are small, but can multiply quickly and form large tumors.
- Some cancers can have features of both cell types

Other Lung Diseases

- Tuberculosis
- Mesotheliomia – found in the sac lining the chest and/or abdomen
- h/o asbestos exposure
- Sarcoidosis – inflammation of the body’s tissue that produces nodules

Diagnostic Studies

- Chest x-ray - typically done first. Find nodule, prompts
- A Chest CT with contrast
- PET scan - useful with lung cancers, not useful when nodule < 1mm
- Fine needle aspiration
- Bronchoscopy

Medical/Surgical Intervention

- GOAL is CURE
- If resectable, a pulmonary resection if offered
- If unresectable, chemotherapy is preferred medical therapy

History of Surgical Resection

- First pneumonectomy
- Smaller resections emerged in the 1940’s
- Robotic surgeries
- Surgical staples

Goal of therapy

- CURE
- Three parts
  - Diagnosis
  - Complete resection
  - Systematic sampling of lymph nodes
Candidate for Surgery

- Emotional barriers
- Physiological barrier
- Pulmonary function tests
  - Standards for pulmonary resection
  - FEV1
  - DLCO

Who is not resectable?

- Invasion into mediastinal vessels/structures
- Malignant pleural effusions
- Contralateral or supraclavicular lymph node metastases
- Poor pulmonary function tests

Indications for Pulmonary resection

- Lung cancer
- Pleural effusions – malignant/non-malignant
- Benign disease, such as bleb disease

Common Operative Procedures

- Lobectomy
- Segmentectomy
- Wedge resection

Pulmonary Lobectomy

Medical art studio, 2009

Results Following Surgical Resection

- Recurrence rates
- Age group mortality
- Major complications
  - Respiratory
  - Cardiac
Complications – Respiratory and Cardiovascular

- Nosocomial pneumonia
- *Persistent air leak
- Atelectasis
- *Pneumothorax
- Bronchospasm
- Bleeding
- *Cardiac arrhythmias
- MI
- Stroke

*Most common


Indications for Chest tube placement

- Emergency situations
  - All patients on mechanical ventilations
  - Pneumothorax
- Non-emergency situations
  - Malignant pleural effusion
  - Pleurodesis
  - Postoperative care

Contraindications for chest tube insertion

- No absolute contraindications, except when a lung is completely adhered to the chest wall
- Relative contraindications
  - Risk of bleeding
  - Abnormal clotting profiles

Pathophysiology of chest cavity

- Normally, chest cavity is a closed space
- Negative pressure surrounds each lung to keep the lungs inflated


Chest tube size

- Can range in size from 14 to 36 French
- Size of the chest tube depends on the problem
- Can be inserted at the bedside or percutaneously
- Can insert medications under certain conditions.

Pleural effusions

- Transudates – “thinner” can be related to CHF.
- Exudate – “thicker” because they contain protein; usually an inflammatory process
- Treated short term with a chest tube as symptoms progress.
- Chest tube size can be a small bore 8Fr to 16Fr for a transudative fluid and 22 Fr for an exudative fluid
Surgical pleurodesis

- Failed attempts at thoracentesis and chemical pleurodesis
- If lung entrapment, may also perform decortication procedure
- Typically indicated for malignant pleural effusions.
- Operative procedure with hospital LOS of 4-5 days

Chemical pleurodesis

- Similar to “reading a wall to paint”
- Focus is to allow lung within pleural space to come back up.
- Two types – chemical or surgical pleurodesis
- Chemical pleurodesis done with either talc or bleomycin that is inserted into a chest tube
- Surgical pleurodesis is a mechanical stripping of the pleural cavity and insertion of talc (sprayed) that is done in the OR

Continuous air leaks

- Is it a closed system?
- Is there an obstruction?
- Patient history
- Is it on suction or water seal?

IV pain medication

- Epidural vs. IV PCA
- Toradol (Ketorlac) – IV and PO
- IV Morphine

Troubleshooting Techniques for Common Problems

- Continuous air leaks
- Change in drainage
- Change in oxygen saturation
- Equipment malfunction

Bubble, Bubble, Toil and Trouble...
Transitioning from IV to PO

- Transitioning from PCA to PO opioids
  - Percocet
  - Oxycontin/Oxy IR
  - MS Contin
  - PO Toradol
- Other Non-steriodals – Motrin, Alleve
- Laxative of choice
- Topical agents – Lidoderm

Case Study

Patient is a 48 year old WM who as part of a preoperative workup, had a chest x-ray that revealed a “shadow”. PCP sent him for a CT scan and then a PET scan. No biopsy have been taken. Prior medical history is unremarkable, except for a 15 year smoking history – 3 packs per day. He stopped one week ago. His only symptoms are shortness of breath and a dry cough. He comes in today for evaluation of his lung mass.

1. Would any other diagnostic workup be necessary?
2. Are there any other symptoms you should ask about?
3. He appears anxious, what, if anything would you do?

Other Therapies

- Mediastinoscopy
  - Selection of patients
  - Purpose of therapy
  - Diagnosis vs Staging
  - Is there a need?

Photodynamic Therapy

- Candidate
- Benefit
- Risks
- Future Implications

Cyberknife Therapy

- Pain free surgical option for inoperable or surgically complex tumors
- Patient looking for alternative to invasive surgery.
- Treatment plan developed specifically for the patient utilizing the Cyberknife software
- Each session between 30 – 90 minutes long, delivered in stages, usually lasting for a period of 5 days.
- Minimal side effects.
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#### Things to Consider

- Reimbursement – FDA approved; but still may not be covered
- Not for everyone; personal choice – look at all options and discuss with family
- Need more studies – 451 patients have been done to date showing promising results
- Long term results not available

**Accrue Incorporated. Cyberknife. 2007-2010**

#### Improving Patient Care Outcomes

- VATS procedure
- Surgical lung sealant
- Molecular detection
- Clinical pathways

#### VATS procedure

- Developed in 1992 at Cedar Sinai Medical Center
- Cedar Sinai Medical Center, studied 1100 patients
- Hope to reduce hospital stay, less risk, quicker recovery, without compromising the completeness of the cancer surgery
- <2 inch incision vs. 8 inch by thoracotomy
- Can be used for removal of lung tumor, pluerodesis, or biopsy


#### VATS lobectomy procedure

- Median length of stay – 3 days
- 84.7% had NO complications
- Not typically used for complex for lung tumors
- Less pain due to no rib spreading
- In octagenerian population, biggest complication was arrhythmias
- As safe as the lobectomy
- Complete node dissection with VATS procedure


#### Lung Sealant

- Indicated for parenchymal air leak due as a complication of lung surgery
- Prolonged chest tube drainage time increase hospital stay and complications
- Placed intraoperatively
- No complications after placement; reduced air leaks and hence, hospital stays


#### Clinical pathways

- Focuses on a systematic “way” of progressing a patient through the preoperative and postoperative period
- Reduces costs and length of stay
- Compare “own” hospital with those statewide
Clinical pathway – A systematic patient care approach

Long term follow-up for lung cancer is the following:
Chest x-rays every 6 months for two years, followed by yearly, until the patient reaches the 5 year mark.

Future Research for Lung Cancer

- Lung cancer screening
  - Mayo Lung Project
  - Spiral lung CT
    - National Lung Screening Trial (NLST)
    - Launched in 2002 - compare CT scans & CXR
  - Tumor markers
    - Current use is to assess tumor response
    - Future use is to detect cancers
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Open Session • 11 am–12:30 pm • W240 CD

Utilizing ASCO’s Quality Oncology Practice Initiative to Promote Excellence in Cancer Care

Session Description: The purpose of this session will be to describe the QOPI process and how it is crucial for oncology nurses to be part of the process. Oncology nurses provide care to patients and this initiative will assist in recognizing the value of the American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards and incorporating them into practice.

Target Audience: Oncology nurses interested in quality improvement as well as incorporating standards of care into their practice

Level of Content: Intermediate

Content Area: Education

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Coordinator/Speaker:
Ruth Gholz, RN, MS, AOCN®
Oncology Clinical Nurse Specialist
Cincinnati Veterans Affairs Medical Center
Cincinnati, OH
gholzcanty@fuse.net

Full Disclosure:
Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Speaker:
Lisa Schulmeister, RN, MN, CS, OCN®
Oncology Nursing Consultant
New Orleans, LA
LisaSchulmeister@hotmail.com

Full Disclosure:
ASCO. Independent contractor

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Identify five measures being reviewed for QOPI program.
2. Describe the nurses role in incorporating this initiative into their practice.
3. Describe the process for QOPI certification.

Bibliography:
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QOPI®
ASCO’s Quality Oncology Practice Initiative

- Practice-based quality assessment and improvement initiative
- Benefit of ASCO membership
- Goal: promote excellence in cancer care by helping practices create a culture of self-examination and improvement
- Process: measurement, review, feedback

Website: qopi.asco.org

Measures
Adapted from existing measures (some examples)
- the National Initiative on Cancer Care Quality (NICCQ)
- National Comprehensive Cancer Network (NCCN)
- American Society of Clinical Oncology (ASCO) Guidelines

Created or revised by Measures Work Group (new study findings incorporated, updated guidelines reviewed)

Created by consensus groups
- ASCO/ONS Chemotherapy Administration Safety Standards (2009)

*Measures focus on process and structure, not outcomes.

Timeline
Key Events in QOPI History

- 2002-2005 Pilot Phase: 23 practices, 37 measures, 6,000 charts
- 2007: modules (menu of measures) offered
- 2008: added measures. 194 practices, 81 measures, 18,509 charts
- June 2010: first 16 practices to achieve QOPI certification announced

QOPI
Evaluates five main areas in cancer care:
- documentation of care
- chemotherapy planning, administration, and treatment
- pain assessment and control
- smoking cessation
- psychosocial support

Also evaluates:
- end-of-life care
- symptom management in four common cancers (breast, colorectal, non-Hodgkin’s lymphoma and non-small cell lung cancer)

QOPI Health Plan Program
- Advocate Physician Partners
- Aetna
- Anthem Blue Cross and Blue Shield (CO, CT, KY, IN, ME, MO, NH, NV, OH, VA, WI)
- Blue Cross Blue Shield Association
- Blue Cross of California; BC Life & Health Insurance Company (California)
- Blue Cross and Blue Shield of Georgia, Inc; Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. (Georgia)
- Blue Cross Blue Shield of Michigan
- Empire BlueCross BlueShield (New York)
- Health Alliance Plan
- HMO Colorado and HMO Nevada
- Humana
- UNICARE Life and Health Insurance Company
- United Healthcare

QOPI Enrollment Process
- Practice registers online
- ASCO staff reviews/validates submission
- Practice training
- Data collection and entry
- Data submission to ASCO
- ASCO review
- Feedback sent to practice

NOTE: Some practices are randomly selected for an on-site audit by ASCO staff and contracted site reviewers (RNs).
Examples of Chemotherapy Administration Safety Standards

- Standard 1: Practice has policies, procedures, and/or guidelines for verification of training and continuing education of staff.
- Standard 2: Prior to prescribing a new chemotherapy regimen, all required chart documentation is completed and available to the prescriber.
- Standard 3: The practice maintains a policy for how informed consent is obtained and documented for chemotherapy.
- Standard 4: Chemotherapy order forms inclusively list all chemotherapy agents and their individual dosing parameters. All medications are listed by full generic names and follow Joint Commission standards for abbreviations.
- Standards 5-6: Chemotherapy orders are independently verified by two qualified individuals, and labeled immediately upon preparation.
- Standard 7: Practices in which intrathecal chemotherapy is administered maintain policies that specify specific handling requirements.
- Standard 8: At least 2 staff members verify patient’s identity and chemotherapy to be administered.
- Standard 9: Extravasation management procedures are defined.
- Standard 10: Practice maintains emergency protocols.
- Standard 11: Staff assess and document psychosocial concerns at each clinical visit.
- Standard 12: Staff assess and document the patient’s prescription and over-the-counter medications.
- Standard 13: Practice maintains a referral list for psychosocial services.
- Standard 14: Practice has a procedure for documenting missed appointments.
- Standard 15: Practice has process to provide care 24/7.
- Standard 16: Toxicity assessment data is available for planning subsequent treatments.
- Standard 17: Practice tracks cumulative doses of chemotherapy agents associated with a risk of cumulative toxicity.

QOPI Feedback

- Accuracy of data collection
- Summary report of measures
- Trend reports
- Narrative comments, unmet requirements, and recommendations

Face to Face Audit

- Presently approximately 25% of practices have been audited
- Goal of 100% audits
- In the audit process teaching occurs regarding rationale of standard/consider the auditor as guide not punisher. Goal is quality
- Each audit involves review by contracted RN
- Practice identifies nurses to be observed
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Role of Oncology Nurse in Audit
- Most reviews are completed with nurse administrator or educator available
- Policies and Procedures must be up to date
- The process is quality care driven—nurses are key to describing from patient arrival to office to completion of visit and follow up
- Individual nurses are interviewed but entire staff must have the same information
- Open communication and process

Day of Audit
- Observe at least two patients to receive chemotherapy
- Observe preparation of chemotherapy and delivery
- Review safety standards—consent, verification of orders, double check, two identifiers prior to administration
- Review of patient record

Review of safety standards
- The RN is key—does the RN know the standards, are they practiced and how are they documented?
- Example: has the ANC been calculated, what is process for ordering therapy, what is policy for extravasation, is it up to date?
- Chemotherapy administration/documentation—from A-Z are all of the ducks in a row?
- Example: no documentation of frequency of blood return when administering vesicant

Policy and Procedure Review for 17 Standards
- Do all staff have access?
- Are they up to date and consistent in satellite offices?
- Does pharmacy have a double check system?
- How are emergencies handled?
- What is educational preparation of nurse administering therapy?
- Is there a process for oral therapies?

Nurse Interview
- What qualifies nurse to administer therapy, and what is utilized for annual review?
- How is consent obtained, where would I find a copy?
- What are mandatory elements required for chemotherapy order to be complete—15 items identified, what percent can nurse report?
- How do you double check chemotherapy orders?

Audit Report
- Following the audit a report is completed
- Results identify any further activities that need to be completed prior to recommending certification
- Response to completion of requirement is due within 10 business days
- Also recommendations are made to enhance care provided
- Process is not punitive, but quality driven
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Recommendation Examples

- Needleless system
- Consent revisions
- Charting missed appointments
- Psychosocial support assessment
- Chairside patient identification
- Competency
- Emergency preparedness

Oncology Nurses are Leaders in Process

- Encourage practice to apply for review
- Be part of the practice planning team
- Begin QI process prior to review
- Establish journal club in support of evidence
- Identify processes for improvement
- Energize staff in the value of process
- Implement change as needed
- Team leader in review process
Dermatologic Toxicities of Targeted Cancer Therapies

Session Description: This didactic presentation will address dermatologic toxicities related to the use of molecularly targeted therapies in cancer treatment. Come explore the scope of the problem and the current evidence and best practice recommendations for managing these toxicities.

Target Audience: Nurses who care for patients receiving molecularly targeted cancer therapies

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Coordinator/Speaker:
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Full Disclosure:
Genentech. Non-CE speakers bureau
Speaker has indicated that he/she intends to discuss unapproved/investigational use of a commercial product/device during this open session.

Speaker:
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Clinical Nurse Specialist for Oncology
Interim LSU Public Hospital
New Orleans, LA
clemoi@lsuhsc.edu

Full Disclosure:
Amgen. Speakers bureau
Wyeth. Speakers bureau
Novartis. Speakers bureau
Pfizer. Speakers bureau
Abraxis. Speakers bureau
Speaker has indicated that he/she intends to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Identify molecularly targeted agents that cause dermatologic toxicities.
2. Analyze clinical trial data exploring strategies for managing dermatologic toxicities.
3. Describe current recommendations for the management of dermatologic toxicities.

Content Outline:
I. Scope of the problem
   A. Molecularly targeted cancer treatment agents that cause dermatologic toxicities
   B. Common dermatologic toxicities
   C. Data on practice patterns
II. Clinical trial data related to the management of dermatologic toxicities
   A. Jatoi
   B. Scope
   C. Mitchell (STEPP)
III. Current recommendations for the management of dermatologic toxicities

Bibliography:
ity associated with anti-epidermal growth factor receptor therapy: Survey results. *Oncology*, 72, 152–159.


Web Sites:
www.afinitor.com
www.erbix.com
www.gleevec.com
www.iressa.com
www.nexavar.com
www.sutent.com
www.tarceva.com
www.us.tasigna.com
www.torisel.com
www.tykerb.com
www.vectibix.com
www.votrient.com
Molecularly Targeted Cancer Agents Commonly Causing Dermatologic Toxicities

EGFR Inhibitors

- Erlotinib (Tarceva®) OSI Pharmaceutical, Inc., and Genentech Inc.
- Gefitinib (Iressa®) AstraZeneca UK Limited
- Cetuximab (Erbitux®) ImClone Systems Inc and Bristol-Myers Squibb Co
- Panitumumab (Vectibix®) Amgen Inc.
- Lapatinib (Tykerb®) GlaxoSmithKline
  - Inhibits HER2 as well as EGFR (dual targeted)


EGFR Inhibitors/Rash

- Skin rash: Due to EGFR inhibition in the skin; is an inflammatory reaction
- Not an allergic reaction
- Usually begins within the first days, week of treatment with erlotinib
- Peaks within 1–2 weeks
- Generally covers < 50% of body
- Usually affects: Scalp, head, neck, face, upper torso
- Usually mild or moderate (fades over time)


EGFR Inhibitors/Dermatologic Toxicities

- Paronychia
- Nail changes
- Dry skin
- Pruritus
- Hair changes
- Telangiectasias
- Ocular toxicities


Multi-targeted Kinases

- Sorafenib (Nexavar®) Bayer HealthCare Pharmaceuticals Inc
  - Rash, desquamation, hand-foot skin reaction, pruritus, dry skin, alopecia
- Sunitinib (Sutent®) Pfizer Inc
  - Rash, hand-foot skin reaction, pruritus, skin discoloration/yellow skin, dry skin, alopecia, hair color changes, erythema
- Imatinib (Gleevec®) Novartis Pharmaceuticals Corporation
  - Rash
- Nilotinib (Tasigna®) Novartis Pharmaceuticals Corporation
  - Rash, pruritus
- Pazopanib (Votrient®) GlaxoSmithKline
  - Hair and skin depigmentation


mTOR Inhibitors

- Temsirolimus (Torisel®) Wyeth Pharmaceuticals Inc.
  - Rash, pruritus, dry skin, nail disorders, acne
- Everolimus (Afinitor®) Novartis Pharmaceuticals Corp
  - Rash, pruritus, dry skin

http://www.afinitor.com; http://torisel.com
Current State of Practice
And Scope of Issues
Related to Dermatologic Toxicities of Targeted Therapies

State of Practice

- Currently, only consensus guidelines, best practices, and anecdotal recommendations available
- Only a few small studies and anecdotal case reports have been published

Scope of Issues

- An increasing amount of molecularly targeted cancer agents are approved for use in a variety of cancers
  - Lung cancer, renal cell, head and neck, breast, pancreatic, colorectal, hepatocellular, GIST, hematologic malignancies
- Many of these agents have some type of dermatologic toxicity as a common adverse event

How Well Are We Doing With Dermatologic Toxicity Management?
Survey of Physicians in the Clinical Setting

- 76% have reported holding treatment with EGFR inhibitors due to skin toxicity
- 32% have reported discontinuing treatment with EGFR inhibitors due to skin toxicity

How Well Are We Doing With Dermatologic Toxicity Management?

- 100% of pts treated with EGFR inhibitors longer than 6 mos. had some type of cutaneous or dermatologic toxicity
- 37% of pts needed dose modifications

SERIES Clinic—Skin and Eye Reactions to Inhibitors of EGFR and Kinases

- Clinic designed to care for patients on EGFR inhibitors and other kinases that exhibit dermatologic adverse events
- Good reminder to involve dermatology as needed to deal with dermatologic side effects from targeted agents
- Effort to build evidence-based guidelines to prevent and treat dermatologic adverse events

Clinical Trials Investigating EGFR Inhibitor-Associated Rash

- Prophylactic oral minocycline and topical tazarotene
- Tetracycline to prevent EGFR inhibitor-induced rashes
- Skin Toxicity Evaluation Protocol with panitumumab (STEPP)

Oral Minocycline vs.. Placebo with and without Topical Tazarotene

- 48 patients with metastatic colorectal cancer (mCRC)
- Randomized to oral minocycline 100mg daily (n=24) or placebo (n=24) in conjunction with tazarotene 0.05% cream to one side of the face
- Study treatment started on same day as 1st day of cetuximab therapy and continued for 8 weeks

Results of Oral Minocycline vs.. Placebo with and without Tazarotene

- Differences between lesion counts and severity of itching at week 4 decreased by week 8 between tx and placebo arms.
- Tazarotene was associated with considerable irritation causing 1/3 of patients to discontinue treatment.
Final Verdict on Oral Minocycline vs. Placebo with and without Tazarotene

• Prophylactic minocycline may decrease rash severity during initial treatment with cetuximab but tazarotene is not recommended.

Results of Tetracycline vs. Placebo To Prevent EGFR Rashes

<table>
<thead>
<tr>
<th></th>
<th>Incidence of Rash Weeks 1-4</th>
<th>Incidence of Rash Weeks 5-8</th>
<th>Rate of Grade 2 Rash by Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline</td>
<td>70% (n=16)</td>
<td>87% (n=13)</td>
<td>17% (n=4)</td>
</tr>
<tr>
<td>Placebo</td>
<td>76% (n=22)</td>
<td>84% (n=16)</td>
<td>55% (n=16)</td>
</tr>
</tbody>
</table>

• Tetracycline arm - 30 patients with at least some data, 15 patients with 8 weeks of data
• Placebo arm – 29 patients with at least some data, 12 patients with 8 weeks of data

Skin Toxicity Evaluation Protocol with Panitumumab (STEPP)

• Examine the differences between a prophylactic vs. a reactive approach to the management of skin toxicities associated with EGFR inhibitors in the treatment of patients with mCRC (n=95)

Skin Toxicity Evaluation Protocol with Panitumumab (STEPP)

• Primary endpoint – estimate the differences in the incidence of ≥ grade 2 skin toxicities between the prophylactic group and the reactive group over a six-week treatment period
• Secondary endpoints
  – Assess incidence of any type skin toxicity over 6 week treatment period
  – Assess efficacy and safety of panitumumab given in conjunction with 2nd line irinotecan-based therapy

Tetracycline vs. Placebo To Prevent EGFR Rashes

• Compare the incidence of rash between the tetracycline study arm and placebo
• 61 patients receiving EGFR therapy initiated 7 days before or after enrolling on trial
• Tetracycline 500 mg po bid for 28 days vs. placebo
• Evaluate weekly for compliance, rash, and quality of life over 4 weeks of study and for an additional 4 weeks

Final Verdict on Tetracycline vs. Placebo To Prevent EGFR Rashes

• Tetracycline did not prevent the EGFR rash but did seem to reduce the severity of the rash and improve quality of life
Skin Toxicity Evaluation Protocol with Panitumumab (STEPP)

- 48 assigned to prophylactic treatment group
  - Daily moisturizer daily in am
  - Sunscreen before going outdoors
  - Topical steroid (1% hydrocortisone cream) daily at hs
  - Doxycycline 100mg po bid
  - Educated on all interventions
- 47 in reactive treatment group
  - Moisturizer/sunscreen optional but pts were not specifically instructed to do so.
  - Treatment per clinician judgment upon emergence of skin toxicity

Results of the Skin Toxicity Evaluation Protocol with Panitumumab (STEPP)

Incidence of Grade 2 or Higher Skin Toxicities of Interest

<table>
<thead>
<tr>
<th></th>
<th>Incidence of Grade 2 Skin Toxicity</th>
<th>Incidence of Grade 2 Skin Toxicity</th>
<th>Incidence of Grade 3 Skin Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prophylactic Treatment</td>
<td>29%</td>
<td>23%</td>
<td>6%</td>
</tr>
<tr>
<td>Reactive Treatment</td>
<td>62%</td>
<td>40%</td>
<td>21%</td>
</tr>
</tbody>
</table>

Final Verdict on Skin Toxicity Evaluation Protocol with Panitumumab (STEPP)

- Prophylactic treatment
  - Resulted in 29% ≥ Grade 2 skin toxicities compared to 62% ≥ Grade 2 skin toxicities in the reactive treatment group
  - Well tolerated
  - Was not associated with decreased antitumor efficacy
  - Resulted in less QOL impairments

Current Recommendations for the Management of Dermatologic Toxicities

Skin Toxicity Evaluation Protocol with Panitumumab (STEPP)

- Patients monitored weekly for compliance, skin toxicity, and QOL
- Response to treatment was evaluated using Response Evaluation Criteria in Solid Tumors (RECIST)
- Skin toxicities of interest included pruritus, acneiform dermatitis, skin desquamation, exfoliative dermatitis, paronychia, nail disorder, skin fissures, skin laceration, pruritic rash, pustular rash, skin infection, skin ulceration and local infection.

Results of the Skin Toxicity Evaluation Protocol with Panitumumab (STEPP)

- Antitumor efficacy – similar in both prophylactic and reactive groups
- Safety – similar in both groups; adverse events reported less frequently in the prophylactic group compared to the reactive group include
  - Dermatitis acneiform (77% vs. 85%)
  - Pustular rash (27% vs. 40%)
  - Paronychia (17% vs. 36%)
- QOL – less impaired in the prophylactic group

Upon What do We Base Our Practice?

- Absence of any Level 1 evidence to support standards of care for the prevention and management of dermatologic toxicities associated with targeted therapies
- Current care is based on anecdotal information, consensus statements, guidelines, recommendations and best practices
- Further clinical trials are needed to create a body of evidence that is robust enough to serve as the basis for standards of care

A Word about Assessment

- The foundation of care starts with a thorough and accurate baseline assessment with reassessment at logical intervals based on side effect profile
- Wide variety of dermal manifestations associated with targeted therapies making characterization and documentation challenging

Common Toxicity Criteria for Adverse Events (CTCAE) v4.03

- National Institutes of Health/National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE v4.03) published June 14, 2010 is comprehensive, detailed and specific and fosters a standardized means for categorizing and documenting toxicities

NCI CTCAE v4.03

- Within the System Organ Class (SOC) of Skin and Subcutaneous tissue disorders, there are 34 categories of adverse events (AEs) listed including
  - Alopecia
  - Bullous dermatitis
  - Dry skin
  - Hypertrichosis
  - Nail discoloration/Nail loss/ Nail ridging
  - Palmar-plantar erythrodyssesthesia syndrome
  - Pruritus
  - Rash acneiform/Rash maculo-papular
  - Other, specify

Published Guidelines

- Canadian Recommendations
- NCCN Task Force Report

Grading ranges from 1-5 based on severity of AE

- 1 – Mild – observation only, intervention not indicated
- 2 – Moderate – limiting age appropriate instrumental ADLs, minimal intervention warranted
- 3 – Severe – medically significant, disabling, limiting self-care ADLs, hospitalization indicated
- 4 – Life threatening – urgent intervention indicate
- 5 – Death related to AE
Canadian Recommendations

- For management of skin rash during treatment with EGFR inhibiting monoclonal antibodies for GI malignancies
- Preemptive strategies
- Treatment recommendations


Canadian Recommendations
Pre-Emptive Rash Strategies

- Protect from sun exposure
- Avoid activities and products that dry skin i.e. alcohol based products, hot showers, OTC acne meds
- Moisturize frequently with emollient creams rather than greasy ointments
- Oatmeal baths can be very soothing
- Choose creams over lotions and keep cool to increase comfort


Canadian Recommendations
Rash Treatment Recommendations

- Grade 1 – Mild pustular or papular rash with minimal symptoms
  - Topical clindamycin 2% plus hydrocortisone 1% lotion to affected area twice daily until resolved


Canadian Recommendations
Rash Treatment Recommendations

- Grade 2 – Moderate pustular or papular rash or erythema associated with moderate symptoms
  - Topical clindamycin 2% plus hydrocortisone 1% lotion to affected area twice daily until improvement by 1 grade
  - Minocycline 100mg twice daily or doxycycline 100mg once-twice daily for 4 weeks or until rash becomes asymptomatic
  - If scalp lesions are present, use topical clindamycin 2% lotion plus triamcinolone acetamide 0.1% in equal parts of propylene glycol and water until lesions resolve


Canadian Recommendations
Rash Treatment Recommendations

- Grade 3 – rash so severe, extensive, and/or painful that it interferes with daily life
  - If on panitumumab, withhold until ≤ Grade 2
  - If on cetuximab, withhold treatment for 1 week
  - Recommendations as per Grade 2 except for scalp lesions, use clindamycin powder 2% in amcinonide lotion twice daily
  - Improvement?
    - Yes → Resume treatment as per PI
    - No → Discontinue monoclonal antibody therapy


Canadian Recommendations:
When to Refer to Dermatology

- If no improvement after 1-2 weeks of treatment
- If necrosis, blistering, or petechial lesions develop
- If multiple dermalologic issues arise, i.e. hair, nail and skin issues
- If dermal toxicity is unusual in appearance or distribution

NCCN Task Force Report

- Addresses management of toxicities associated with EGFR inhibitors
  - Prophylactic approaches to skin toxicity
  - Treatment of skin toxicity
  - Treatment of xerosis and fissures
  - Pruritus
  - Paronychia
  - Skin lesions in the hair
  - Ocular toxicities


NCCN Task Force Report: Prophylactic Approaches to Skin Toxicity

- Oral tetracycline (minocycline 100 mg po daily or tetracycline 500mg po bid) doesn’t prevent rash but may help to decrease rash severity
- Oral doxycycline 100mg po bid along with daily moisturizer, sunscreen and 1% topical hydrocortisone decreased the incidence of skin toxicities
- Topical steroids won’t prevent but may decrease severity of radiation dermatitis
- Consider using sunscreen, especially non-alcohol based agents and physical blocking agents like zinc oxide or titanium oxide with UVA and UVB protection and an SPF of 30.


NCCN Task Force Report: Treatment of Skin Toxicity

- Consider topical agents such as clindamycin or erythromycin for treating papulopustular rashes
- Consider low-strength topical steroids for facial rashes or medium-strength topical steroid for rashes on the body if the patient is symptomatic
- Use petrolatum jelly, ammonium lactate or dilute hydrogen peroxide (not in areas with hair) to remove yellow crusty debris from dried rash


NCCN Task Force Report: Treatment of Skin Toxicity

- If superinfection suspected, culture suspicious lesions for organism and sensitivity
- Prevent staph aureus colonization in nose by using long-term prophylactic mupirocin ointment
- Cautiously consider brief dosing interruptions of EGFR inhibiting agents
- For telangiectasias, consider pulsed dye laser and intense pulsed light therapy to decrease redness and vessel prominence


NCCN Task Force Report: Treatment of Skin Toxicity

- Systemic therapy may be appropriate for severe, infected or refractory/recurrent rashes despite therapy
- Consider oral antibiotics (tetracycline, doxycycline, minocycline) and treat as per standard of care for positive cultures.
- There may be a very limited role for systemic steroids or oral retinoids


NCCN Task Force Report: Treatment of Xerosis and Fissures

- For xerosis
  - Avoid hot showers, alcohol-based lotions, and antibacterial soaps
  - Apply thick emollients i.e. zinc oxide (30%), petroleum jelly, Aquaphor, Aveeno, Bag Balm, Eucerin, Cetaphil or Cutemol

- For fissures
  - Consider silver nitrate, cyanoacrylate aluminum chloride solution or zinc oxide (20%-30%)
  - To prevent infection with fissures use 1 quarter cup of bleach in 3 gallons of water and soak for 10 minutes/day

IOL

NCCN Task Force Report: Pruritus

- ↓ use of soap
- Avoid alcohol-based skin products
- Maximize use of emollient moisturizers and topical antipruritics (Aveeno, Anti Itch, Sarna Ultra)
- Consider fluocinonide 0.05%, clobetasol foam or steroid shampoo for itchy scalp
- Consider cold compresses and sedating antihistamines (i.e. diphenhydramine) at hs


NCCN Task Force Report: Pruritus

- Pregabalin (100mg po bid) may be helpful
- Monitor for superinfection due to scratching
- Clinical trials underway investigating topical lidocaine, fusidic acid with erythromycin, and 1% metronidazole cream


NCCN Task Force Report: Paronychia

- Avoid frequent immersion in water, harsh chemicals, and trauma
- Wear well fitting shoes
- Assess for peripheral neuropathy as a contributing factor
- Apply petroleum jelly frequently to periungual tissue around nail bed
- Use bleach soaks or white vinegar soaks for comfort and to prevent infection
- Silver nitrate can be used especially if bleeding is a problem
- Nails can be removed.
- Culture suspected infected areas and treat accordingly
- If recurrent infections occur, patient should discard old slippers and shoes


NCCN Task Force Report: Skin Lesions in the Hair

- Treat skin lesions in hairy areas to avoid permanent hair loss
- Use 0.2% hydrocortisone valerate, steroid shampoos (i.e. fluocinolone acetonide) or steroid lotions such as clobetasol or betamethasone dipropionate


NCCN Task Force Report: Ocular Toxicities

- Toxicities can include
  - Dry eyes - treated with artificial tears. If unsuccessful, refer to an ophthalmologist.
  - Blepharitis - managed with warm compresses, careful eye hygiene, and anti-inflammatory eye ointment along with a topical steroid
  - Misdirected eyelashes which can turn in and cause microabrasions. Long/misdirected eyelashes should be clipped either by an ophthalmologist or by the patient or a care giver as an alternative. (keep eye shut during clipping procedure)


Hand-Foot Skin Reaction (HFSR) Associated with Sorafenib and Sunitinib

- An international, interdisciplinary panel gathered in Jan 2008 to discuss best practice related to the management of HFSR
- HFSR is significant as a QOL issue and as it may cause dose adjustments/delays that could potentially impact clinical response.
- Develops in first 2-3 weeks of therapy

Hand-Foot Skin Reaction (HFSR) Associated with Sorafenib and Sunitinib
- Initial lesions are tender and scaling, located on finger tips, toes, heels and over areas of flexion.
- Develop into thickened tender areas that are painful and can affect weight bearing and function

Managing HFSR Associated with Sorafenib and Sunitinib
- Prior to initiation of therapy
  - Assess skin
  - Pedicure
  - Orthotist evaluation
  - Instruct pt to wear thick cotton gloves and/or socks, avoid hot water, avoid constrictive footwear, avoid excess friction

Managing HFSR Associated with Sorafenib and Sunitinib
- If symptoms worsen, or if patient presents initially with Grade 2 toxicity, dose reduce to 50% for 7-28 days and add clobetasol 0.05% ointment, 2% lidocaine, codeine, and pregabalin for pain
- If symptoms continue to worsen, or if patient presents initially with Grade 3 toxicities, interrupt treatment for 7 days and until resolution to grade 0-1

NCI CTCAE to Assess HFSR Associated with Sorafenib and Sunitinib
- Thorough and accurate assessment
- Grade 1 — minimal skin changes i.e. erythema, edema, or hyperkeratosis, without pain
- Grade 2 — Skin changes i.e. peeling, blistering, bleeding, edema or hyperkeratosis with pain
- Grade 3 - Severe skin changes i.e. peeling, blistering, bleeding, edema or hyperkeratosis with pain and limiting self care ADL

Managing HFSR Associated with Sorafenib and Sunitinib
- If patient develops grade 1 symptoms within first month
  - Maintain current dose of sorafenib/sunitinib
  - Continue to avoid hot water, use emollient creams, 20%-40% urea and wear thick cotton gloves and/or socks
  - Re-evaluate in 2 weeks

Managing HFSR Associated with Sorafenib and Sunitinib
- Following guidelines for resuming therapy and for making subsequent dose adjustments based on pt’s clinical response, ability to tolerate toxicities, and whether toxicities are occurring for the first, second third or fourth time
Summary

- Targeted therapies are increasingly being incorporated into the treatments of patients with cancer
- There are significant dermatologic toxicities associated with targeted therapies
- Clinical trials aimed at identifying the best approaches to prevention and management of these toxicities have been limited to date
- Currently strategies to prevent and/or manage these toxicities are based on anecdotal information, consensus statements, guidelines, recommendations and best practices
- Nurses are especially well positioned to conduct the critical assessments and provide the essential patient education that can help patients to minimize toxicities, maximize QOL and remain maximally adherent to their prescribed therapeutic regimen.
Session Description: Oncology nurses are required to manage patient care and education as well as the emotional impact of cancer on patients and families. They also experience frequent patient deaths. These demands can be daunting; without self care and an outlet for managing these issues, oncology nurses can face a multitude of challenges that may seem overwhelming. This session will educate you about the impact of suppressed emotions on physical and mental health and how journaling and expressive writing can facilitate the expression of emotions to promote improved well-being for you and your patients.

Target Audience: Oncology nurses or other healthcare professionals

Level of Content: Introductory

Content Area: General

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Coordinator/Speaker:
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Full Disclosure:
Nothing to Disclose

Speaker:
Kathleen Adams, LPC
Founder and Director
Center for Journal Therapy
Wheat Ridge, CO
kadamslpc@gmail.com

Full Disclosure:
Nothing to Disclose

Objectives:
By the end of this presentation, participants will be able to:
1. Discuss the impact of suppressed emotions on physical and mental health.
2. Describe the benefits of expressive writing.
3. Identify journaling techniques or resources that can be used personally or with patients to promote selfcare.

Content Outline:
I. Define and discuss the difference between journaling and expressive writing.
   A. Journaling definition and examples of journaling
   B. Expressive writing definition and example of expressive writing
      1. Review study 1 supporting the benefits of expressive writing.
      2. Review study 2 supporting the benefits of expressive writing.
         a. Discuss the impact of suppressed emotions on physical and mental health.
         b. Give examples of the benefits of expressive writing based on personal and clinical experiences.
II. Prepare participants to begin writing practice.
   A. How to get started and journaling 101
   B. Participate in a guided journaling activity.
      1. Reflection and interactive group discussion
      2. Discuss specific journaling techniques.
         a. Give examples of how these techniques can be useful personally to promote selfcare and with patients and their caregivers.
         b. Review journaling resources available for oncology providers and patients to start and maintain a regular journaling practice.

Bibliography:

Eight Ways to Ground Your Writing

1. **Permission.** Forget everything you think you “should” do if you’re going to write a journal. You don’t have to write every day, or in complete sentences, or in properly spelled and punctuated language. Your handwriting can be messy, your thoughts unclear, and you can quit whenever you want. Lighten up! Give yourself permission to write in whatever way best fits your mood, style or momentary inclination.
   
   *What if I gave myself permission to write without limits?*

2. **Balance.** Journals without balance are like bicycles with leaky tires: Any momentum that is built up is quickly depleted. Remedy if your writing is out of balance: Consciously seek the opposite polarity. If you never write feelings, start naming the “feeling du jour” and jotting a few thoughts and observations about it. If you always write about high drama, try capturing a moment of serenity. If you notice your writing is filled with complaints and frustrations, stop and make a list of things you are grateful for.
   
   *Where might I notice that I am out of balance?*

3. **Privacy.** Respect privacy and boundaries – your own, and those of others. Leave the first page of any new journal or notebook blank, so that there is a discreet barrier between your private thoughts and someone else’s eyes. Protect your privacy by keeping your journal in its own special place, whether that is a nightstand drawer, a briefcase, a locked file cabinet or a password-protected computer program. And extend these same privacy privileges to others. Don’t read anyone else’s journal without express permission.
   
   *Do I have privacy concerns? If so, how might I proactively manage them?*

4. **Honesty.** Don’t be afraid of your own truth. The more honestly and deeply you are able to write, the more healing benefit you will receive.
   
   *How honest can I be with myself? Am I willing to tell myself the truth?*

5. **Silence.** Honor journal silence. It can be a valuable messenger. It does not automatically mean you are “failing” at keeping a journal if it falls silent for days, weeks or even months at a time. Know that you can always come back and pick up right where you left off.
   
   *Have I ever quit writing a journal and decided this meant that I wasn’t doing it right?*

6. **Attention.** Pay attention to the subtle differences that begin to emerge and reveal themselves as you write your healing journey. Noting them allows you to find connections and bridges between your inner and outer worlds.
   
   *How much attention do I pay to my inner experience? How can I extend this attention?*

7. **Structure.** When you write, you are moving thoughts, feelings and energy out of your mind and body into a neutral, receptive place where they are safely stored. This can feel unpredictable, unboundaried and even frightening without some simple foundations and structures. Set limits and stay with them. Write for only ten minutes, or stop when you feel fatigued, or stand up and stretch in the middle of a write.
   
   *Where in my life do I appreciate structure and form? How can I transfer these habits or techniques to the journal experience?*

8. **Reflection.** Before you begin to write, develop the habit of closing your eyes, taking a few deep breaths, and turning your attention inward. And at the end of each writing session, harvest the learning by re-reading what you’ve written and reflect on what you notice, how you feel, what action steps you might take. This takes just a few extra minutes and provides valuable pathways.
   
   *What am I noticing about myself as I respond to these questions?*

Saturday, November 13

Journaling

Definition:

- A record of dated entries containing one’s experiences, written consistently, but not necessarily daily
- Journals contain: reports of daily events, recorded feelings, dreams, dialogues, fantasies, sketches, quotes, photographs, letters, cards, anything the writer wants to record

Expressive Writing (Emotional Release Writing)

Definition:

A term developed by social science researcher Dr. James W. Pennebaker to describe a series of structured writing processes designed to explore one’s deepest thoughts and feelings about stressful life experiences.

Journal Therapy

Definition:

The purposeful and intentional use of (life-based) writing to further treatment goals.

(Adams, 1999)

Effect of Suppressed Emotions on Physical and Mental Health

Commonly acknowledged symptoms of emotional suppression include:

- Headaches
- Insomnia
- Irritability
- Illness
- Fatigue
- Depression
- Substance Abuse

Burnout, Stress & Compassion Fatigue

- Stress: A mental or physical tension. (Webster’s Dictionary)
- Burnout: Extended exposure to physical or interpersonal stressors causing withdrawal, fatigue and inefficiency.
- Compassion Fatigue: Secondary traumatic stress.
  - A consequence of working with people who are experiencing extreme stress, illness or trauma.
  - A severe fatigue which occurs due to caring for patients who are suffering.

(Krohmer, Patraw, Marsalek, 2000)

Journaling in Health Care

- JAMA 4/99 study: 112 patients with rheumatoid arthritis or asthma wrote 20 minutes for three consecutive days. Two thirds wrote about a very stressful life event; one third wrote about plans for the day.
- After 4 months 47.1% of patients in the intense writing group showed substantial improvement in symptoms (i.e. improved lung function and decreased pain) vs. 9% in control group.

(Smyth et al., 1999)
**The Power of Words for Cancer Patients**

- Researchers from Lombardi Comprehensive Cancer Center in Washington, DC studied the effects of expressive writing on 71 adults with Leukemia & Lymphoma

- Each participant was asked to journal their thoughts while waiting for their oncology appt.

- Prompt used: “How has cancer changed you and how do you feel about those changes?”

**Results**

- 49% of the patients reported the exercise changed their thinking about their illness immediately after completing the exercise

- 53% reported changes in their thoughts about their illness at the 3 week follow-up

- Reports of changes in thoughts about illness immediately post writing were significantly associated with better quality of life at follow-up, controlling for baseline quality of life (Morgan, 2008)

**Benefits of expressive writing**

- Journaling has been shown to aid in the physiologic process of assimilating and sorting new information

- Finding meaning in a difficult situation has been linked with a positive outcome in terms of coping

- Some researchers have demonstrated a reduction in anxiety and depressive symptoms, enhanced immune function, lowering blood pressure, and increased cognitive function

**There are NO Rules!**

- Speling doszn’t matter

- Grammar don’t matter

- Writing every day doesn’t matter

- Whether you got good grades in English class 20 years ago doesn’t matter

- Writing by hand or on a computer doesn’t matter

- If you can THINK it – you can INK it!

- PS – Do date every entry!

**It’s Easy to W.R.I.T.E.!**

**Sentence Stems** – finish a sentence starter one or more ways

- Right now I feel....

- The most important thing to do....

- If I could, I would stop....

- I feel healthiest when....

- My most reliable self-care involves....

(Words for Cancer Patients)

(Adams, 2010)
Patient Sentence Stems

The best moment of my day is ______
I wish I could __________
I felt great the last time __________
I often dream about __________
I am worried about __________
I think I’m avoiding __________
I feel most at peace when __________
Today I want to __________

Technique: Unsent Letter

Unsent Letter - write a letter expressing thoughts, feelings...to a person or situation and do not send

• Write an Unsent Letter to a patient, family member or colleague with whom you have unfinished business.
• Write an Unsent Letter to a mentor or teacher whose role modeling contributed to your professional growth.
• Write an Unsent Letter to an addiction or unhealthy behavior.
• Write an Unsent Letter to your inner child or inner teen.
• Write an Unsent Letter of gratitude to someone who has been kind to you. Consider sending this one!

Techniques: Dialogue

Dialogue - have a conversation where you write both parts. (talk with your body, a situation, a person in your life, an event...)

• Dialogue with a challenging patient.
• Dialogue with a patient you admire.
• Dialogue with cancer.
• Dialogue with your Inner Wisdom.
• Dialogue with your Healthy Self.

Technique: Five Minute Sprint

Five Minute Sprint - Set your timer for five minutes. Choose a topic and write as fast as you can without lifting the pen from paper. Stop when time is up.

• Write for 5 minutes about a moment of beauty.
• Write for 5 minutes recapping your day.
• Write for 5 minutes about something that is stressful to you.
• Write for 5 minutes about the Best Thing/Worst Thing about a situation.
• Write for 5 minutes about what you need right now.

Technique: Perspectives

Perspectives - Alter point of view by writing in a different voice, or by jumping ahead in time.

• Think of someone with whom you’re having conflict. Write in the “I” voice from that person’s perspective.
• Write as if you were one of your patients struggling with a cancer diagnosis.
• Imagine yourself on the other side of a block or stuck place. Write from that perspective.
• Write in the 3rd person (he/she) voice about a sticky situation of your own.
• If you’re having trouble making a decision, write as if you are living with Choice A. Then repeat for Choice B (etc.)

Resources

My Healing Companion: A Journal for the Healthcare Provider — Kirkhart, Putrino, Sliwoski
Journal to the Self — Kathleen Adams
The Way of the Journal — Kathleen Adams
The Write Way to Wellness — Kathleen Adams
Writing to Heal — James Pennebaker
The Writing Cure — Lepore, Smyth
Cancer as a Family Diagnosis

Session Description: This presentation will cover family issues that arise in oncology treatment. Speakers will use case studies and give examples to illustrate ways of helping families cope. You’ll also receive tips for caregivers and information about family/caregiver resources.

Target Audience: Oncology nurses and advanced practice nurses

Level of Content: Introductory

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Coordinator/Speaker:
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Full Disclosure: Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Describe basic family theory, assessment, and supportive interventions.
2. Explain special issues with young cancer survivors and families.
3. Identify how the cancer diagnosis affects the patient as well as the partner and family.

Content Outline:
I. Family and caregiver tips and issues
   A. Basic family communication patterns
   B. Family issues from survivor and caregiver perspectives
      1. Young cancer survivor and family issues
      2. Recurrent cancer survivor and family issues
         a. Dual roles—professional and survivor
         b. Case examples of families and interventions in clinical practice

II. Family theory
   A. Helping to alleviate and support caregiver strain and burden—ONS PEP information
   B. Resources to assist families and survivors
      1. Wellness community and Gilda’s Club
      2. Web sites for family communication
         a. Caring bridges, my lifeline
         b. Caring pages—with two-minute video

Bibliography:
LovedOneWithCancer/index


**Web Site:**
Post-traumatic Stress Disorder: www.mental-health-today.com/ptsd/dsm.htm
Family Theory & Cancer

- **Communication**: The ability to keep family issues in perspective while also attempting to understand other member’s viewpoint. In unhealthy families there may be secrets, assumptions, or misinterpretations.

- **Structure**: Organized, predictable patterns of family behavior and interaction. Structure includes roles, rules, and boundaries governing the family system. Healthy families will adjust and cope with the demands of the cancer crisis; unhealthy families will become stuck and the family will have difficulty functioning.

Veach, et al, 2002

Family Theory & Cancer

- **Cohesion**: Emotional connection with one another. Health is determined by the ability to be both connected and independent as opposed to enmeshed or disengaged.

- **Adaptability/Flexibility**: Degree of appropriate and necessary change in the family’s leadership, discipline, control, and ability to negotiate to accommodate to the needs of the cancer experience. Unhealthy families are “rigid”, they resist change and are unable to flex roles so they may become chaotic.

Veach, et al, 2002

Dealing with Family Dysfunction

Family dysfunction is difficult to change, we recognize destructive patterns, set limits as needed, and make referrals for assistance with difficult family issues

Referrals for assistance with family issues:
- Psychiatric APRN’s, Social Work, Psychologist, Chaplain of family’s choice, Primary Nurses

The Wellness Community or local family support agencies: [http://www.thewellnesscommunity.org/](http://www.thewellnesscommunity.org/)

Fiker & Henry, 2008

10 Tips for Cancer Caregivers

- **Relieve Your Mind, Recharge Your Body**
  Try simple activities like taking a walk around the block or closing your eyes for 10 minutes in a comfortable chair. Taking time for yourself is not selfish – it’s necessary. Time spent recharging your mind/body will allow you to avoid depression or burnout. Seek ways to rejuvenate your spirit/physical, meditation, reading an uplifting book, finding your own ways to meet this need.

- **Take Comfort in Others**
  You are still allowed a life of your own. Take part in community or school activities and time with friends if possible; it is helpful to have someone to turn to as you care for your loved one.

- **Plan for the Future**
  Try to schedule fun activities on days when your loved one is not feeling the side effects of treatment. Planning for a future in the long term can be increasingly stressful for a caregiver when sometimes, two futures are being planned – one based on survival and the other based on the possibility of losing your loved one.

The Wellness Community, 2010

10 Tips for Cancer Caregivers

- **Accept a Helping Hand**
  Learning to let go and to say “yes!” will ease your anxiety and lift your spirits. Helpful to keep a list of all caregiving tasks, small or large. That way, when someone asks “Is there anything I can do?” you are able to offer them specific choices.

- **Be Mindful of YOUR Health**
  Be sure to tend to any physical ailments of your own that arise – this includes scheduling regular checkups and screenings. And just like your mother told you: eat well and get enough sleep.

- **Consider Stress-Management Techniques**
  Examples include meditation, guided imagery, and healing therapies that tap your creative outlets such as art, music or dance. Wellness Communities and Guild’s Clubs across the country offer mind-body therapy and guided imagery programs on a monthly basis.

The Wellness Community, 2010
Saturday, November 13

10 Tips for Cancer Caregivers

- Do What You Can, Admit What You Can’t
  Even seasoned caregivers find themselves caught up in the whirlwind of appointments, daily errands and medicine doses. No one can do everything. It’s O.K. to acknowledge your limits. Come to terms with feeling overwhelmed (it will happen) and resolve to be firm when deciding what you can and cannot handle on your own. Your loved one needs you. You cannot do this alone. Together, you can get through.

- NURSES are CAREGIVERS too!!! What are you doing to maintain or improve your physical, mental, and spiritual health? How do you deal with work related stress, loss, and other emotions? How do you develop a healthy balance between work, family, leisure, scholarly and professional activities?

The Wellness Community, 2010

Family Coping Cases

- Jenny
- Forbes Family [www.kristeneve.org](http://www.kristeneve.org)
- Wilson Family “Cast Away with Cancer”
- Non-Acceptance When Death is Imminent
- Art Therapy Interventions
  - Handprint Molds/Tracing
  - Oncology Art on Canvas Events-Nick & Family
  - Conversation-special interests, photographs
  - Relate to your patients and families holistically-talk about non-cancer interests, (as appropriate-need to have trust/timing)


What do Oncology Nurses do to recognize and treat Cancer as a Family Diagnosis?

- Be yourself-therapeutic/caring presence
- “Staff who were “more business-like” were not as helpful as those with genuine warmth”
- Share positive stories with patients & families, uplifting comments, mainly just listen
- Assess when a patient/family member needs to talk or needs time alone, don’t pry
- Look at their photos, share special interests

Feiler & Henry, 2008

Caregiver Strain & Burden

- Caregivers also experience significant distress and deserve attention from oncology nurses.
- **Caregiver strain:** perceived difficulty in performing the caregiver role
- **Caregiver burden:** alterations in caregivers’ emotional & physical health that can occur when care demands outweigh available resources

Eaton & Tipton, 2009

Websites for Families

Care Pages websites are free patient blogs that connect friends and family during a health challenge

- [www.carepages.com](http://www.carepages.com)

Interventions to Address Caregiver Strain & Burden

- **Recommended:** (CBT)-Cognitive Behavioral Therapy - referral to appropriate internal or external psychotherapist
- **Likely to be Effective:** Supportive Interventions-teach caregivers to monitor their own feelings, challenge negative thoughts that increase emotional distress, help with problem solving-focus on time management and overload prevention, help them engage in pleasant activities and positive experiences, & include time outside the “cancer world”

Eaton & Tipton, 2009

Oncology Nursing Society Institutes of Learning
November 12–14, 2010

139
Saturday, November 13

My story

21 years old diagnosed with HL while completing nursing school many miles away from my parents...

Adolescents/young adults with cancer

- Social support helps decrease stress and enhance coping in adolescents
- Higher levels of perceived support =
  - fewer health complaints
  - lower depression levels
  - higher positive health practices
  - higher optimism and self esteem
  - fewer behavioral problems and better adjustment to illness.


i2y.com “Stupid Cancer”

- Taken from i2y.com: STUPID CANCER 101
- Approximately 70,000 Americans between 15-40 are diagnosed with some form of cancer every year. 10,000 will not make it to another year.
- Quote from the website: “Unlike every other age group, there has been little to no improvement in both the quality of life and the 5-year survival of young adults in 30 years.” This is not OK. Young adults also face unique issues that are not currently being met by the current continuum of care including fertility, isolation, insurance, dating/sexuality, financial assistance, education, employment and age-appropriate peer support such as social networking, both off and online.”

OMGI CANCER SUMMIT FOR YOUNG ADULTS

OMGI is an international oncology conference with social networking for patients, survivors as well as providers who are in their late teens, 20s and 30s. This year was their 3rd annual. This came about in 2007 through a partnership between (i2y) and the Leukemia & Lymphoma Society.

i2y.com

Adolescents with cancer

- Small sample sizes in most research of adolescents and young adults.
- Highest need for friends during initial phase of treatment. Family provided greatest support as friends less available over time. (10 patients)
- Establishing and maintaining relationships with friends and classmates seen as most important (only 5 patients evaluated)


Adolescents with cancer

- Ages 12-17: peers were reported increasingly more important (12 patients)
- 32 patients ages 8-16: earlier and more information received about dx had greater availability of courses of support which = less anxiety, less depression, and less negative self esteem. Also preferred information from another young person with cancer.
- High uncertainty and low social support in adolescent ca survivors had greatest psychological distress.
- Ages 17-18 identified friends as their primary emotional support and satisfied with amount of emotional support from family (45 adolescents)
- 48 survivors compared with 40 healthy adolescents – strong positive relationship between self image and social support for both groups.
- Reluctance from adolescent survivors to discuss cancer experience with their parents.


Children with cancer...effect on parents

- Mothers of all children in study reported feeling depressed.
- Some mothers felt they had not cared for their other children as well
- 2 mothers were blamed by their husband for the child’s disease
- Fathers were initially upset, but had to go back to work

Rajajee, et al., 2007
Parents of child with cancer

- High rates of acute stress symptoms
- Just over 50% of moms and 40% dads met criteria for acute stress disorder in first 2 weeks after diagnosis of their child’s cancer.
- Surviving Cancer Competently Intervention Program – Newly diagnosed
- Maternal problem solving skills training

Patino-Fernandez, 2008

What we can do...

- Best to screen patients and families to determine what interventions fit best for them.
- Patient handouts
- Assessment tools
- CNE and CME’s
- Self-care for healthcare professionals

The Healthcare Toolbox at:
http://www.healthcaretoolbox.org/research_say_02.php

Post Traumatic Stress Disorder (PTSD)

*Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV): Learning that one’s child has a chronic and potentially life threatening illness is included as a qualifying event for PTSD.

Yalug, et al., 2008

See the following website for more details on PTSD:
http://www.mental-health-today.com/ptsd/dsm.htm

Parents’ response

- PTSD was seen in 34.6% of parents
- MDD seen in 37.5% of parents
- More PTSD seen in parents of children who had or were receiving chemo + XRT vs surgery alone or surgery + chemo
- Frequently seen in total sample of parents: re-experiencing, avoidance/numbing, and arousal symptom clusters

Yalug, et al., 2008

Parents’ trauma

- 89.4% of parents said this was the most severe trauma they had experienced.

- 10% said the worst trauma of their lives:
  - sudden death of loved one
  - being involved in a traffic accident
  - having lived through the earthquake.

Yalug, et al., 2008

Parent’s cancer effect on adolescents

- Significantly higher levels on internalizing problems self reported by adolescents.
- Evidences suggest children of early cancer parents are at slightly increase risk for internalizing problems. Adolescents self-reported more problems than their parents.
- Adolescent daughters reported higher levels of worry about breast ca than daughters of healthy mothers
- Adolescents reported less PTSD and lower stress response levels than children of healthy parents.

Osborn (2007)
**Parent’s with cancer: adolescent response**

- Previous studies show clinically elevated levels of distress 35% adolescent daughters and 21% adolescent sons
- Higher levels of emotional problems in adolescent daughters and elementary school age sons of cancer patients

Gazendam-Donofrio (2008)

**Can caregivers rate how a patient is “doing”?**

- In pts with advanced cancer: Caregivers could accurately rate:  
  - patients global QOL  
  - patients level of functioning  
  - patients degree of symptom distress  
- Milne (2006): caregivers rated patients level of functioning and QOL less than the patients and rated slightly more symptomology than patients did.  
  - One exception: diarrhea – pts thought was worse than their caregivers thought it was for them.

**Family**

- “Forgotten Priority”  
- “Unknown Soldiers”  
- “Co-patients”  
- “Co-sufferers”  
- “Complex Dyad”  
- “First Responders”  
- “Emotional System”

**Family-Centered Care**

Family is defined as:  

“Whomever the patients says it is.”

- Patient Dyad  
- Patient’s Children  
- Patient’s Extended Family  
- Patient’s Friends  
- Patient’s Community  
- Patient’s Religious Affiliations  
- Patient’s Home/Pets

**Coping Conceptualized**

- A disposition or trait, of person & family  
- A process that the person & family engage to respond to a new, unfamiliar crisis  
- Coping is influenced by personality traits, life experiences, & family systems  
- Coping is a process that changes over time, dependent upon the challenges  
- Goal of coping is “emotional equilibrium”

**Coping and Adaptation**

- Coping is a complex phenomena  
- Many variables influence coping responses  
- Coping is a “dynamic process,” changing over time and trajectory of illness  
- Context of stress or challenges will influence coping responses  
- Coping is influenced by personality of family, past experiences & demands of the crisis  
- “Appraisal” or perception of crisis
### Dispositional Coping

- Personality, habitual way of stress response
- Stable personality traits of family members
- Optimism vs. pessimism, “fighting spirit,” locus of control, hardness, resiliency
- Family system influences coping: communication & problem solving
- *Coping is a disposition or trait of person & family that responds to stress*  
  (Lazarus & Folkman, 1984)

### Factors Influencing Psychological Adaptation

**“Sociologic”**
- Attitudes towards cancer & treatment
- Stigma associated with disease
- Myths & misconceptions
- Access to health care
- Insurance or lack of insurance
- Job discrimination

**“Medical”**
- Tumor site & stage
- Prognosis
- Functional losses
- Treatments required
- Symptom management
- Co-morbid diseases
- Clinical course

**“Psychological”**
- Prior experiences with cancer
- Concurrent life crises
- Social support resources
- Personality of patient & family
  - Ability to cope with life crises
  - Level of maturity/insight
  - Developmental life-stage
  - Ability to accept altered life goals

### Normal Psychological Responses to Cancer

- Fear & Anxiety
- Anger
- Powerlessness
- Self-esteem disturbances
- Body-image disturbances
- Sexual dysfunction
- Mood disturbances
- Grief & loss
- Role changes
- Quality of life & existential concerns

### The Effect of Cancer on The Quality of Life of Family

**Physical Well-Being**
- Caregiver fatigue
- Caregiver cognitive dysfunction/distraction
- Caregiver burden & strain
- Caregiver health risks
- Comorbid illnesses in caregivers

**Spiritual Well-Being**
- Meaning & purpose
- “Reframing”
- Reliance on each other
- Resiliency
- Resetting priorities
Patient & Family Needs

- Information & education per family needs
- Concrete assistance (instrumental)
- Expression of & validation of feelings
- Maintenance of hope & goal setting
- Personal control & decision-making
- Sense of purpose and value to self & family
- Communication skills & intimacy

Barriers to Helping Families
Northouse & Song, 2010

- Time constraints in healthcare settings
- Lack of clarity of professional roles, e.g., who is responsible for psychosocial assessment?
- Lack of value placed on family caregiving, e.g., family often seen as a “burden”
- Lack of professional-family communication
- Lack of cultural sensitivity, e.g., collective/family decision-making the norm in many cultures

Caregiver Assessment

- Who is the primary family caregiver?
- Can you describe the effect the illness is having on you and other family members?
- How confident do you feel to provide emotional and physical care?
- How well are you, family members, and the patient communicating about the illness?

Duhamel & Dupuis, 2004; Northouse & Song, 2010

Caregiver Assessment

- How are you managing the stress that caregivers often experience?
- What social support services are available to you and your family?
- What kind of information do you want or need to help you cope with the illness?
- What is your family’s greatest challenge, concern or problem, right now?

Duhamel &Dupuis, 2004; Northouse & Song, 2010

Distress Thermometer

- “Sixth Vital Sign”
- Validated, self-report, single item tool
- Measures mood, powerlessness, fear, etc.
- Score range 0-10; 10= extreme distress
- Score of 4 or > identifies need for further evaluation and possible intervention
- Complete upon initial assessment & each subsequent clinic visit

Spirituality Assessment

- “HOPE” Assessment
- H- Sources of hope, strength, comfort
- O- Role of organized religion
- P- Personal spiritual practices
- E- Effects on medical care

Anandarajah & Hight
**Programmatic Approaches to Psychosocial Support**

- **“Psychoeducational”**
  - health education regarding disease & treatment
  - decision-making & problem solving skills
  - active coping techniques
- **“Psychotherapeutic”**
  - one to one family support
  - Individual & family counseling
  - group support, e.g., Wellness Community®

**Positive Impact of Cancer Trajectory on Family System**

- Search for meaning: *“family teamwork”*
- Family cohesion & boundary setting
- Gain listening skills & communication
- Demonstrate affection & care
- Positive reframing & optimism
- Family-transcendence
  - *“Post-traumatic growth”*
Stereotactic Body Radiation for Early-Stage Lung Malignancies—Who Qualifies?

**Session Description:** In this session, speakers will discuss stereotactic radiosurgery, stereotactic body radiation, lung tumor staging, radiation delivery systems, the use of HDR in lung malignancies, and criteria and management of cancer patients.

**Target Audience:** Radiation oncology nurses, radiation oncology mid-level providers, or any other healthcare professional.

**Level of Content:** Intermediate

**Content Area:** Clinical Practice

**Continuing Nursing Education:** Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

**Estimated # minutes of Pharmacology Content to be presented:** 10

**Coordinator/Speaker:** Jennifer Varga, MSN, APRN
Family Nurse Practitioner/Radiation Oncology
Henry Ford Hospital
Detroit, MI
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**Full Disclosure:**
Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

**Objectives:**
By the end of this presentation, participants will be able to:
1. Define the type of lung tumor, location and stage in which a candidate can be for SBRT.
2. List the side effects of SBRT and what to do for the patient.
3. Explain HDR and outline how HDR differs for SBRT.

**Content Outline:**

I. Stereotactic radiosurgery (SRS) for lung malignancies
II. Stereotactic body radiotherapy (SBRT) for lung malignancies
III. Delivery system of SRS/SBRT and immobilization devices
IV. Tumors and conditions warranting treatment using SRS/SBRT
   A. Location
   B. Size
   C. Karnofsky performance status criteria
V. Tumor management post SRS/SBRT
VI. Complications of lung SRS and SBRT
   A. Treatment options
VII. Symptom management for lung tumors
   A. Before treatment
   B. During treatment
   C. After treatment
VIII. High-dose rate brachytherapy for lung tumor treatment.

**Bibliography:**


McGarry, R.C., et. al. (2005). Stereotactic body radiation therapy


“Lung Cancer” - 2 basic divisions

1. **NSCLC- Non-small cell Lung Cancer (85%)**
2. **SCLC- Small Cell Lung Cancer (15%)**

**NSCLC Lung Malignancies that warrant SBRT (Stereotactic Body Radiosurgery)**
- **Squamous cell carcinoma**: usually found near the bronchus
- **Adenocarcinoma**: can be found in the tissues of the lung
- **Large cell undifferentiated carcinoma**: can start anywhere in the lung and has been known to grow quickly and spread.

**Early Signs and Symptoms of Lung Cancer**
- Weight loss
- Cough may or may not be productive
- Hemoptyis
- Wheezing
- Dysphagia
- Fatigue
- Chest, shoulder, and bone pain

**What are the Conventional Ways to Treatment?**
- 1. Depends on staging
- 2. Depends on health status
- 3. Depends on cell Type
- 4. Depends on Treating Institution

**Conventional Treatment “External Beam Radiation”**
- Prior to the introduction of “high intensity radiation” – the standard is 1.8- 2 Gy/ fraction to >65 Gy definitive RT to the primary tumor +/- involved lymph nodes for early stage inoperative NSCLC (that adds up to about 6-7 weeks of daily radiation).
- Then came SBRT—so what is that?

**Lung SBRT was born**
- Popularized by Dr. Robert Timmerman (I.U./U.T. Southwestern-Dallas, Texas) and Japanese investigators
- Adapted from intracranial SRS (Stereotactic Radiosurgery) concept to thorax and called it SBRT (Stereotactic Body Radiation)
- Intended for medically unresectable stage I patients
- The study (known as RTOG 0236) enrolled 59 patients with stage I (T1 to T2N0M0) non-small-cell lung cancer between May 2004 and October 2006

Stereotactic Radiosurgery (SRS)

Stereotactic radiosurgery (SRS) treats brain disorders with a precise delivery of a single, high dose of radiation in a one-day session that involves preparatory time and a fixation device to the head.

Delivery System of SRS/SBRT

- There are three types of radiosurgery energy emission devices each with a different energy source and delivery techniques.
  
  *The three are:*

- 1. Particle beam (proton)
- 2. Cobalt-60 based (photon)
- 3. Linear accelerator based (linac)

Stereotactic Body Radiotherapy (SBRT)

“Stereotactic body radiation therapy (SBRT), defined as the treatment of an extra cranial lesion with a single or very few (5 or fewer) high-dose fractions, is one such application of these technologies.”

Thomas J. Dilling, MD, and Sarah E. Hoffe, MD Cancer Control April 2008, Vol. 15, No. 2

NSCLC Lung Cancer Staging

- **T1:** The tumor is no larger than 3 cm across, has not reached the membranes that surround the lungs and does not affect the main branches of the bronchi.  
  
  - **T1a:** A T1 tumor that is 2 cm or less across.  
  - **T1b:** A T1 tumor that is larger than 2 cm but not larger than 3 cm across.

T2 - tumor

- Greater than 3 and smaller than 7 cm
- **T2a:** 3 cm - 5 cm
- **T2b:** 5 cm - 7 cm
- Invasion of the visceral pleura
- Atelectasis or obstructive pneumopathy involving less than the whole lung
- Tumor involving the main bronchus 2 cm or more distal to the carina.

***** NO SBRT for T2b *****
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“SBRT for STAGE 1 ONLY”

N0 – no lymph nodes
MO- No metastasis

- Stage 1a- T1N0M0- up to 3cm across.
- Stage 1b- T2aNOMO- only or less than 5cm at largest diameter.

Does Size Matter?

- “Conclusions: Stereotactic body radiation therapy as delivered was ineffective for curing the patients whose GTVs were larger than 65 cm³. SBRT was promising for those with GTVs less than 65 cm³.”

Options for Stage 1

1. Surgery is #1 option:
   Minimally invasive surgery is used if the cancer is stage I or II.
   However, this procedure is not appropriate for everyone and is not available at every treatment facility.
2. Radiation opinion #2 if surgery not viable.
3. Chemotherapy not recommended for Stage 1 lung cancer

NCCN patient guidelines, 2009

A significant number of patients are medically unfit to undergo surgical resection due to:

- Serious medical co-morbidities
- Poor pulmonary function
- Refusal to undergo surgery

Alternative to Lobectomy

- Limited Resection (Wedge) alone
- Wedge Resection Followed by Radiotherapy
- Standard Radiation Therapy ~ 70Gy/7 weeks
- Stereotactic Body Radiotherapy (SBRT)
- Radiofrequency Ablation (RFA)
- Cryotherapy

Excessive Toxicity When Treating Central Tumors in a Phase II Study of Stereotactic Body Radiation Therapy for Medically Inoperable Early-Stage Lung Cancer

- 70 patients enrolled (35 Stage IA, 35 Stage IB)
- Severe Toxicity at 2 years:
  - Perihilar /Central Tumors: 46%
- Four of the six deaths as a result of toxicity were in patients with perihilar /central tumors.

Stereotactic Body Radiation for Early-Stage Lung Malignancies—Who Qualifies?

Dose and Fractionation

- 60 Gy/3 fractions/8-14 days
  - BED 180 Gy
  - Most widely accepted in U.S.
- 48 Gy/4 fx/4-8 days
  - BED 106 Gy
  - Possible alternative for
    • Larger tumors
    • More central tumors

Evidence-based standards for Nursing Care of SBRT patients, to date have not yet been established.

The Initial Consultation and Simulation

During the consultation, the specialist will explain in detail the therapeutic procedure and answer any questions for the patient and family.

The concept of “respiratory gating” is done at the time of simulation or planning during a 4-D CT scan. The patient’s respirations are visualized and calculated into the plan of care to allow for tumor movement within the chest.

NURSING INTERVENTIONS “with regards to breathing”

- Elevate the head of the bed to ease the work of breathing and to prevent fluid collection in upper body (from superior vena cava syndrome).
- Teach breathing retraining exercises to increase diaphragmatic excursion and reduce work of breathing.
- Augment the patient’s ability to cough effectively by splinting the patient’s chest manually.

“Yes- Breathing is a Good Thing..”

- Instruct the patient to inspire fully and cough two to three times in one breath.
- Provide humidifier or vaporizer to provide moisture to loosen secretions.
- Teach relaxation techniques to reduce anxiety associated with dyspnea. Allow the severely dyspneic patient to sleep in reclining chair.
- Encourage the patient to conserve energy by decreasing activities.

Feelings of claustrophobia — immobilization devices and/or mold, fit closely to your body. The mold is made of a reusable inflatable bag that conforms to the patient’s body.

Cellophane material wraps the patient around the chest and a mild vacuum device withdraws most of the air below the cellophane to form a tight seal.

This technique reduces movement of the chest wall and abdomen/pelvis.
**Skin changes or irritation** – skin changes are rare with SBRT, although they may occur on the patient’s chest or back; the amount of skin irritation is most often minor, although everyone’s skin reacts differently.

While the patients are receiving treatments the nurse will check their skin, provide creams, and talk to them about ways to protect their skin.

**Fatigue** – although patients can occasionally notice some forms of fatigue, many patients find they are able to carry out their normal routines with very little problem.

**Hair loss** – hair loss if it occurs at all, is most often minor, it may occur in small patchy areas on their chest in the treatment field only.

**Nutritional needs** – nutrition affects how one feels during treatment, and how quickly one recovers after treatment; good eating and drinking habits will help lessen the side effects.

**Sore throat and difficulty swallowing**: Some people will begin to have a sore throat during the end of treatment, as the soreness increases. Patients should be told to let their physician and/or nursing staff know about swallowing problems. There are medications that can be prescribed to help ease pain and discomfort. This is a potential temporary side effect.

**NURSING INTERVENTIONS “with regards to diet”**

- Ensure adequate protein intake such as milk, eggs, oral nutritional supplements; and chicken, fowl, and fish if other treatments are not tolerated – to promote healing and prevent edema.
- If patient is vegetarian, still needs to intake adequate protein sources.
- Advise the patient to eat small amounts of high-calorie and high-protein foods frequently, rather than three daily meals.
- There are a number of nutritional supplements on the market to maintain adequate caloric intake and hydration.
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“Pain Control can Lead to Strain Control”

- Monitor bowel movement to avoid constipation.
- Reinforce need for safety on narcotics.
- Reinforce need to seek professional assistance if pain becomes to great.

We can use “Pre-medications”

1. Oral Steroid – 15-60 minutes prior to each treatment to help with acute inflammation of the lung tissue.
2. Analgesic – consider to reduce patient discomfort and motion during long treatment time (dependent on individual institution policy)
3. Anxiolytics - to assist with acute anxiety issues while being confined.

Radiation Pneumonitis

Since the volume of lung exposed to clinically significant doses with SBRT is small, some studies have demonstrated the risk of radiation pneumonitis developing later (median of ~ 5 months) after SBRT versus conventional radiotherapy is less.

Pulmonary Emboli

A true medical Emergency

- Shortness of breath
- Rapid breathing with anxiety or restlessness
- Pain in the chest
- The first symptoms are light-headedness, fainting, or seizures
- In older people, the first symptom may be confusion or deterioration of mental function

Pulmonary Emboli Continued

- Heartbeat may become rapid, irregular, or both.
- Coughing that may produce blood-stained sputum, sharp chest pain when breathing in, and in some cases fever.
- A Pulmonary Embolus is a medical emergency as it may lead to stroke or cardiac arrest.

Esophageal Toxicity

With standard fractionation, the volume, length and surface of esophagus exposed to supra threshold radiation increases the risk of toxicity.

SBRT can reduce the amount of esophagus exposed to therapeutic doses, though hypofractionated radiation does raise concern for esophageal toxicity.

Generally, the dose constraints adhered to for esophagus have proven to be safe.
Assessment:
Nursing Care Plan For Lung Cancer

- Early lung cancer may cause no symptoms patient’s history, be sure to assess his exposure to carcinogens. If he’s a smoker, determine pack years.
- Hemoptysis,
- Dyspnea
- Hoarseness
- Short of breath
- Finger clubbing; edema of the face, neck, and upper torso

Radiographic Changes
Following SBRT, the lung parenchyma undergoes acute (occurring after weeks to months) and late (after 6 months) changes reflected by characteristic radiographic findings.

HDR Definition
- High dose rate, or HDR brachytherapy is a revolutionary new form of internal radiation which temporarily exposes abnormal tissue to a high amount of radiation.
- Under CT and fluoroscopy guidance, a bronchoscope is used to deliver a catheter into a position at the site of the bronchial tumor.

HDR for Lung- “When to use it?”
- If the tumor is on the outside of the airway and compressing on the airway from the outside, this procedure is typically not used.
- The reason is that endobronchial HDR treatments only penetrate 5mm to 1cm.
- There is a rapid fall off in dose. So they are perfectly suited for treating something in close proximity that isn’t very thick.

RTOG Trials for SBRT
Future Directions

Multi-institutional Prospective Trials
- RTOG-0236: Phase II trial - Stereotactic radiotherapy utilizing the dosing scheme of 20 Gy x 3 fractions for peripheral tumors
- RTOG-0618: Phase II trial - To define the role of SBRT in patients who are operable candidates is underway
- RTOG-0813: Phase I trial - to define the role of SBRT in patients with central lesions in a dose escalation trial
- RTOG-0915: Phase II randomized – to compare 2 SBRT dose schedules for peripherals tumors
- Future RTOG Trial- Protocol to define the role of SBRT in patients with metastases to the lung

Brief Overview of This Talk
Why abandon conventional RT for stage I?
- Local control is only 15-45% with conventional RT.
- Surgical local control 60-90% - however is the standard of care in operable patients but inoperable patients need something else.

Remember...SBRT for Early Stage Lung Tumor is:
- Only used for small single lung tumors less 5cm that are from the NSCLC category.
- For tumors that are generally 2cm away from the carina or bronchi
- A radiation treatment that consists of high dose radiation less than 5 fractions.
- Sometimes used in combination with chemotherapy.
Survivorship Updates and Issues in Patients With Myeloma

Session Description: Examine the disease trajectory of patients with myeloma and review the current overall survival data for this population. In addition to survivorship issues, you’ll learn about their implications on nursing practice. Speakers will use case studies to demonstrate the need for survivorship care plans for these patients.

Target Audience: Oncology nurses and advanced practice nurses

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Estimated # minutes of Pharmacology Content to be presented: 10

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Nothing to Disclose

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Full Disclosure:
Celgene. Speaker, consultant
Millennium. Speaker, consultant

Objectives:
By the end of this presentation, participants will be able to:
1. Describe the improvement of overall survival data in patients with myeloma in the past decade.
2. Appraise the potential areas of concern related to survivorship in myeloma patients.
3. Summarize the survivorship care needs of myeloma patients.

Content Outline:
I. Survival data
   A. Latest Kaplan-Meier Curve for patients with myeloma 1975–2004
   B. Impact of novel agents in overall survival
      1. Thalidomide
      2. Bortezomib
      3. Lenalidomide

II. Areas of concern
   A. Bone health
   B. Kidney function
   C. Safety and mobility
   D. Financial health
   E. Psychological health—fear of recurrence, anxiety
   F. Sexual health
   G. Health maintenance

III. Summary of survivorship care plan
   A. Treatment history
   B. Specific recommendations addressing the concerns mentioned earlier

Bibliography:


Multiple Myeloma

- A cancer of bone marrow plasma cells
- Incurable but very treatable
- Side effects of treatment are manageable
- Newer agents offer hope of improved survival in the last decade
- SEER data—5-year OS 26% → 33%

Immunoglobulin Structure and Dysfunction

- Immunoglobulins: Integral to immune system function
- Dysfunction of Heavy and light chains
- Heavy: IgG, IgA, IgD and IgE
- Light: Kappa, Lambda
- Serum Kappa/Lambda Free Light Chains
- Non-secretory MM

Diagnostic Tests

- Blood and Urine Tests
  - Generic blood analysis
    - Complete blood cell counts (CBC)
    - Calcium, uric acid and creatinine
    - Albumin, beta-2-microglobulin, LDH
  - M proteins
    - Blood—Serum protein electrophoresis and Immunofixation
    - Urine protein electrophoresis and immunofixation
    - Quantitative Immunoglobulins, serum free light chain assay
- Radiologic
  - Skeletal survey; MRI/computerized tomography (CT) scanning or PET if needed
- Bone Marrow
  - Aspirate and biopsy with karyotyping and plasma cell labeling index

Criteria for Diagnosis of MM

- Monoclonal plasma cells in bone marrow (10% 30% if non-secretory)
- Monoclonal protein present in serum and/or urine
- Myeloma-related organ dysfunction
  - Calcium in serum (>10.5 mg/L)
  - Renal insufficiency (SCr >2 mg/dL)
  - Anemia (hemoglobin <10 g/dL or 2 g normal)
  - Bone lesions or osteoporosis

Kaplan-Meier Curve for Myeloma patients 1975-2004

Myeloma Survivorship: Average Years of Life Lost in Patients Treated With Conventional or High-Dose Therapy

<table>
<thead>
<tr>
<th>Age at Diagnosis</th>
<th>60-69</th>
<th>70-74</th>
<th>75-79</th>
<th>80+</th>
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<tbody>
<tr>
<td>Conventional Chemo</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>High-Dose Chemotherapy</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Non-related</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Normal related</td>
<td>48.5</td>
<td>47.9</td>
<td>47.1</td>
<td>46.4</td>
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<tr>
<td>Age ≥ 70 &amp; Fcast</td>
<td>26.8</td>
<td>26.4</td>
<td>25.1</td>
<td>24.4</td>
</tr>
</tbody>
</table>

Impact of Novel Agents: Overall survival from diagnosis of MM

Cumulative relative survival in patients treated with conventional therapy (A) and high-dose therapy (B) in patients younger than 50 years or 50 years and older and in patients younger than 60 years and 60 years and older (E2E). Small blue line: Treatment A; large blue line: Treatment B; large red line: Treatment C.

What to look for...

- Unexpected long term complications
- Second cancers (alkylating agents)
- Maintenance vs. No maintenance
- Sexuality issues
- Family/Social problems
- Financial/Insurance problems
- Other

Thalidomide (Thalomid®)

- FDA approved for newly diagnosed and relapsed MM
- Patients who receive thalidomide had improved survival over patients receiving steroids in clinical trials
- When given to patients after transplant, thalidomide has been shown to improve survival and extend remission

Side Effects of Thalidomide

- Common
  - Birth defects
  - Peripheral neuropathy
  - Somnolence, Fatigue
  - Rash
  - Constipation
  - DVT (common in combination with Dex or other agents)
- Less Common
  - Stevens-Johnson syndrome (adverse reaction to drug)
  - Elevated liver enzymes
  - Malaise
  - Peripheral edema

Bortezomib (Velcade®)

- FDA approved for newly diagnosed and relapsed MM
- Has been shown to improve survival in elderly patients with newly diagnosed MM compared to dex, MP or VMP
- Extends remissions in patients with relapsed MM
Frequent Side Effects of Bortezomib

- Thrombocytopenia
- Asthenia
  - Fatigue, weakness
- GI effects
  - Nausea, vomiting, diarrhea
- Peripheral neuropathy
- Hypotension

Lenalidomide (Revlimid®)

- FDA approved for relapsed MM
- Clinical trials have demonstrated improved remission rates in combination with dexamethasone and bortezomib
- Will extend progression free survival in elderly patients when len is given after MPR
- Extends remission after transplant

Lenalidomide

- Only available through restricted distribution program “RevAssist®” because of potential for human birth defects.
- Different toxicity profile than thalidomide
  - Greater myelosuppression
  - Fatigue, Asthenia
  - Renally excreted
  - GI

Bone Health: Scope of Problem

- Over 58% of patients have back and bone pain at diagnosis
- 15%-30% develop VCFs annually leads to altered biomechanics and increases risk of health problems
- About half of patients with at least 1 osteolytic lesion develop pathologic fractures within 9 months
- Patients at risk for pain, hypercalcemia, decreased mobility and spontaneous fractures if MM not controlled

Pathobiology of Bone Disease

- Pathobiology: malignant cells produce osteoclast-activating factors that destroy bone cells
  - Osteoclast stimulation leads to extensive osteolysis, severe bone pain, and pathologic fractures
  - Spinal cord compression
- Skeletal survey, MRI, CT, PET to diagnose
- Treatment: Analgesia, bisphosphonates, treat disease if relapse, vertebroplasty or balloon kyphoplasty

Interventions for Bone Disease

- Patients with bone disease are at risk of increased morbidity and mortality
  - VTE, Pneumonia
- Quality of life
- Vertebroplasty vs Balloon Kyphoplasty
- Radiation for identified lesions
- Physical therapy to increase function, mobility
- Bisphosphonates, Ca++, Vit D
Kidney Dysfunction

- Bence-Jones proteinuria/Free monodonal light chains: Incidence ~70%
  - Light chain IgGs can precipitate and damage renal cells
  - Free light chains filtered in the nephron’s glomeralus, then absorbed and metabolized by proximal tubular cells
  - Heavy and light chains can cause renal tubular damage
  - Serum Free light chain assay more reliable than urine
  - ATN secondary to NSAID use, dehydration, nephrotoxic agents (CT dyes)
- Supportive therapy
  - Hydration, correct underlying cause with treatment
  - Avoid IV contrast and nephrotoxic agents (IV dyes, NSAIDS, aminoglycosides especially)
  - Plasmapheresis, dialysis

Conclusions

- Patients with MM are living longer than ever!
- Nurses are in a unique position to educate patients, assess for side effects, and intervene when appropriate
- New and unidentified survivorship issues may become apparent with increased lifespan

Safety and Mobility

- Approximately 90% of patients with multiple myeloma (MM) will develop bone lesions that are purely osteolytic.
- Severe morbidities from pathologic fractures and other skeletal events could lead to poor circulation, blood clots, muscle wasting, and overall poor survival.

Safety and Mobility

- Supportive care targeting bone disease prevention is an essential part of anti-myeloma therapy.
- Maintenance of bone health in patients with MM can significantly affect functional mobility and safety

Key Elements of Care Plan

- Safe administration of biphosphonates
- Promotion of exercise
- Maintaining adequate nutrition and vitamin supplementation
- Monitoring of bone complications

Clinical Challenges

- How to effectively manage bone disease and maintain bone health in MM patients and survivors.
- Early detection of bone disease to prevent serious skeletal complications — lack of biomarkers, no screening test
Financial Health

• Since the 1960s through the 1990s, the Alkeran-Prednisone combination was the golden standard in the treatment of myeloma.
• In the mid 1990’s, the treatment results in younger patients were dramatically improved by high-dose chemotherapy with autologous transplantation.

Financial Burden on Patient and Family

- Annual Deductible
- Physician/clinic visit fee
- ER visit fee
- Prescription co-pay
- “Donut hole”
- Very expensive cancer drugs for those who are underinsured or uninsured
- Insurance denials of claims

What can nurses do?

- Help patients complete the co-pay assistance form from Leukemia Lymphoma Society or Patient Access Network
- Submit social security disability forms immediately with critical medical information to facilitate approval
- Encourage use of 90-day supply for maintenance drugs

Psychological Health

- Intrusive thoughts associated with High Fear of Cancer Recurrence (FCR) presented more characteristics of obsessions.
- There are different profiles of FCR, which vary according to its severity and the type of coping strategies used.

What can nurses do?

- Enroll patients in drug assistance program ASAP if eligible
- Facilitate short-term and long-term disability forms completion
- Assist patients in the appeal process for denials
- Follow precertification rules per patient’s insurance policy

Financial Health

• The first decade of the new millennium has brought about even better results after the introduction of thalidomide in the initial treatment in patients not indicated for transplantation.
• Improvement is also expected in patients of a younger age group thanks to the combination of new drugs with autologous transplantation.
Fear of Cancer Recurrence

Components of fear of cancer recurrence:
- Triggers
- Severity
- Psychological distress
- Coping strategies
- Functional impairments
- Insight
- Reassurance

What can nurses do:
- Assessment – use the FCR inventory
- Identify effective coping strategies
- Assist with ADLs and IADLs
- Provide realistic reassurance
- Refer patient to psychosocial services

Sexual Dysfunction

- Sexual desire disorder (decreased libido)
- Sexual arousal disorder
- Orgasm disorder
- Sexual pain disorder

The Impact of Myeloma

<table>
<thead>
<tr>
<th>Immunomodulators</th>
<th>Thalidomide</th>
<th>Lenalidomide</th>
<th>Bortezomib</th>
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<tbody>
<tr>
<td>Side Effects and Clinical Observations</td>
<td>Reported to induce impairment in male patients</td>
<td>Unpublished reports of erectile dysfunction and increased libido</td>
<td>Unpublished reports of erectile dysfunction and increased libido</td>
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</tbody>
</table>

Our knowledge of the effects of novel myeloma treatment on sexuality is very limited
- Patients are reluctant to discuss the issue
- Sexuality assessments are not performed

Strategic Recommendations

- Urgent need for open communications
  - Physicians
  - Nurses
  - Patients
- Interventions
  - Pharmacologic and Non-pharmacologic
- Patient Education Tool and additional educational materials

Health Maintenance

- The IMF Nurse Leadership Board identified areas for health maintenance:
  - The NLB has chosen to focus on the recommendations pertaining to:
    - Cardiovascular disease
    - Secondary malignancies
    - Endocrine disorders
    - Bone metabolism disorders
    - Sensory changes
    - Depression
    - Chemical dependency
    - Nutrition
Major Risk Factors Affecting Health Maintenance

- Lifestyle choices
- Mental risk factors
  - Substance abuse
  - Depression
- Fatigue
  - Depression, pain, and anemia
- Cognitive changes
  - “Chemo brain” effect
- Dermatological issues
  - Immune system weakened by therapy
  - Radiation
  - Increased risk for skin cancer

In Summary

- SCP is a document:
  - Summarizes what transpired during cancer treatment
  - Gives recommendations for follow-up care
- It needs to:
  - Be prospective
  - Identify known and potential long-term effects
- It aims to:
  - Promote a healthy lifestyle
  - Prevent recurrence of cancer
  - Reduce risk of co-morbid conditions
  - Ensure adherence to follow-up recommendations

Implementing Cancer Survivorship Care Planning [http://www.nap.edu/catalog/11739.html]

- It aims to:
  - Promote a healthy lifestyle
  - Prevent recurrence of cancer
  - Reduce risk of co-morbid conditions
  - Ensure adherence to follow-up recommendations
  - Be prospective
  - Identify known and potential long-term effects

Key Elements for Cancer Survivorship Care Planning

- Diagnosis and stage
- Treatment plan and dates
- Expected short and long-term effects
- Late toxicity monitoring
- Surveillance for recurrence or 2nd cancer
- Responsibility for survivorship care
- Psychological and vocational needs
- Recommended preventive behaviors and recommendations

Next Steps

- Create a comprehensive survivorship care plan that address the following:
  - Bone health
  - Kidney function
  - Safety and mobility
  - Financial health
  - Psychological health
  - Sexual health
  - Health maintenance

Next Steps

- Get a review/feedback from myeloma experts (nurses and physicians)
- Pilot test the survivorship care plan
- Identify implementation barriers
- Evaluate and revise as needed
- Identify outcome measures related to the survivorship care plan
Beyond Survival: Managing Late-Effect Complications of Allo Stem Cell Transplantation

Session Description: This presentation will address the late effects associated with allogeneic blood and marrow transplantation, focusing on chronic graft vs host disease, endocrine dysfunction, and quality of life.

Target Audience: Nurses and other healthcare professionals who specialize in blood and marrow transplantation and hematology/oncology

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 2.5 continuing nursing education credits for successful completion of this mini-institute.

Estimated # minutes of Pharmacology Content to be presented: 30

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Full Disclosure:
Nothing to Disclose

Speaker:
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Clinical Nurse Specialist/Nurse Practitioner
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Full Disclosure:
Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Objectives:
By the end of this presentation, participants will be able to:
1. Identify key issues facing survivors of allogeneic blood and marrow transplantation.
2. Identify clinical manifestations and key therapies for chronic GVHD.
3. Recognize unique challenges in endocrine dysfunction in this population.
4. Understand QOL issues specific to this population.
5. Identify strategies to provide enhanced care for this specific population.

Content Outline:
I. Allogeneic HSCT
   A. Increasing number of transplants performed
   B. Increasing numbers of transplant survivors
      1. Unique subset of cancer survivorship
      2. Unique physical and psychosocial challenges
II. Chronic GVHD
   A. Background
   B. Clinical manifestations
   C. Emerging therapies
III. Endocrine dysfunction
   A. Metabolic syndrome
   B. Sexual dysfunction
IV. Quality of life following allogeneic transplant

Bibliography:
myeloablative and reduced-intensity conditioning regimens. *Bone Marrow Transplantation, 43*, 949–951.


Oncology Nursing Society Institutes of Learning

Saturday, November 13

305–310.


Chronic Graft vs Host Disease

Stephany Rodriguez RN, MS, NP
University of California, San Francisco

Chronic Graft versus Host Disease “cGVHD”

- Occurs in 30-70% of HSCT recipients surviving more than 100 days
- “Typically” occurring greater than 100 days post-HSCT
- Treatment typically requires immunosuppressive medications for median of 2-3 years
- Remains the major cause of late deaths

Predictors of CGVHD

1. HLA disparity:
   - CGVHD Incidence
   - Donor
   - Onset of CGVHD
     - 40% ID sibling D201
     - > 50% non-ID sibling D159
     - 70% ID unrelated D133

2. Age of recipient: CGVHD Incidence (after ID sibling HCT)
   - <10 years: 13%
   - >20 years: 46%

3. Prior Acute GVHD

4. Donor Age and Donor Sex

5. Source of Hematopoietic Cells: BM vs PB vs UCB

Blood 2001;97:1196; Blood Reviews 2006;20:15–27

Clinical Manifestations

Pathophysiology

NIH Consensus Development Project on Criteria for Clinical Trials in Chronic GVHD

Working Groups:
1. Diagnosis and Staging of CGVHD
2. Histopathology
3. Biomarkers
4. Response Criteria
5. Supportive Care
6. Design of Clinical Trials

Recategorizing Acute and Chronic GVHD

<table>
<thead>
<tr>
<th>Condition</th>
<th>Time of symptoms (after HCT or DLI)</th>
<th>Presence of Acute GVHD Features</th>
<th>Presence of Chronic GVHD Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic AGVHD</td>
<td>≤ 100 days</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Persistent, recurrent or late AGVHD</td>
<td>&gt; 100 days</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Acute and Chronic Overlap</td>
<td>No time limit</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Chronic GVHD</td>
<td>No time limit</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* Rash or GI symptoms typical of AGVHD

Based on NIH Consensus Development Project

cGVHD: Treatment

- Initial therapy: corticosteroids 1mg/kg/day actual body weight
- Approximately 1/3 of patients will respond to initial therapy and never receive secondary agents
- “Steroid-refractory”: failure to improve after at least two months or progression after one month of corticosteroid therapy
- No consensus exists regarding choice of therapy for steroid-refractory cGVHD

cGVHD: Novel Therapies

- **Barriers to Novel Therapies**
  - Small, single center case studies
  - Stagnant and inadequate staging and diagnostic criteria
  - Poorly understood pathophysiology
  - Problematic endpoints to clinical trials

Future directions....

- Improved initial and/or secondary therapies
- Therapy targeted towards most morbid manifestations
- Cellular therapies directed at the donor graft
- Treg cell enriched donor grafts?
- All cGVHD patients enrolled in clinical trials

Novel Therapies

- ECP
- Rituximab
- Sirolimus
- Mycophenylate Mofetil
- Imatinib
Endocrine Dysfunction Following Allogeneic Transplant

Nonniekaye Shelburne CRNP, MS, ADON
National Institutes of Health

Endocrine Toxicity:
Possible damaging factors

• Aggressive treatment
  – Total Body Irradiation
    • Originally thought to be the culprit
  – Less incidence in fractionated TBI
  – Significant prevalence in non TBI regimens (Reduced intensity)
  – Alkylating agents
  – Heavily pre-treated patients

• Immune system derangements
  – Cytokine releases / immune deficiencies
  – Chronic Graft Versus Host Disease (GVHD)
  – Auto antibodies

• It all comes back to the Hypothalamus

Gonadal toxicity:
Hypothalamus-Pituitary-Gonadal Axis

• Most common late effect
  – Females (57 - 95%)
  – Males (20 - 72%)

• Female
  – Ovarian Failure
  – Infertility / Early menopause
  – Chronic GVHD
    • Vaginal stenosis
    • Muscular changes

• Male
  – Azooospermia
  – Infertility
  – Sexual dysfunction

Ovarian Failure

• Pathophysiology
  – Damage to oocytes and follicle support
  – Follicle support damage most prominent
  – Signs:
    • ↑ FSH (follicle stimulating hormone)
    • ↑ LH (luteinizing hormone)
    • ↓ Estradiol
    • Amenorrhea

• Prevalence:
  – 90 – 95% of all females
  – Highest in women transplanted after menarche
  – Normal development can occur in pre-menarche females
  – Risk for early menopause
  – Return of function: < 21 yrs at time of BMT and > 2 yrs post BMT

Early Menopause & Infertility

• High risk for all females

• Many women become amenorrheic during BMT

• Risks without treatment:
  – Early and extensive osteoporosis
  – Cardiovascular disease
  – Early dementia

• Treatment
  – No menstruation post BMT, consider Hormone Replacement Therapy (HRT):
    • Most important in patients under the age for normal onset of menopause – higher potential for success
    • Alleviate symptoms & possibly restore organ function
  – Pre-BMT fertility counseling

Ovarian Failure

• Screening:
  – FSH
  – LH
  – Estradiol

• Treatment
  – Pre-BMT fertility counseling
  – Estrogen and cyclic progestin

• Research: ovarian protection
  – Gonadotrophin releasing hormone agonist (GnRHa) during conditioning regimen
  – Decrease ovarian perfusion thus less exposure to toxicity

References:
Tauchmanova, 2003; Tauchmanova, 2007; Yi, 2009

Oncology Nursing Society Institutes of Learning
November 12–14, 2010
**Azospermia / Infertility**

- Pathophysiology
  - Germinal epithelium responsible for spermatogenesis
  - More sensitive to toxicity than ovaries
  - Leydig cells responsible for testosterone production (sexual function and gonadal development)
  - Less affected by toxicity
- Prevalence
  - Difficult to assess due to refusal of semen sampling post BMT
  - Low Testosterone: 20.3% pediatric boys > 10 yrs post BMT
  - Azospermia: 72% adult males > 2 yrs post BMT
  - Spermatogenesis damage or ↑ TSH: 47% ped/adult > 1 yr post BMT
  - Return of function highest in:
    - <25 years at time of BMT
    - > time since BMT
    - Absence of chronic GVHD
    - Age < 25 and > 9 yrs post BMT + 56% normal spermatogenesis

**Pregnancy post BMT**

- Partners of male BMT recipients have higher success rates than female BMT recipients
  - But successful cases reported in both
- Female BMT recipients have increased risk for:
  - Pre-term deliveries
  - Low birth weight
  - Caesarian section deliveries
- Infants of BMT recipients:
  - <1 % have congenital anomalies, developmental delays, or malignancies

**Thyroid Dysfunction**

- Prevalence
  - 22 - 48% of all patients 3-10 years post BMT
  - Highest in children < 10 years and adult > 40 years at time of BMT
  - Female > male
  - Myeloablative > RIC
- Screen with Thyrotropin Releasing Hormone (TRH) stimulation test
  - Identifies derangements in gland function
  - Normal thyroid = ↑ TSH up to 5 fold
  - Subclinical hypothyroid = ↑ TSH > 5 fold
  - Overt hypothyroid = ↑ TSH > 5 fold
- Thyroid Ultrasound

**Thyroid Dysfunction: Hypothalamus-Pituitary-Thyroid Axis**

- Subclinical hypothyroidism / Thyroid impairment - most common
  - ↑ Thyroid Stim Hormone (TSH) with normal T4 & T3
- Overt Hypothyroidism
  - ↑ TSH with ↓ T4 and/or T3
- T3 syndrome
  - ↓ T3 with normal T4 and TSH
  - Seen in chronic GVHD
- Hyperthyroidism
  - ↓ TSH with normal T3 and T4
  - Seen 12 – 18 months post – some resolve
- Proposed cause: T cell mediated damage to thyroid and long term immunosuppressive therapy

**Thyroid Dysfunction**

- Thyroid replacement therapy
- Rational to treat sub-clinical hypothyroid
  - Decrease risk of thyroid adenoma
  - Decrease risk of carcinoma
  - Children
    - Prevent growth failure and delayed development
- Many subclinical hypothyroid on prolonged immunosuppression become symptomatic and need treatment
- Hypothesized antibody-mediated autoimmune process disproved
Growth Hormone (GH) Deficiency: Hypothalamus-Pituitary-Growth Hormone Axis

- Pathophysiology
  - Disregulation of growth hormone

- Signs:
  - Short stature
  - Decreased growth velocity
  - Increased fat around the waist
  - Delayed tooth development
  - Delayed onset of puberty

- Prevalence
  - BMT pre to full development
  - Heavily pre-treated patients, TBI, High dose / long term steroid use, GVHD
  - Any bone/soft tissue that is irradiated prior to full development will have decreased growth capacity (e.g. spine = final height)
  - 30% of children 10 yr post BMT
  - 80% with GH deficiency also have hypothyroidism

Growth Hormone Deficiency

- Screening post BMT:
  - Growth charts
  - Growth Velocity
  - Growth Hormone levels
    - Insulin-like growth factor (IGF)

- If deficiency, follow with:
  - Provocation tests
    - Subnormal response of GH after stimulation = GH < 10mU/L
  - Bone age tests

- Treatment
  - Growth hormone injections
  - Small risk of secondary malignancy
    - Cell proliferation of benign and malignant cell lines
    - No standard guidelines for treatment

Adrenal Insufficiency: Hypothalamus-Pituitary-Adrenal Axis

- Pathophysiology
  - Chronic suppression of Corticotropin Releasing Factor (CRF) and Adrenocorticotropic hormone (ACTH) by glucocorticoids = decreased cortisol production

- Symptoms
  - Fatigue & weakness
  - Anorexia & weight loss
  - Abdominal pain
  - Nausea / vomiting
  - Severe: hypotension & hypoglycemia

- Prevalence
  - 10% of all long term survivors
  - Increased in chronic GVHD
  - Cumulative dose > 10 g/m²
  - > 10 months post BMT
  - Some patients have recovered function

Adrenal Insufficiency

- Lab Testing
  - ↓ ACTH (serum)
  - ↓ Cortisol < 18 (serum before 8am)
  - Abnormal cortisol stimulation test

- Treatment
  - Hydrocortisone 5mg, 10mg, 20mg
  - If mineralocorticoid deficiency (low aldosterone) also, use fludrocortisone

Psychosocial Issues and QOL following allogeneic transplant

- What does the literature tell us about the general QOL of transplant patients so far?

Psychosocial Issues and QOL following Allogeneic Transplant

Liz Cooke RN MN ANP AOCN
Nurse Practitioner and Senior Research Specialist
Department of Nursing Research
City of Hope Medical Center

Psychosocial issues and QOL following allogeneic transplant

- Description of the transplant as a psychological assault, trauma, stressor, challenge
- Quality of Life Model as a Conceptual Framework
- Risk factors for Psychosocial issues
- Psychosocial Issues/Disorders/Diagnosis
- Treatment options

Risk factors for Psychosocial issues

- Individual
- Environmental
- Transplant-related


Psychosocial issues and QOL following allogeneic transplant:

Psychological Well-Being

- Distress
- Fear of Recurrence
- Grief/Loss
- Survivor Guilt

Psychosocial Issues/Disorders

Physical Well-Being

- Worry/concern over physical issues
- Sexual Issues
- Body Image
- Physical Symptoms impacting psych well-being: fatigue, insomnia, cognitive


Description of the transplant as a psychological assault

- Intense
- Life-threatening
- Isolating
- Long recovery
- Uncertainty
- Frequent readmissions
- Traumatic
- Physical discomfort
- Multiple stressors
- Last chance for cure

Psychosocial Issues/Disorders/Diagnosis

Physical Well-Being

- Worry/concern over physical issues
- Sexual Issues
- Body Image
- Physical Symptoms impacting psych well-being: fatigue, insomnia, cognitive


Psychosocial Issues/Diagnosis

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Psychological Well-Being

- Distress
- Fear of Recurrence
- Grief/Loss
- Survivor Guilt

Saturday, November 13

Psychosocial Issues/Diagnosis
Psychological Well-Being

- Adjustment disorder
- PTSD
- Depression
- Coping with Long-term issues


Psychosocial Issues/Disorders/Diagnosis
Social Well-Being

- Financial
- End-of-life Issues
- Role Issues
- Caregiver Burden
- Work/Occupational


Psychosocial Issues/Disorders/Diagnosis
Spiritual/Existential Well-Being

- End-of-life Issues
- Spiritual/Existential Crisis
- PTSD/Benefit Finding

Wingard, 2003; Zebrack, 2009; Cooke, et al, 2009

Intervention Treatment Options
Psychosocial Issues/Disorders/Diagnosis

- Comprehensive assessment including physical, psychosocial and existential issues
- Psycho educational
- Removal of barriers to assessing mental health services
- Support groups


Intervention Treatment Options
Psychosocial Issues/Disorders/Diagnosis

- Self-care training
- Social support
- Medication management: i.e. antidepressants
- Physical activity/Exercise
- Referral to a mental health professional: psychotherapy

Wilson, et al, 2005; Podmore, 2009

Intervention Treatment Options
Psychosocial Issues/Disorders/Diagnosis

- Rehabilitative team approach
- Resilience: Charting the Heroic Journey
- Cognitive-Behavioral Therapy
- PTSD-specific interventions

Saturday, November 13

Intervention Treatment Options
Psychosocial Issues/Disorders/Diagnosis

- Mindfulness
- Hypnotherapy
- Imagery

Herwig, 2010; Tacon, 2009
Saturday, November 13

Mini-Institute • 2:30–5:30 pm • W232 AB

Domestic Violence: The Ripple Effect

Session Description: This mini-institute will offer information on the risk factors of domestic violence (DV), potential signs, screening questions and assessments, and potential resources for victims. Speakers will discuss how Moffitt Cancer Center, with input from staff nurses who encounter abuse victims in their practice setting, set up a hospital-wide DV educational initiative and how it has expanded into a communitywide program with multiple community partners.

Target Audience: All healthcare professionals

Level of Content: Introductory

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 2.5 continuing nursing education credits for successful completion of this mini-institute.

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Full Disclosure:
Nothing to Disclose

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Full Disclosure:
Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Objectives:
By the end of this presentation, participants will be able to:
1. Summarize risk factors and warning signs of potential abuse.
2. Differentiate types of abuse and describe characteristics related to each.
3. Identify screening techniques that may be used in patient care settings.
4. Demonstrate acquired knowledge into clinical practice.
5. Describe resources typically available in most communities.

Content Outline:
I. Introduction and case study
   A. Defining domestic violence (DV) and intimate partner violence (IPV)
   B. Statistics and prevalence
   C. Risk factors for violence
II. Recognizing potential abuse victims in healthcare settings
   A. Characteristics of DV and IPV victims
   B. Characteristics of perpetrators
III. Screening for domestic violence
   A. Paper versus computer
   B. Barriers to assessment
IV. Building an educational initiative: the ripple effect
   A. Journal clubs
   B. Creation of a task force
   C. Community involvement

Bibliography:
http://www.aacn.nche.edu/publications/positions/violence/htm
**Saturday, November 13**


Domestic Violence
Intimate Partner Violence

- Any form of physical, sexual or emotional abuse which takes place within the context of a close relationship
- Slapping, pushing, hitting, throwing objects, punching, kicking, threatening with weapons and attempts to smother or strangle
- Non-violent abuse-causing fear through verbal threats and taunts, causing shame and guilt and made to feel to blame for situations

Intimate Partner Violence

- More than just hurting someone physically or emotionally- exerting power over to control through violence
- Rarely an isolated event
- Can begin at any time in a relationship
- Usually increases in severity over time

Types of Abuse

- Coercion and threats
- Intimidation
- Emotional abuse
- Isolation
- Male privilege
- Economic abuse
- Minimizing abuse, blaming and denying

Non-Violent Abuse

- Over time subtle brainwashing can have even more terrifying effects that actual violence
- Tormented about inferiority, lack of social status without partner, uselessness as a wife and mother, and total meaningless existence
- It is this false perception of self to a large extent that prevents them from leaving

Prevalence

In the United States it is estimated that between 2 and 4 million, and possibly as high as 8 million, women are battered every year by men that they live with

Or

1 in 4 marriages

Statistics Difficult to Decipher

Self reporting – many victims in denial and many feel that it is too unsafe to disclose

Many do not disclose because they believe that it is somehow their fault and they are too ashamed to admit it or get help

**Perpetrator Characteristics**

- History of living in household with domestic violence
- History of abuse as child
- History of sexual abuse

**Vulnerable Populations**

- Pregnant women
- Younger than 30
- Those abused as children
- Those that witnessed DV as children
- Those with physical or mental disabilities

**Characteristics of IPV Victims**

- All ages, all classes, all ethnic backgrounds
- Probably not reported as often with middle and upper class because they have larger support system and more resources

**Victim Characteristics**

- Experience gradual social isolation, including loss of contact with family and friends
- Has a generational history of witnessing abuse in her family
- Participates in a “pecking order” abuse, sometimes treating her children with abuse
- High risk for assault in pregnancy
- History of minor attempts at suicide
- Unable to convince partner that she is loyal

**The Cycle of Abuse**

- Tension or Building Up Phase
- Battering Phase
- Honeymoon Phase
**Physical Indicators**

- Evidence of injuries in many stages of healing
- Injuries on areas covered by clothing
- Injuries on areas not normally injured by accidents and falls
- Sexually Transmitted Diseases
- Gastrointestinal disorders
- Facial and Head injuries

*Max, J. (2006).*

**Other IPV Characteristics**

- Frequently raped by partners, given STDs
- History of alcohol or drug abuse
- History of depression with attempted suicide
- Panic attacks, emotional and mental disorders
- Chronic anxiety
- Signs of anger, betrayal, distraught, inadequate, isolated and have low self-esteem
- Frequently missed appointments or lack of prenatal care

*Glanz, K., et al (2008).*

**Behavioral Indicators**

- Lack of eye contact
- Apathy
- Lack of trust of people, including healthcare personnel
- Depression

**Health Outcomes**

- Non compliance with care
- Suicide
- Substance Abuse
- Depression
- Chronic pain
- Chronic disease

**Medical Advocacy Wheel**

- Respect confidentiality ...
- Verify identity ...
- Develop and validate...
- Help her plan for safer
- Support her ...
- Acknowledge her ...
- Respect her right ...

*The Missouri Coalition Against Domestic Violence, Advocacy Empowerment Wheel. Used with permission.*

**Overview**

- Background
- Purpose of research
- Methods
- Findings
- Implications
- Acknowledgments
- Contact information
### Background

- Domestic violence (DV) linked to:
  - Delayed cancer diagnosis
  - Difficulties obtaining treatment
  - Inadequate emotional/functional support
- By identifying patients experiencing abuse, nurses and other healthcare providers can offer appropriate support, safety planning, referrals to domestic violence services
- No reports available on the implementation of routine domestic violence screening in an oncology setting

### Purpose of Research

- Evaluate implementation of a DV screening protocol in gynecologic oncology clinic
- Examine barriers to DV screening and documentation
- Explore potential solutions to these barriers

### Methods: The DV Task Force

- Gillette Center for Women’s Cancer at Massachusetts General Hospital (MGH)
- Multidisciplinary (oncology nurses, social workers, administrators)
- Aim: improve services for patients with cancer experiencing DV

### Methods: The Screening Protocol

- Developed by the task force
- Called for screening all female patients for DV, regardless of disease status
- Screening conducted by nurse practitioners and colposcopy nurses when getting the patient’s history
- Staff asked to screen patients every three months
- Screening results documented on screening record, a paper form attached on top of all other documents on inside of patients’ charts
- Patients disclosing past or current abuse referred to the gynecologic oncology social worker and on-site DV program

### Methods: Medical Record Abstraction

- Data abstracted from patient charts scheduled for gynecologic oncology or colposcopy appointments 6 months and 12 months following implementation of screening program
- Random sample of 250 medical record numbers
- Abstractions completed on 204 charts
- Abstraction data
  - Whether DV screening record present and, if so, whether any documentation was made
  - Patient demographics (age, race/ethnicity, primary language, type of health insurance, marital status)
  - Visit history (date of initial clinic visit, date of most recent visit during the 12-month time period, number of visits during the time period, and usual provider)
  - Clinical information (type of cancer, stage at diagnosis, pain level, and cancer status at the most recent visit during the 12-month time period)

### Methods: Nurses Survey

- Purpose of survey: understand barriers to DV screening and documentation as well as potential solutions to those barriers
- Staff members conducting the DV screening asked to complete survey
  - What do you see as the main barriers to screening our patients for domestic violence?
  - Do you have any suggestions for things we can do or change to facilitate domestic violence screening?
  - What do you see as the main barriers to documenting screening?
  - Where is it most convenient for you to document domestic violence screening?
  - Do you have any other comments on domestic violence screening or documentation?
Findings: Medical Record Analysis

• Majority (63%) of charts reviewed had screening record present but only 7% \( (n = 13) \) of all charts, or 12% of charts with a screening record, had DV screening documented on the form
  – Of the 15 charts with screening documentation, 13 patients reported no abuse, 1 reported past abuse by an ex-partner, and 1 reported childhood abuse
• Patients with DV screening documentation more likely than those without documentation to have had ≥ five clinic visits during study period \( (p = 0.03) \)
• Patients with DV screening documentation did not differ significantly from patients without screening documentation in regard to demographics, visit history or clinical information

Findings: Nurses Survey

• Barriers and potential solutions
  – Forgetting to screen or document
  • Add screening questions to patient intake or follow-up forms
  • Send e-mail reminders to nurses
  • Ask medical assistants to check charts and indicate to nursing staff whether screening was needed
  – Discomfort with screening
    • Intermittent, mandatory DV training
  – Concerns about confidentiality (patients often accompanied by family or friends; concerns that documentation might end up “in the wrong hands”)
    • Documentation may be most convenient and confidential in patients’ electronic medical record
  – Other barriers
    • Time constraints
    • Patients have “more pressing issues”

Implications

• This study one of the first to evaluate implementation of routine screening for DV in an oncology clinic
• Despite efforts of highly motivated task force, only 12% of patients’ charts in the gynecologic oncology clinic had DV screening documentation
• Several barriers, solutions identified
  • Although feasibility of screening patients who are severely ill requires further investigation, no barriers were encountered that would preclude DV screening of patients with cancer

Acknowledgments

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Contact Information

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Domestic Violence in Healthcare

• Need identified through multiple sources
• Journal club for nurses
• Findings reported to hospital Environment of Care committee
• Domestic violence task force formed & multi-disciplinary
• Educational programs launched
• Outcomes measured
Domestic Violence in Healthcare: Be Part of the Solution!
Moffitt Cancer Center
Nursing Orientation
October, 2009

Behaviors we might see in a healthcare setting

- Fear or visual appearance of distress
- Avoids eye contact
- Hand/voice tremors
- Refuses to change into exam gown
- Visible shaking, flinching, or trembling when touched for exams
- Seems overly anxious when assessed or examined and partner/caregiver is present
- Partner/caregiver is overprotective, controlling, or dominates the visit
- Partner/caregiver refuses to leave patient alone during examination


What Health Outcomes Stem from Abusive Situations?

- Impaired immune system from activated stress system
- Some cancer risk factors related to: smoking, alcohol use, and unhealthy diet
- Exposure to HPV/STD from non-monogamous male partner
- Preventative healthcare may have been denied/delayed


What can I do?

- Do assessment for abuse in private area- ask neutral questions
- Make it a part of routine screening & new patient packets
- Offer non-judgmental support
- Provide resources for patient- they must decide what to do, if anything, with them
- Know the laws of the state you practice in- what must you report??

Other Behavioral Indicators of Abuse.... When Domestic Violence Comes to Work

- Assaults or bullies others
- Threatens self-harm
- Depression or hopelessness
- Excessive crying
- Bizarre behavior
- Delusions or hallucinations
- Poor self-control
- Calls off work often

Domestic Violence Assaults in the Workplace Study October 2009, PreventIfBlack
Violence Against Women. Issues in Response: U.S. Department of Justice, Federal Bureau of Investigation

What if it is myself or a colleague??

- You are NOT ALONE- there is help! We want you to be SAFE!
- Lend a non-judgmental ear- it may be the first cry for help the person has made
- Each unit has a domestic violence resource manual with multiple contacts for assistance. Security also has referral numbers for the shelters & community resources (free)
- Notify your manager and security if you feel threatened at work- set up a safety action plan
- Access the Employee Assistance program (free) 1-800-788-5614 code: 45751
- Access the USF Advocacy program (free) 813-974-5757
**Saturday, November 13**

**Domestic Violence Task Force**
- Nursing
- Security
- Human Resources
- Palliative/ Psychosocial Care
- Social Workers
- Employee Health
- Nutrition Services
- Legal
- Public Relations & Marketing
- Senior Management/ Administration
- Lifetime Cancer Screening
- Pastoral Care
- Business Center
- Patient Relations

**Task Force Tasks**
- Develop new employee safety plan - make sure hospital standards are current/ consistent with state laws
- Educate areas where there is an identified need
- Stall cards & resource manuals
- Community partner development
- Employee wellness fair
- Reach out to the neighboring healthcare institutions
- Include domestic violence information in yearly employee mandatory education

**Outcomes**
- May-December 2009 - 716 direct contacts
- 5 employees referred to security for safety plans
- Community partnerships developed with 7 agencies
- Increased violence reporting - including interpersonal relationship violence & proactive domestic violence injunctions

**Moving Forward**
2010- Joint Commission Sentinel Event Alert: Preventing violence in the healthcare setting
- Expand education to include workplace violence awareness
- Develop confidential reporting system for employees
- Management/ stakeholders buy-in
- Examine the relationship between workplace environment & worker behavior
- Include more Spanish resources for patients/ staff
- Cultural diversity programs
- For more information: [http://www.jointcommission.org](http://www.jointcommission.org)

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**Oncology Nursing Society Institutes of Learning**
November 12–14, 2010
Don’t Miss the Mark: Biomarkers and Cancer

This session has been developed in collaboration with the Targeted and Biological Therapies Special Interest Group.

Session Description: Gain an understanding of the evolving role of biomarkers in the treatment and prognosis of cancer. As new information is discovered about tumor cell biology and behavior, decisions about cancer treatment and patient education will be necessary for clinical decision making.

Target Audience: Advanced practice nurses

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 2.5 continuing nursing education credits for successful completion of this mini-institute.

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Full Disclosure:
Nothing to Disclose

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Full Disclosure: Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this mini-institute.

Objectives:
By the end of this presentation, participants will be able to:
1. Distinguish between biomarkers, proteomics, and genomics.
2. Describe the role of predictive and prognostic biomarkers.
3. Describe how ethnicity and acculturation to a westernized diet impact cancer risk and detection using biomarkers.
4. Discuss the clinical implications of 2 biomarkers in breast cancer, non-small cell lung cancer (NSCLC), or colorectal cancer.

Content Outline:
I. Biomarkers, proteomics, and genomics
   A. Predictive
   B. Prognostic
II. Clinical applications: family history taking, risk calculation, patient education, genetic testing, impact on other family members, and follow-up
   A. Breast cancer
   B. NSCLC
   C. Colorectal cancer
III. Case study: application of concepts

Bibliography:
in the treatment of colorectal cancer. Clinical Colorectal Cancer, 8, 15–21.
Richman, S.D., Seymour, M.T., Chambers, P., Elliott, F., Daly, C.L., Meade, A.M., . . . Quirke, P. (2009). KRAS and BRAF mutations in advanced colorectal cancer are associated with poor prognosis but do not preclude benefit from oxaliplatin or irinotecan: Results from the MRC FOCUS trial. Journal of Clinical Oncology, 27, 5931–5937.
From Genetics to Genomics to Proteomics:  
What is the difference?  
What do Nurses Need to Know?  
Are there nursing best practices for application of genomic science and technology?

Seeking a Cure  
• The gap from bench to bedside  
• The emerging goal of individualized medicine  
• The business of biomarkers  
  • Clinical trials  
  • Drug development  
• The science of biomarkers  
  • Genomics  
  • Proteomics  
  • Metabolomics

Genomics  
• The Human Genome project:  
  • Gene mapping  
  • DNA sequencing  
  • Nature vs. nurture in carcinogenesis  
• Epigenetics and cancer  
• The development of DNA and RNA biomarkers that enable cancer prevention, diagnosis, and treatment  
  • Individuals  
  • General populations

Proteomics  
The study of proteins, how they are modified, when and where they are expressed, how they are involved in metabolic pathways, and how they are interact with each other.  
• The development of protein biomarkers  
  • Cells are proteins  
  • Proteins are a good target for most drugs  
  • Insulin, estrogen, cell surface antigens, VEGF, etc

Metabonomics  
Genomics + Proteomics = Metabonomics  
• Metabolic responses to drugs  
• Metabolic responses in the presence of environmental changes  
• Metabolic responses in the presence of disease  
Analysis of metabolites and evaluating individual toxicities to drugs

Biomarkers  
Measurable indicator(s) of normal or pathogenic processes  
Can be predictive, prognostic, preventative (for use as screening in high risk populations), diagnostic, and/or therapeutic.  
Future perspectives of biomarkers:  
• clinical research  
• FDA: identification and qualification of biomarkers

**Genetics**
DNA Double Helix
- Chromosome Painting
- Karyotyping for "Birth Anomalies"
- Developmental Disabilities
- Cancers

**Genomics:**
is the study of DNA sequences and the processes that lead to the creation of proteins from Genes as influenced by: chemical modifications, transduction signals, regulator sequences & enzyme restriction cut sites

**Proteomics**
- Most disease processes manifest themselves at the level of protein activity
- It is now feasible to perform mass screening of proteins and this is creating a revolution in proteomics.

**Aims of Proteomic Research**
- Target identification for drug discovery and drug development
- Diagnostics (e.g. tumor markers)

**Why Proteome Research?**
- The level or degree of gene expression does not represent the amount of active protein in a cell.
- Gene sequence does not describe post translational modifications, which are essential for the function and activity of a protein.
- Genome does not describe dynamic nature of protein structure or function.

**Why Do Nurses Need to Know Genetic Science?**
- Application of Genetic Science in Nursing Practice and in Clinical Trial Research
- Specialized Roles for Nurses in Clinical Practice & in Clinical Research settings that Apply Genetic Science
- Teach Genetic Science to Families and Communities including relevant Healthcare Policy (GINA Act, 2009)
- Understand and Explain how Genetic Science is Changing how we Think about Human Health, Disease, and Treatments
ONCOLOGY NURSING SOCIETY
http://www.ons.org/Publications/Positions/GeneticCounseling/

Oncology nursing practice related to cancer genetics includes three levels:
- The general oncology nurse
- The advanced practice oncology nurse
- The advanced practice oncology nurse with specialty training in cancer genetics and genomics.

Understanding Cancer Biomarkers

Biomarkers Use Genetic, Genomic, and Proteomic technologies to identify relevant molecules controlling proliferation, differentiation, angiogenesis or immune response.

Prognostic biomarkers provide information regarding disease outcome irrespective of therapy.

Predictive biomarkers provide information regarding response to therapy.

Cancer Case Study

Julie a 40-year-old, non-smoking woman who presented to her local hospital ED with significant back and left hip pain
MRI of the hip revealed a lytic lesion and fracture of the femoral neck
CT scan of the chest revealed a 2x2.5 cm right upper lobe lung mass and a right breast mass measuring 2x2.5
Physical exam revealed a palpable right supraclavicular lymph node
Julie underwent an excisional biopsy of this node. The oncology surgeon ordered gene and protein microarray analysis to diagnose the type of cancer, stage of progression, and prognosis.
Did the cancer originate in the breast or the lung?

The Need For and Limitations of Breast Cancer Biomarkers

- 200 breast cancer markers, reported in studies between Jan 2003 and May 2010 (ASCO).
- They provide information regarding molecular features, stage of breast tumors, and possible treatments.
- They still do not enable accurate predictions as to which early stage breast cancers will progress or recur if removed surgically.
- 40% of women diagnosed with breast cancer die from the disease regardless of the treatment regimen, and there are no reliable biomarkers to predict the fate of this subset of breast cancers as of yet.

Prognostic Breast Cancer Biomarkers

- Elevated proliferation indices such as Ki-67 and proliferating cell nuclear antigen (PCNA)
- ER and PR overexpression
- Oncogene overexpression such as c-erbB-2, TGF-a and EGFr
- Indicators of apoptotic imbalance including overexpression of bcl-2 and bax/bcl-2 ratio
- Her2/neu gene expression

- 70-80% of patients receiving treatments could have survived without them, as those patients presumably have a less aggressive form of breast cancer.
- Some women receive chemotherapy or anti-hormone therapy, which both can reduce the risk of metastasis by one third but they also can have dangerous side-effects.

ER/PR by IHC tamoxifen
HER2 by IHC trastuzumab
Disordered cell signaling such as p53 nuclear protein accumulation
- Alteration of differentiation signals such as overexpression of c-myc, UBE2C and related proteins (aggressive cancers)
- Loss of cell differentiation such as TGF-β II receptor and retinoic acid receptor
- Alteration of angiogenesis proteins such as VEGF overexpression.

Non Small Cell Lung Cancer
Lung cancer is the leading cause of cancer death for men and women
Across all stages and all types, overall 5-year survival is 15%
Non-small cell lung cancer (NSCLC) accounts for approximately 85% of lung cancer cases

Markers of Interest for EGFR TKIs: EGFR
- EGFR expression by IHC
  - Least helpful
- EGFR gene copy number by FISH
- EGFR mutations
  - Sensitizing: exons 19, 21, and others
  - Predictive of resistance: exon 20, T790

Molecular Targets for Therapy
(FDA-approved therapies for solid tumors)
- Extracellular targets
  - EGFR/HER (cetuximab, panitumumab, trastuzumab)
  - VEGF (bevacizumab)
  - HER2 (trastuzumab)
- Intracellular targets
  - EGFR (erlotinib)
  - VEGFR (sorafenib, sunitinib)
  - mTOR (temsirolimus)
  - PDGFR (sorafenib, sunitinib)
  - RAF/MAP kinase (sorafenib)
  - HER2/EGFR1 (lapatinib)
  - C-kit (sunitinib)

Implications for NSCLC Treatment
- Bevacizumab-containing regimens are now the standard of care for front-line therapy in select patients with metastatic non-squamous NSCLC
- Median survival with metastatic NSCLC is now greater than 1 year
- Results from studies with bevacizumab in patients with CNS metastases are pending (PASSPORT)
Biochemical Markers in Colorectal Cancer

- **Prognostic Markers**
  - Microsatellite instability (MSI)
  - Loss of heterozygosity of 18q and 17p

- **Predictive Markers**
  - Microsatellite instability (MSI)
  - Loss of heterozygosity of 18q and 17p
  - KRAS
  - BRAF
  - UGT1A1*28
  - DVD deficiency
  - ERCC-1

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Position Statements on KRAS Testing

- American Society of Clinical Oncology (ASCO) in 2006 recommended against KRAS testing as data was considered "heterogeneous and often conflicting."
- ASCO (2008) clinical opinion unequivocally recommending KRAS testing in patients with mCRC to select patients appropriate for therapy with cetuximab or panitumumab.
- ASCO states that patients with CRC and KRAS mutations should be spared the toxicity and economic cost of an ineffective therapy.
- National Comprehensive Cancer Network (NCCN) in 2009 recommended KRAS testing patients with KRAS mutations should not be treated with cetuximab or panitumumab either alone or in combination with other drugs.

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KRAS and Relationship with EGFR

- Ras proteins have key position in EGFR signaling pathway
- KRAS functions downstream of EGFR, thus controlling responses to EGFR activation/inactivation
- Activation of KRAS caused by mutations (“turned on all the time”) leads to unchecked tumor growth and resistance to EGFR inhibition
- EGFR inhibitors bind to the extracellular domain, prevent ligand binding, and inhibit activation of signaling cascades
- EGFR inhibition can lead to cell cycle arrest and apoptosis
- KRAS biomarker of response to anti-EGFR therapies
- EGFR expression is not correlated with response to EGFR inhibitors

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Treatment with EGFR Inhibitors

- Presence of WT gene does not dictate that anti-EGFR therapy will be effective
- 40-60% of patients with KRAS WT do not respond to EGFR MoAbs
- Existence of additional molecular markers within pathways involved in resistance
  - BRAF
  - PI3K
  - PTEN
  - EGFR copy number

---

BRAF

- A member of the RAF family which acts in the signaling cascade with KRAS
- In patient with WT KRAS, may have BRAF mutation
- Mutation rate for BRAF is 5-10%
- Best described and most prevalent mutation is V600E
- A number of studies have reported that patients with BRAF mutations do not respond to cetuximab
- Recent study also reported shorter PFS and OS in BRAF-mutated tumors
- Clinical data thus far strongly indicate that mutation in BRAF associated with resistance to anti-EGFR therapies
- Role of BRAF mutation as possible prognostic marker is emerging

---

Clinicopathological Features of Tumors and BRAF V600E Mutation

- Mutations are 5-10 fold more frequent in tumors with:
  - Infiltrating lymphocytes
  - Location in the proximal colon
  - Poor histological grade
  - Mucoepidermoid appearance
- Tumors were 10-20 fold more likely to show:
  - Microsatellite instability
  - Frequent DNA methylation
- BRAF mutations are found only in MSI-positive sporadic tumors and not MSI-positive tumors associated with Lynch Syndrome.


UGT1A

- ~10% of North American population have polymorphism in the UGT1 enzyme.
- Significant association of UGT1A1*28 with frequency of grade 4 neutropenia as well as trend toward severe diarrhea
- Label warning: patients homozygous for UGT1A1*28 allele are at high risk for severe neutropenia-implement a lower initial dosing schedule
- Conflicting data as a number of studies have failed to demonstrate UGT1A1*28 polymorphism with increased toxicity
- Limited utility in clinical practice as result of recent data and less hematologic toxicity with lower doses of irinotecan in combination chemotherapeutic regimens


ERRC1 Gene Expression

- Excision repair cross-complementing group 1
- Correlation of ERCC1 levels with clinical outcomes in patients receiving platinum-based regimens
- Oxaliplatin works by reacting with DNA to cause platinum-DNA (pt-DNA) cross-links blocking DNA replication and transcription, resulting in extensive DNA damage and apoptosis
- Nucleotide excision repair (NER) pathway primarily responsible for removal of pt-DNA adducts
- Resistance to platinum has been associated with enhanced tolerance to pt-DNA adducts, decreased drug accumulation and an increase in DNA repair
- ERCC1 plays a key role in repair of DNA damage from platinum


Genomic Instability in CRC as a Biomarker

- Microsatellite instability (MSI) status
- Chromosomal instability with deletion of chromosome 18q and 17p (loss of heterozygosity [LOH] status)

Microsatellite Instability (MSI)

- Microsatellites are repeated sequences of DNA (e.g. CACACA)
- A condition involving mutations in these repetitive DNA sequences that results when there is inactivation of the DNA mismatch repair (MMR) system
- These repetitive sequences accumulate errors and become longer or shorter (have insertion/deletion errors) when the mismatch repair (MMR) genes are not functioning properly
- Proteins from MMR genes (e.g. MLH1 or MSH2) act to repair nucleotide mismatches, if inactivated, MSI can result
- Germline mutations associated with Lynch Syndrome OR sporadic mutations from sporadic colorectal cancers with defective expression of MMR genes
- Present in ~15% of patients with sporadic CRC; ~90% of patients meeting Amsterdam Criteria have MSI

Assessing MSI Status

- Assesses the length of 5 microsatellites or more using tumor DNA and for comparison normal DNA.
- MSI status:
  - High-tumors having changes in the length of at least 2 of the 5 (>20%) microsatellites in tumor DNA versus normal DNA
  - Low-tumors having changes in the length of 1 of the 5 (≤20%) microsatellites
  - Stable-tumors with no changes in the length of the microsatellites
- Some studies have associated with improved survival

1. Rodríguez-Bigas M et al. 1997. / Natl Cancer Inst 89:173A

Loss of Heterozygosity (LOH) of 18q and 17p

- Loss of heterozygosity-loss of normal function of one allele of a gene in which the other allele was already inactivated
- Deletions involving chromosome 18q and 17p occur > 70% of CRC
- Retention of 18q alleles in MSS tumors-favorable outcome after 5-FU regimen for stage III CRC
- 18q loss appears to have a worse disease-free and overall survival
- A recent large prospective study did not find any prognostic significance of 18q loss of heterozygosity in patients with non-MSI-H CRC
- ECOG 5202-biomarker driven clinical trial randomizing stage II disease based on MSI and 18q


Treatment Implications of MSI Status

- Recent meta-analysis evaluating MSI status and efficacy of 5-FU based chemotherapy
- 3690 patients with Stage II or III CRC
- 24% had MSI-H tumors
- Regardless of whether treatment with or w/o chemotherapy, patients with MSI-H had no significant difference in recurrence free survival (HR, 0.96; p=.86) or overall survival (HR, 0.70, p=.12)
- Patients with MSS-CRC did benefit from 5-FU based chemo with significant difference in recurrence free survival (HR, 0.77, p=.001)


Characteristics of MSI-Positive and LOH-Positive CRC Tumors

**Microsatellite Instability-Positive**
- Present in 15-20% of cases
- Diploid
- Allelic loss not frequent
- Rare mutation of APC and p53 genes
- Frequent mutation: BRAF
- Defective DNA mismatch recognition and repair system (MLH1, MSH2, MSH6, MSH3)
- Genetic instability
- Mally locate in proximal/right colon
- Improved survival
- Chemosensitivity?

**Loss of Heterozygosity-Positive**
- Present in 80-85% of cases
- Hyperploid
- Frequent allelic loss (17p, 18q, 5q, 8p, 22q)
- Frequent mutation APC and p53 genes
- Frequent mutation:KRAS
- Chromosomal instability
- Mainly located in distal/left colon

Laurent-Pag & Lionne. 2005. JNM
Cancer Patients Need Beauty Sleep Too!

**Session Description:** Come to this session, where speakers will share nonpharmacologic strategies that have been proven effective in improving the quality and quantity of sleep in hospitalized patients.

**Target Audience:** Frontline nurses, nurse managers, and nurse educators

**Level of Content:** Introductory

**Content Area:** Clinical Practice

**Continuing Nursing Education:** Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

**Coordinator/Speaker:**
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**Full Disclosure:**
Nothing to Disclose

*Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.*

**Speaker:**
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Nurse Clinician V
University of Texas Medical Branch at Galveston
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**Full Disclosure:**
Nothing to Disclose

*Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.*

**Objectives:**
By the end of this presentation, participants will be able to:
1. Describe the purpose of sleep and rest.
2. Identify the barriers to restful sleep for hospitalized patients with cancer.
3. List methods to enhance patients’ ability to sleep.

**Content Outline:**
I. Goal of sleep
   A. Awaken refreshed, capable of moving throughout the day feeling alert without effort
   B. Brief review of the physiology of sleep
      1. Review of literature
         a. How much sleep do you need?
         b. What are the contributing factors to prevent sleep?
         c. Are the needs of patients with cancer any different?
   C. Methods that promote adequate sleep and rest
      A. Discuss barriers to sleep in hospital.
      B. Discuss sleep promotion strategies.
         1. Assessment of sleep history and primary sleep disorders
            a. Identify underlying medical conditions which contribute to poor sleep.
            b. Snoring, COPD, CHF
         2. Assessment of physical needs
            a. Pain control
            b. Environmental modifications
            c. Promotion of comfort and relaxation
      3. Translating evidence into practice
         a. Educate healthcare workers about sleep physiology, the value of uninterrupted sleep, and how nursing staff impacts patients’ sleep (negatively versus positively).
         b. Formulate sleep promoting protocol on unit to address effects of oncology treatment plans.
         c. Develop a nursing practice standard order set for “quiet time protocol.”
         d. Include sleep hygiene as part of nursing assessment during hospital admission process.
         e. Develop a fact sheet about sleep: “How to get a good night’s sleep.”
         f. Participate in the design and development of nursing research to study sleep promotion in hospitalized adult patients with cancer.

**Bibliography:**


Question:

In hospitalized adult cancer patients, what non-pharmacologic strategies improve the quality & quantity of sleep?

Definitions

- Sleep
- Quantity of Sleep
- Quality of Sleep
- Sleep Deprivation
- Sleep Disturbances
- Sleep-Wake Disturbances

Purpose of Sleep

- Awaken refreshed, renewed
- Able to move through the day alert, without effort

PHYSIOLOGY OF SLEEP

- 2 distinct sleep states
  - Non-REM sleep
  - REM sleep
- Generally adults need 7-8 hrs
- Lowest mortality & morbidity

Inadequate Sleep

- Short term restriction of sleep
  - HTN, impairment of glucose control, increased inflammation, activation of the sympathetic nervous system
- Sleep is valuable component of healthy lifestyle

Barriers to Sleep:

- Anxiety
- Pain
- Environment
- Sleep disorders
- Medical conditions

Alvarez & Ayas, 2004; National Sleep Foundation

BARRIERS TO SLEEP: IN CANCER PATIENTS

- Pain
- Fatigue
- Sleep-Wake Disturbances
- Side-effects of treatment
- Hospital admissions

Barick, et al., 2009; Battista, 2010; Bowman, A.M., et al., 1998; Gibbons, et al., 2009; Oh, et al., 2010

BARRIERS TO SLEEP: IN CANCER PATIENTS (CON’T)

Disease process

Fatigue

Sleep-wake disturbance

Gibbons, et al., 2008; Kwakkelboom et al, 2010; Zee & Ancoli-Israel, 2009

BARRIERS TO SLEEP: IN CANCER PATIENTS (CON’T)

Cancer-related fatigue

Sleep-wake disturbances

Gibbons, et al., 2008; Kwakkelboom et al, 2010; Zee & Ancoli-Israel, 2009

BARRIERS TO SLEEP: IN HOSPITAL SETTING

- Pain causing procedures
- Side effects of treatment
- Disturbances day & night
- Hospital noise

Redeker, 2004; Tembo & Parker, 2009

BARRIERS TO SLEEP: HOSPITAL NOISE

Max 30 decibels in hospital rooms (World Health Organization)
45 decibels during day & 35 decibels at night for indoor activity (Environmental Protection Agency)

---Versus---

75 decibels during day and 60 decibels at night (Gardner, et al., 2005)

SEDATIVE-HYPNOTICS?

- Non-pharmacologic approaches preferred
- Sedatives increase risk:
  - Falls
  - Delirium
  - Functional decline

Bartick, et al., 2008; Nagel, et al., 2002
Methods to Promote Sleep

Assess sleep history

- Determine sleep pattern
- Quality/quantity
- Continue to assess sleep pattern following admission

Assess physical needs

- Pain control
- Symptom management
- Positioning with pillows
- Personal bedtime rituals

Promote comfort & relaxation

- Modify environment
- Minimize interruptions
- Increase daytime activity
- Explore activities to enhance relaxation
- Develop sleep promotion plan
- Cognitive behavioral therapy

Cognitive Behavioral Therapy

- Interventions to change perceptions and beliefs
  - Patients taught how thoughts affect feelings and behavior
- Combination of cognitive and coping strategies
  - Guided imagery
  - Breathing exercises
  - Meditation

Translating Evidence into Practice
Limited Nursing Research

- Limited information on hospitalized cancer patients
- In general, most effective strategies take into consideration patient preferences, sleep pattern, and combined interventions

Educate Healthcare Workers

- Sleep physiology
- Value of uninterrupted sleep
- Nursing practices which impact patient’s sleep
- Methods to enhance sleep

Nursing Interventions

- Examine what nurses can do independently to promote sleep
  - Quiet time
  - Lighting
  - Cluster care
  - Anticipate needs
  - Massage/back rub

Develop Fact sheet: “How to get a good night’s sleep”

- Effects of disease
- Effects of treatment
- Value of interrupted sleep
- Methods to enhance sleep

Develop sleep promoting protocol

- Address effects of oncology treatment plans
- Include sleep hygiene in admission assessment
- Nursing practice standard order set for “quiet time”

Educate Patients & Care-givers

- Sleep physiology
- Value of uninterrupted sleep
- Methods to enhance sleep
- Cognitive behavioral therapy
- Environmental changes
Nursing Research

- Participate in design & development of study
- Sleep promotion in the hospitalized adult cancer patient
Session Description: This session will provide you with the fundamentals to identify the patient who is experiencing cardiopulmonary complications and the interventions needed to manage this oncologic emergency to prevent a life-threatening event. Speakers will also address quality-of-life issues in the management of malignant pleural effusion.

Target Audience: Experienced oncology nurses, advance practice nurses, and nurse educators with experience caring for patients with thoracic complications of cancer

Level of Content: Advanced

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Estimated # of minutes of Pharmacology Content to be presented: 10

Coordinator/Speaker:
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Full Disclosure:
Nothing to Disclose

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Full Disclosure:
Nothing to Disclose

Objectives:
By the end of this presentation, participants will be able to:
1. Explain the pathophysiology of pleural effusions.
2. Describe the clinical presentation and discuss diagnostic workup of the patient with malignant pleural effusion.
3. Generate a nursing and medical management plan for the patient with malignant pleural effusion.

Content Outline:
I. Pleural effusion
   A. Definition, incidence, and risk factors
   B. Pathophysiology
   C. Differential diagnosis
      1. Transudate
      2. Exudate
II. Clinical presentation
   A. History
   B. Physical examination
III. Diagnostic evaluation
   A. Radiographic tests and findings
   B. Thoracentesis
   C. Fluid analysis
      1. Light’s criteria
   D. Surgical interventions
   E. Patient education
IV. Management
   A. Multimodality care
   B. Treatment modalities
      1. Therapeutic thoracentesis
      2. Pleurodesis
         a. Talc
         b. Bleomycin
      3. Chest tube and chronic indwelling catheter
         a. Denver PleurX
         b. Bard
      4. Pleuroperitoneal shunt
      5. Surgical modalities
      6. Medical modalities
         a. Chemotherapy
         b. Radiation
      7. Symptom management
V. Quality of life
   A. Side effect and symptom management
   B. Education and self-care management
VI. Case study
Bibliography:
Incidence

- Approximately 150,000 cases annually
- Most common causes:
  - Cancer
  - Congestive heart failure (CHF)
  - Pneumonia

Incidence

- Cancer
  - 42-77% of all exudative effusions
  - 50% of patients will develop malignant pleural effusion (MPE) at some point in their disease course
  - Incidence by cancer: lung (30%), breast (25%), lymphoma (25%)
  - Higher incidence in women
  - Median incidence: 4 months

Risk Factors

- Malignancy
- Treatment of malignancy
  - Radiation
  - Chemotherapy
- Concurrent nonmalignant disease

Paramalignant Effusions

<table>
<thead>
<tr>
<th>Cause</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation</td>
<td>Early: pleuritis</td>
</tr>
<tr>
<td></td>
<td>Late: fibrosis, constrictive pericarditis, vena caval obstruction</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Methotrexate, procarbazine, bleomycin, cyclophosphamide, bleomycin</td>
</tr>
<tr>
<td>Post obstructive</td>
<td>Parapneumonic effusion</td>
</tr>
<tr>
<td>pneumonia</td>
<td></td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>Hypercoagulable state</td>
</tr>
<tr>
<td>Chylothorax</td>
<td>Thoracic duct obstruction related to lymphoma</td>
</tr>
<tr>
<td>Hypoalbuminemia</td>
<td>Associated anasarca</td>
</tr>
<tr>
<td>(serum albumin &lt;1.5)</td>
<td></td>
</tr>
</tbody>
</table>

Pathophysiology

- Pleura—two layers
  - Visceral: adheres to and encases lung
    - Blood supply: supplied by bronchial circulation
    - Lymphatic channels present
    - No nerve endings
  - Parietal: lines mediastinum, diaphragm, and chest wall
    - Blood supply: intercostal arteries
    - Nerve endings present: produces referred pain in chest wall, shoulder and abdomen

American Thoracic Society (ATS), 2000
ATS, 2000
ATS, 2000
ATS, 2000
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Pathophysiology

- Pleural space: potential space between two layers
  - Contains 5-15ml fluid, serves as lubricant
  - Fluid exchange: 100-200 ml/day
  - Fluid produced by systemic capillaries, absorbed by pulmonary capillaries and lymphatics of visceral pleura


- Pleural effusion: fluid production>fluid removal
  - Increased production of fluid in normal capillaries
  - Capillary leak—increased fluid production, increased microvascular pressure
  - Decreased lymphatic function in pleural space= decreased fluid removal
  - Decreased plasma oncotic pressure=increased accumulation in pleural space


Malignant Pleural Effusion

- Obstruction of pleural/pulmonary lymphatic system by tumor/pleural implants

- Tumor cell suspension
  - Shed from pleura, grow freely in pleural space
  - Associated w/ ovarian and lung cancers

- Direct invasion of blood vessels/tumor-induced angiogenesis
  - Pleural effusions and vascular endothelial growth factor (VEGF)

  Antunes, et al., 2003

Clinical Presentation

- 25% found incidentally on xray or CT scan--asymptomatic
- Dyspnea at rest and exertion
- Dry, non-productive cough
- Chest pain
- Anxiety
- Feeling of suffocation
- Malaise/weight loss
- Hemoptysis

  Mechem, 2009; ATS, 2000

Diagnostic evaluation

- Chest xray
  - Lateral decubitus
  - Upright
  - >1500ml: opacification of one lung, mediastinal shift

- Computerized tomography (CT) of the chest

  Moffett, Moffett, and Laber, 2009.

Physical Examination

- Usually no findings with small effusions
- Dullness to percussion
- Decreased/absent breath sounds
- Decreased vocal fremitus, egophony, bronchial breath sounds
- Tachypnea/hypoxia/labored breathing/cyanosis
- Accessory muscle use
- Restricted/asymmetric chest wall expansion
- Left shift or PMI (for right sided effusions)
- Tracheal deviation to unaffected side
- Lymphadenopathy
- Cardiac: 53 gallop, JVD, peripheral edema

  Story, 2006.
Diagnostic evaluation

- Ultrasound
  - Useful to evaluate location of fluid and marking for thoracentesis
- Positron Emission Tomography (PET)
  - Duysinx, et al (2004) demonstrated 96.8% sensitivity, 88.5% specificity for identifying malignancy
  - Talc pleurodesis produces pleural thickening, increased fluorodeoxyglucose (FDG)—mimics recurrent disease
- MRI

Heffner, 2008.

Diagnostic evaluation

- Thoracentesis
  - Indication: new finding of pleural effusion
  - Contraindications: minimal effusion, therapeutic anticoagulation, mechanical ventilation
  - Complications: pneumothorax/hemothorax, empyema, spleen or liver laceration, postexpansion pulmonary edema
    - Several studies show decreased complication rate when using ultrasonographic guidance


Thoracentesis

- Ultrasound to mark site
- Universal “time-out”
- Local anesthetic to superficial and deep subcutaneous tissues
- Insert needle posteriorly at 6th to 7th rib space, aspirate fluid using suction
- Increased risk for reexpansion pulmonary edema with removal of large volumes
- Post-procedure chest x-ray


Transudates

- Transudative effusions: impaired reabsorption caused by an imbalance between hydrostatic and oncotic forces in pleural surface capillaries
- Capillaries impermeable to large positively charged proteins—retained in vascular space
- Characteristics:
  - Watery, clear, straw colored effusion
  - pH>7.4
  - Low protein
  - Typically nonmalignant

Light, 2002.
Exudates

- **Exudative effusions**: impaired reabsorption caused by pleural and lung inflammation
- Capillary leak caused by vascular injury, infarction, infection, inflammation, or tumor seeding—proteins (LDH, globulins, albumin) leak into tissues
- Characteristics:
  - High content of protein, cells, and cellular debris
  - Less watery, sometimes bloody appearance
  - pH < 7.3
  - Typically malignant


Fluid Analysis

- Color:
  - Purulence: empyema/infection
  - Milky/chylous: chylothorax
  - Bloody: cancer (47%), trauma (12%), pneumonia (10%), pulmonary embolism, postcardiac injury syndrome
  - Serous/straw-colored: transudate, nonmalignant
- Odor:
  - Putrid: anaerobic empyema
  - Ammonia: urinothorax

Light, 2002.

Fluid Analysis

- Protein, LDH, albumin-serum and pleural fluid
- Cell count and differential
- Cultures, gram stain
- Cytologic evaluation


Fluid Analysis

- Light’s Criteria for exudate(at least one present):
  - Pleural fluid protein/serum protein ratio >0.5;
  - Pleural fluid LDH/serumLDH ratio >0.6;
  - Pleural LDH > 2/3 upper limit of serum LDH
- Other rules:
  - Albumin to protein gradient >1.2—transudate
  - Two-test rule:
    - Pleural fluid cholesterol >450mg/dl AND Pleural fluid LDH >0.45X upper limit normal serum LDH


Differential Diagnosis

- **Transudate**
  - Congestive heart failure
  - Pericardial disease
  - Cirrhosis
  - SVC obstruction
  - Pulmonary embolism
  - Myxedema/hypothyroidism
  - Cachexia
  - Nephrotic syndrome
  - Extravascular migration of CVC

- **Exudate**
  - Malignancy
  - Mesothelioma
  - Infection/pneumonia: TB/bacterial/fungal/Viral
  - Sarcoidosis
  - Trapped lung
  - Radiation therapy
  - Chylothorax
  - Hemothorax


Cytology

- Most specific test
- Sensitivity: 40-87%
- Initial thoracentesis for large pleural effusions may be negative—dilutional effect. Repeat in a few days.
- Higher rates of diagnosis: adenocarcinoma (>70%)
- Lower rate of diagnosis: mesothelioma (10%), squamous cell CA (20%), lymphoma (25-50%), sarcoma (25%)

Light, 2002.
Sunday, November 14

**Treatment Modalities**

- **Goal:** relief of dyspnea
- **Observation:** for smaller, asymptomatic effusions
- **Therapeutic thoracentesis**
  - Generally no more than once weekly
  - Outpatient procedure
- **Chest tube drainage**
  - Loculated effusions
  - Large volume effusions with dyspnea/hypoxia and rapid reaccumulation (<30 days)
  - Trapped lung, lung expansion <2/3 after thoracentesis

- **Pleurodesis**
  - Ideal pleurodesis candidate:
    - Life expectancy >2-3 months
    - ECOG 0-2
    - Evidence of near complete re-expansion of lung after thoracentesis
    - Relief of symptoms after evacuation of pleural fluid vs. alternative causes of dyspnea
    - Absence of visceral pleural thickening and large intrapleural tumor masses

- **VATS pleurodesis/thorascopic pleurodesis**
  - General anesthesia
  - Allows wider access to pleural space
  - Can lyse loculations and adhesions, increased success rate
  - Better option for patients with trapped lung
  - Increased risk of pneumothorax
  - Morbidity 3-26%, mortality <1%

Heffner & Klein, 2008.

- **Chest tube insertion + pleurodesis**
  - Obliterating the pleural space with introduction of chemical agent into pleural space
  - Hospital stay: 4-8 days
  - Mechanism of action: varies based on agent used
  - Generally causes influx of macrophages, with rapid deposition of pleural fibrin and fibroblast proliferation—fibrosis of pleural space


- **Common agents used:**
  - Talc (success rate 70-100%)
  - Bleomycin (64-84%)
  - Doxycycline (60-81%)
  - Controversial as to which is best...
    - Cochrane Review (Shaw & Agarwal, 2004) showed talc to have the lowest chance of recurrence
    - Multiple studies show equal efficacy and increased patient comfort with use of small bore chest tube


- **Complications:**
  - Pain, fever, empyema, reexpansion pulmonary edema, pneumonia, arrhythmias, reaccumulation of effusion and respiratory failure

Heffner & Klein, 2008.
**Treatment Modalities**

- Chronic indwelling catheter
  - Outpatient placement of tunnel pleural catheter under ultrasound guidance
  - Indications: primary management, failed pleurodesis, trapped lung, ECOG >2, short life expectancy
  - Improves symptoms in 89% of patients, 43% achieved spontaneous pleurodesis w/o talc
  - Patient or caregiver can drain fluid at home
  - Complications: infection, occlusion, localized skin breakdown, tumor spread along catheter track

**Chronic Indwelling Catheter**

- Tenckhoff Catheter
- Denver PleurX® (Cardinal Health, McGaw Park, IL) – FDA approval for treatment of malignant pleural effusion
- Bard Aspira™ (Bard Access Systems, Salt Lake City, UT)
- Placed in similar fashion
- No head to head studies measuring efficacy

**Treatment Modalities**

- Pleuroperitoneal shunt
  - Not frequently used
  - Helpful w/ trapped lung and chylothorax
  - Placed during thoracoscopy under general anesthesia
  - Unidirectional pump chamber—moves fluid from pleural space to peritoneum
  - Manual compression 5–10min, 4 times daily
  - Complications: shunt failure (12%), fluid and protein loss

**Treatment Modalities**

- Pleurectomy/decortication
  - Removal of pleural lining and/or all or part of the lung
  - Use only if all other measures have failed AND good performance status
  - No advantage over chemical pleurodesis unless unresectable tumor found at time of thoracotomy
  - May be useful in mesothelioma
  - Complications: empyema, bronchopulmonary fistula, mortality 12%

**Treatment Modalities**

- Chemotherapy
  - Most effective in lymphoma, small cell lung cancer, germ cell tumor, and breast cancer
- Diuretics
  - Spironolactone, furosemide—cautious use with mild effusions
  - Will alter results of fluid studies
- Radiation
  - May help resolve effusions if mediastinal lymph node disease present

**Nursing Management**

- Monitor for signs of respiratory compromise
  - Hypoxia
  - Change in mental status/level of consciousness/increased anxiety
  - Increased shortness of breath/DOE
  - Change in sputum—amount or color
  - Chest pain
  - Clubbing, cyanosis

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*Heffner & Klein, 2008; Schneider, et. al (2003)*

*Walker & Bryden., 2010; Spector & Pollack, 2008,*

*Heffner& Klein, 2008; Genc, et al (2000); http://www.denverbio.com*

*Story, 2006*
Nursing Management

- Maintain optimal pulmonary status
  - Keep sats >92% (unless COPD)
  - HOB up
  - Energy conservation, rest periods
  - Incentive spirometry, deep breath and cough, postural drainage
- Pain management
- Chest tube/drain care and education

Case Study

- A 62yo female with metastatic breast cancer presented to the clinic with increasing dyspnea and fatigue over the last two days. She has received chest wall radiotherapy in the past and was recently started on exemestane. She is unable to lay flat because of increased shortness of breath, and has referred pain in the left shoulder. She has a h/o diabetes, HTN, cardiomyopathy (EF 15%) with a pacemaker and atrial fibrillation.

Summary

- Treatment modalities:
  - Thoracentesis
  - Pleurodesis (chest tube, VATS)
  - Chronic indwelling catheter
  - Pleuroperitoneal shunt
  - Pleurectomy
  - Performance status, life expectancy and expansion post thoracentesis important in choosing most effective treatment modality
- Nursing care: focus on maintaining stable cardiorespiratory function, pain control, and management of dyspnea to maintain patient’s quality of life.

Summary

- Malignant pleural effusion: an abnormal collection of fluid in the pleural space
  - Occurs when fluid production is greater than fluid reabsorption
  - Life threatening oncologic emergency; can lead to respiratory failure/arrest
  - Occurs in up to 50% of patients
  - Causes:
    - Malignancy
    - Treatment of malignancy
    - Paramalignant effusion
  - Generally associated with advanced disease

2010 NCCN guidelines; http://www.nccn.org

Story, 2006
Staff Retention: A New Discussion of an Old Problem

This session has been developed in collaboration with the Management and Program Development Special Interest Group.

Session Description: This presentation will discuss the organizational and individual themes that lead to positive staff retention.

Target Audience: All healthcare professionals

Level of Content: Intermediate

Content Area: Administration

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Coordinator/Speaker:
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Consultant
Scottsdale, AZ

Full Disclosure: Nothing to Disclose

Speaker: Diane Drexler, MBA, BSN, FACHE
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Diane.Drexler@ctca-hope.com

Full Disclosure: Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Discuss the accountabilities and competencies of the leadership team in promoting an environment conducive to staff retention.
2. Describe the link between self management and job satisfaction.
3. Describe the role of individual positivity in enhancing team performance.

Content Outline:
I. Leadership team and work environment
   A. Accountabilities
   B. Competencies
      1. Self awareness
      2. Personal examples of leading teams
II. Job satisfaction
   A. The role of positivity and team outcomes
   B. The role of stress in the workplace
      1. Being your best in any environment
         a. Energetics
         b. Compassion

Bibliography:


Staff Retention

- Chronic avoidable turnover is very costly in both direct dollars and in indirect negative consequences
- The loss of one well-trained nurse is estimated to be at least 1 and ½ times the individual's annual salary
- Negative impact on morale, patient, employee, and physician satisfaction

Whose problem is it?

Every one of us has both responsibility and accountability for turnover and the work unit culture and climate

In The Workplace Stress is Exhibited in:

↑ Staff turnover/burnout
↑ Absenteeism/sick leave
↓ Employee satisfaction
↓ Communication and teamwork
↑ Injuries/accidents
↓ Patient satisfaction
↑ Medical errors
↓ Quality
↑ Workers comp claims/costs
↑ HRA data (bp, cholesterol, BMI, etc.)

The Impact of Stress

- Health care costs in the US now exceed $2 trillion each year
  - Per citizen, US spends nearly double the next highest country (Japan)
  - US ranks #37 in health care quality
- Most costly health expenditures are for stress-related disorders
- 75-90% of all primary care visits are for stress-related conditions
- Large body of research clearly shows stress reduces overall well-being

Over Time, Chronic Stress Activation Produces an Ongoing Cascade of Undesirable Effects:

- Increased stress hormones
- Decrease immunity
- Increased anxiety and fear
- Hyper-vigilance (micro-management)
- Perceptual distortions
- Shortened emotional triggers
- Poor decision making [WHY SMART PEOPLE DO and SAY DUMB THINGS]
- Defensive aggression
- Regret, self-degradation
- And, over time, depression, helplessness...
Consequences

- “Stress” results in:
  - High, often hidden, avoidable health care costs for employees and patients
- Either we teach people to manage stress or stress will manage us by
  - Shortening and diminishing our quality of life and our effectiveness both as employees and human beings

Common Perception:

Some people seem to thrive on stress and think stress is good because it motivates:

- Stress can be a motivator, up to a point. However, studies have clearly shown that at a certain point – long before most people realize it – stress begins to diminish our performance and negatively impact our health
- One of the best ways we can help other people is to encourage them to take better care of themselves and to reward them when they do

How Stressed Are You?
Everyone responds to stress differently

Take this quick test to see if there are areas in your life where you are experiencing stress:

- I often am nervous, anxious or depressed
- I feel driven, hyperactive, and restless
- I tend to make snap decisions but with errors
- I have sleep problems
- I have repeated headaches or minor aches and pains
- I worry about work, job security, financial obligations or relationships
- I feel overly tired or fatigued

What are The Signs/Symptoms That You are Not Bringing Your Best Self To The Workplace?

- What do you notice about your:
  - Performance
  - Relationships
  - Physical/emotional/mental experiences
- What do others notice about you?

Emotional Fall Out

...Stress commonly expresses itself as resistance, tension, frustration and negative emotions such as anxiety, anger, sadness, loss of confidence, blaming and job dissatisfaction. Stress upsets our physiological and psychological equilibrium, keeping us out of sync

Our Health Care Imperative

- We must learn to manage our stress or stress will manage us by shortening and diminishing our quality of life and our effectiveness both as employees and human beings. We have research to prove that we can choose to manage our stress
- Our work demands won’t change, complaining about the demands doesn’t help and only contributes to higher levels of stress and a negative work environment (negative emotions are “contagious”)
Our Best Self
People who feel good about themselves produce good results

When Your Best Self is Out (and you are in the zone)
How Do You Work...Physically, Mentally, Emotionally?
How would other people describe you?

- Energized
- Connected
- Mindful
- Approachable
- Pleasant
- Joyful
- Happy

What Gets in the Way of Being our Best Self
Obstacles
- Deadlines/lack of time
- Other people
- Money/resources
- Staff shortages
- Unrealistic expectations

What is the Impact of These Obstacles?
Obstacles
- Deadlines/Lack of Time
- Other People
- Money/Resources
- Staff Shortages
- Unrealistic Expectations
Impact
- Anger
- Anxious
- Tired
- Headaches
- Confused
- Irritable

Autonomic Nervous System
Sympathetic Pathway—Accelerator
High Effort
Adrenaline
Parasympathetic Pathway—Brake
Low Effort/Relaxation
Acetylcholine

Hormonal System
Cortisol
DHEA
Emotional Hijacking

- Think about a time when your response to a person or situation was out of proportion and irrational
  - What happened?
  - What were the consequences?
  - Why did you do it?

Bosses Matter

- Having a good boss decreases your chances of getting a heart attack by 20% (considerate, specified clear goals and got changes implemented) Swedish Study by Anna Nyberg
- This 2008 study fits a long standing pattern; Researcher Richard Hogan found repeated consistent results in multiple locations and among many diverse occupations (1948,1958,1968,1998)
- Results indicated 75% of the workforce studied reports that their immediate supervisor is the most stressful part of their job
  - Reported in Good Boss, Bad Boss
    - Robert Sutton, PhD 2010

Managers are Chief Retention Officers

- Lead by example
- Rid the unit of toxic individuals
- Exhibit courage and vulnerability
- Work on “Being” as a leader versus “Doing”

Resilience

- Our goal is to have a resilient workforce (all of us)
- ASU (Arizona State University) has a Resilience Group that starts out with this working definition:
  “Resilience is the capacity to recover fully from acute stressors, to carry on in the face of chronic difficulties. To regain one’s balance quickly after losing it…”

Resilience is Our Goal

- John Reich, a social psychologist on the ASU team, adds this dimension:
  “At the heart of human adaptation is resilience, the ability to create a positive world for ourselves, often in the face of stressful life experiences, and the ability to resist being overtaken by negative experiences when they seem to be overwhelming”

Key Team MemberCompetencies

- Cultivate and grow your emotional intelligence in particular self awareness
- Cultivate authentic caring behaviors and compassion toward self and others
- Put people at ease, use humor, shift your perspective
- Consistently observe and ask yourself and others: Do I suck out team energy or boost it? Do my team colleagues feel energized when they spend time with me or drained?
- Take responsibility for your own emotional pollution or your enhancement of the team environment
- Don’t avoid conflict, demonstrate courage and speak your truth (crucial conversations/confrontations)…… “I feel like this……when you do that”
Leadership Imperatives

Be an excellent listener, be “present”
Do you know that everything you say and do as a leader is scrutinized (including the little things)
Do your staff feel you have their backs?
Do you put people first, paper second? Do you believe and demonstrate that you really do “care” about your team? Do you have their backs and fight for them when necessary? How do you demonstrate this?
How emotionally intelligent are you? (self awareness)
Do you have the courage and desire to change yourself?

Workplace Civility

• Back to basics
• Please, thank you and eye contact
• Helpful behaviors
• Smile
• You are always “on”
• Manners

The Good News:

We can learn to manage our stress, increase our resilience, improve our emotional intelligence, be better TEAM MEMBERS, improve job and life satisfaction!!

What is Emotional Intelligence?

• “The capacity for recognizing our own feelings and those of others, and managing emotions (stress) in ourselves and in our relationships”

Multiple Strategies for Managing Stress and Enhancing Our Resilience

• Traditional Strategies
  – Diet
  – Exercise
  – Rest
  – Bio Feedback
  – Medication
• Research strongly shows these external actions alone aren’t enough to have an optimum stress lowering response

Multiple Strategies for Managing Stress and Enhancing Our Resilience (continued)

• Additional Strategies
  – Mindfulness Based Stress Reduction (MBSR)
  – Positivity practices
Mindfulness Based Stress Reduction (MBSR)

- MBSR is a structured educational program founded in 1979 by Jon Kabat-Zinn at the University of Massachusetts Medical Center
- MBSR focuses on mindfulness meditation training as a way to enhance individuals’ ability to cope with stress, pain and illness
- It’s about being “here” – learning how to be totally focused on the moment and on the person or task with which we are engaged

Wisdom

“Being negative is easy. There will always be a downside to everything good, a hurdle to everything desirable, a con to every pro. The real courage is in finding the good in what you have, the opportunities in every hurdle, the pros in every con.”

Carolyn Hax
Viruses and Their Influence on Head and Neck Cancer

Session Description: Heavy tobacco and alcohol consumption have been identified as major risk factors for the development of head and neck cancers. Despite current declines in tobacco exposure, there has been a resurgence in head and neck cancer rates. This increasing trend has been associated with viral infections, particularly the human papilloma virus and Epstein-Barr. This session will address the influence of viral infections as a contributor to the development of this disease. Speakers will discuss treatment strategies and future treatment approaches.

Target Audience: Oncology nurses and nurse practitioners

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Estimated # of minutes of Pharmacology Content to be presented: 20

Coordinator/Speaker:
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Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Speaker:
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Oncology Nurse Practitioner
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sharon.etris@emoryhealthcare.org

Full Disclosure:
Nothing to Disclose
Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Identify factors associated with resurgence head and neck cancer incidence rates.
2. Identify viruses contributing to head and neck cancer development.
3. Describe treatment strategies including current management and future treatment approaches.

Content Outline:
I. The resurgence of head and neck cancer rates
   A. Incidence in the United States and worldwide
   B. Lifestyle risk factors associated with head and neck cancer resurgence rate
II. Human papilloma virus—its link with head and neck cancer
III. Discussion of current treatment strategies and future treatment approaches
IV. Nasopharyngeal cancer
   A. Biology—clinical behavior
   B. Lifestyle risk factors and incidence
V. Epstein Barr virus—its link with nasopharyngeal cancer
VI. Discussion of current treatment management and future treatment approaches

Bibliography:
Elliott, S., Suhrbier, A., Miles, J., Lawrence, G., Pye, S.J., Le, T., ...


Web Sites:


Centers for Disease Control and Prevention: www.cdc.gov/hpv/

National Comprehensive Cancer Network: www.nccn.org/clinicalasp


**The Pharynx**

- Pharynx = throat
- Divided into 3 parts: oropharynx, nasopharynx, and laryngopharynx
- Serves as the passageway for entry of food and air

---

**The Oropharynx**

- Lies just behind oral cavity
- Anterior wall - consists of the base of the tongue and vallecula
- Lateral wall contains the tonsils
- Superior wall - interior surface of the soft palate (the posterior portion of the roof of the mouth) and Uvula

---

**Oropharyngeal Ca Statistics**

- 11th most common cancer worldwide
- Incidence 2X greater in men; yearly in US 5700 cases in men, 1700 in women
- Recent studies indicate > 50% now related to HPV
- Smokers are 6 times more likely to develop oral cancers than nonsmokers

---

**Risk Factors for Oropharyngeal Cancer**

- Tobacco & Alcohol
- Infection with HPV
  - Sexual Practices
  - Number of sexual partners
- Compromised immune system
- Dietary Factors
  - Lack of fruits & vegetables

---

**Human Papilloma Virus**

- Most common sexually transmitted virus in the US
- Greater than 50% of sexually active people will have HPV during lifetime
- By age 50, 4 out of 5 women will have had HPV

---

**Facts about HPV**

- A heterogeneous virus with 106 genotypes identified and over 100 additional strains not sequenced
- HPV 16 - type most frequently associated with oropharyngeal cancer
- HPV 18 is second most common oncogenic type, rarely HPV 33

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Centers for Disease Control and Prevention, 2009.


**HPV Infection**

- Cervical cancer—most common HPV induced malignancy
- HPV now linked to oropharyngeal cancer
- In 90% of cases, immune system clears HPV virus within 2 years
- HPV viral oncogenes E6 & E7 frequently overexpressed in oropharynx
- Virus persists with incompetent immune system
- Lingering HPV promotes change to pre-cancer or cancerous cells


**HPV Induced Malignancy**

- HPV -most prevalent in tonsil and base of tongue
- Tend to occur in younger population
- Epidemiological studies hindered by lack of worldwide standardized testing
- Studies are looking at whether tests to detect HPV DNA may help in earlier diagnosis.


**HPV Induced Malignancy**

- HPV promotes growth and transforming activity
- HPV DNA can instruct cells to make proteins (E6) that inactivate p53
- Malfunctional p53 gene allows cells with altered or damaged DNA to continue growing; leads to cancers
- HPV related OPG cancer assoc. with better survival

Oral Cancer Foundation, n.d.; Ang et al., 2010

**Oropharyngeal Cancer (OPC) Classification**

Squamous cell carcinomas — begin in mucosal cell
Adenocarcinomas — begin in glandular cells

Newly diagnosed oropharyngeal cancers should also be classified by:
- HPV Status
- P16 status (surrogate marker for HPV status)

Gillison et al., 2000; National Cancer Institute, n.d.

**OPG Cancer Staging**

<table>
<thead>
<tr>
<th>Stage</th>
<th>T</th>
<th>N</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>T1</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>II</td>
<td>T2</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>III</td>
<td>T3</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>III</td>
<td>T1-3</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td>IV a</td>
<td>T4a or</td>
<td>N2</td>
<td>M0</td>
</tr>
<tr>
<td>IV b</td>
<td>T4b or</td>
<td>N3</td>
<td>M0</td>
</tr>
<tr>
<td>IV c</td>
<td>Any T</td>
<td>Any N</td>
<td>M1 (distant mets)</td>
</tr>
</tbody>
</table>

American Cancer Society, n.d.

**Treatment for OPC**

- **Surgery**
  - For early stage I-II
  - Neck dissection as indicated
- **Radiation Therapy**
  - Concurrent treatment for most cases
  - Definitive for early stage
- **Chemotherapy**
  - Concurrent with radiotherapy; or alone for distant metastatic disease

NCCN Practice Guidelines
Current Management and Prevention Strategies

- Target risk factors
  - Abstain or limit alcohol use
  - Smoking/tobacco cessation
- Oral screenings
- Change in sexual practices
- Dietary interventions


Future Management Strategies

- Vaccine prevention
- Chemoprevention
- Targeted therapy
- Gene therapy
- Clinical trials

Oral Cancer Foundation, n.d.
**Case Study**

- MH - 39 year old male with persistent sore throat in Jan./Feb., 2009 -treated with antibiotics, minimal improvement. March, 2009 2nd round of antibiotics
- April, 2009 noted small (1.5 cm) neck nodule while shaving. Medical attention delayed (no insurance).
- May, 2009 Saw community ENT. Oral exam and FNA negative; Cancer suspected, referred to ENT at Emory. Neck mass growing rapidly, now 3cm. Second FNA + for SCC. Panendoscopy and biopsy + for mod. diff. SCC of R tonsil and base of tongue. HPV/p16 positive.
- CT showed T2 N2b Stage IV disease.
- PET: no distant mets.

**Case Study**

- Case presented in tumor board. Recommendation: combined modality treatment with daily RT and Cisplatin @ 100mg/m2
- Dysphagia and odynophagia increasing. PEG placed.
- 06/09 Treatment initiated. Hospitalized X1 during treatment with febrile neutropenia, poor pain control and dehydration.
- 07/09 Treatment completed

**Case Study**

- 09/09 Restaging PET/CT showed small (1.5 cm) R neck node without increased SUV.
- PEG removed 09/09.
- 12/09 Restaging CT: no evidence of residual or recurrent dx.
- 2010 - F/U CT q3 mos: NED
- Side effects of decreased taste and saliva persist but improving. Tinnitus almost resolved.

**Discussing Survivorship and HPV Tumor Status with Patients and Family**

- Fear of recurrence
- Guilt
  - Delayed screening or treatment
  - Lifestyle behaviors related to risk
  - Possible transmission of HPV
- Financial burden on loved ones
- Side effects and quality of life after treatment for oropharyngeal cancer

**Take Home Message**

- HPV related incidence of oropharyngeal cancer is increasing
- In future, HPV related and non-HPV related OPG cancers may be treated as distinctly different cancers
- HPV vaccine may prove effective for prevention of HPV related OPG cancers
- Clinical trials needed to determine best management of HPV positive OPG cancer
- New treatments may offer hope for improved QOL after treatment

**Clinical Trials**

- NIH website lists current clinical trials:
  - Sexual behaviors in H & N cancer patient
  - Oral papillomavirus in teens and twenties
  - Serologic studies of HPV type
  - Response of chemotherapeutic agents
  - Long term impact of HPV SCC CA of oropharynx

Sunday, November 14

Additional Resources
- NCI - [www.cancer.gov](http://www.cancer.gov)
- ACS - [www.cancer.org](http://www.cancer.org)
- Oral Cancer Foundation - [www.oralcancerfoundation.org](http://www.oralcancerfoundation.org)

Key Discussion Points
- Nasopharyngeal Cancer: its distinction from other head and neck cancers
- Epstein Barr Virus: Its Association with NPC development
- Current Treatment Strategies and Future Treatment Approaches

The Nasopharynx
- Posterior Nasal Space
- Houses the Adenoids (pharyngeal tonsils) & Eustachian tubes
- Serves as the passageway for entry of air only

Nasopharyngeal Cancer
“A Different Head and Neck Cancer”
- Epidemiology
- Pathology
- Natural History
- Response to Treatment

Causes of NPC
- Genetic Etiology
- Dietary Factors (salted fish, Nitrosamines)
- Inhaled Agents (smoking)
- Viral Etiology (EBV Infection)
Epstein Barr Virus

- Member of the herpes virus family
- 95% of the world population has been infected with EBV during childhood.
- 50% with delayed onset of EBV infection result in mononucleosis.
- EBV establishes a lifelong latency.

Active EPV Infection

- Active EBV infects 2 cell types:
  - B Lymphocytes
  - Epithelial cells (salivary gland)
- Immune Response
  - Activation of T Lymphocytes
  - Regression of infected B Lymphocytes
- 100 different antigens are produced by EBV during active phase

Inactive EBV

- 10 antigens during the inactive phase are produced including EBNA (1-6) and LMP (1-3)
- These EBV infected B cells escape the immune response and remain latent

Nurse’s Guide to Cellular Bio

<table>
<thead>
<tr>
<th>EBER</th>
<th>EBV Encoded RNA</th>
<th>Epstein Barr nuclear protein seen in latent cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBNA</td>
<td>Epstein Barr Nuclear Antigen</td>
<td>Epstein Barr nuclear protein seen in latent cycle</td>
</tr>
<tr>
<td>LMP</td>
<td>Latent Membrane Protein</td>
<td>Plays a role in the immortalization of B cells. Essential for EBV mediated growth transformation</td>
</tr>
<tr>
<td>LCL</td>
<td>Lymphoblastic B Cell Lines</td>
<td>occurs when EBV infects B lymphocytes has indefinite growth</td>
</tr>
</tbody>
</table>

EPV Induced Malignancy

- Linked with EPV latent cycle
- All tumors are EBER+
- Immortalized EBV transformed lymphoblastic B cell lines
**EBV antigen expression in different tumor types**

<table>
<thead>
<tr>
<th>Type I latency</th>
<th>Type II latency</th>
<th>Type III latency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burkitt's lymphoma</td>
<td>Hodgkin's lymphoma</td>
<td>Nasopharyngeal carcinoma</td>
</tr>
</tbody>
</table>

NPC Classification

- **WHO Classification of NPC**
  - **Type I**: Keratinizing Squamous Cell Cancer (no detectable EBV)
  - **Type II**: Non-keratinizing squamous cell cancer (Lower EBV titers)
  - **Type III**: Undifferentiated Ca (Elevated EBV titers)

**Future Management Strategies**

- **Vaccines**
  - Strong Association of EBV and NPC
  - Promising Treatment Approach
  - Experimental

  - Dendritic Cell Vaccines
    - Use dendritic cells that recognize, process foreign antigens to T cells and B cells
    - Enhance the cell killing properties of cytotoxic killer T cells

Treatment for NPC

- **Surgery**
  - Unresectable due to complex anatomical location
  - Neck dissection can be done as indicated

- **Chemotherapy**
  - Induction Therapy
  - Concurrent Treatment

- **Radiation Therapy**
  - Considered Primary Treatment Modality

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Clinical Trials

- Phase I Trials: Baylor College of Medicine Houston, Texas
- Using Dendritic Cell Vaccine that targets EBV specific CTL
- 33 pts studied
  - 8: remission
  - 23: active disease
  - 2 abnormal imaging
- Response
  - 7/8 remained in remission for 6-24 months post tx
  - 25 pts: overall avg response: 50%
  - 6 CR: 2-4 yrs post tx, 2 relapse more than 2 yrs post tx
- Ongoing trials continue

Case Study

- In 11/05: MS, a 26 yo male, was dx’d NPC WHO II Stage T4N2 (Stage IVA)
- SS: Nasal Obstruction, nose bleed, HA’s, decrease hearing due to middle ear effusion, neck mass
- TX: Induction CTX: TIC x 3 (Paclitaxel, Ifosfomide, Cisplatin), followed by XRT & concurrent high dose cisplatin (100mg/m2) every 21 days

Case Study Continue

- 4/06 MS completed tx
- 7/06 left neck dissection: no viable tumor
- 11/07, MS developed recurrent dz:
  - PET scan showed new dz in left ileum, left pleura consistent of mets
  - 6 cycles of cisplatin and docetaxel
  - 3/08 completed tx
  - Follow up scans: full response

Case Study Continue

- MS referred to BCM for dendritic cell vaccine study
- Rec’d 2 dendritic vaccine infusions: 7/15/08 and 7/29/08
- No further cancer tx given to MS since 7/08
- 9/08, 12/08, 3/09, 8/09, 12/09 PET studies demonstrated no active dz
- 6/10 PET scan continues to show no active disease
Future EBV Vaccine?

- Phase I studies in Australia and Belgium, looking at EBV vaccine to protect against mononucleosis
- Hong Kong and UK are using a modified vaccinia virus against two EBV proteins expressed in NPC pts
- Preliminary results are promising
- Currently no FDA approved EBV vaccine
What’s New in Colorectal Cancer

Session Description: Don’t miss this discussion of the changes in staging of colorectal cancer (CRC) and an update on available genetic tests to determine recurrence risk in stage II disease. During this session, speakers will describe the current NCCN guidelines for treatment and review biomarker-driven decisions for tailored therapy and management strategies for associated common toxicities of therapies for CRC.

Target Audience: Oncology nurses and other healthcare professionals

Level of Content: Intermediate

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for attendance and successful evaluation completion of this open session.

Estimated # of minutes of Pharmacology Content to be presented: 30

Coordinator/Speaker:
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Editor in Chief, JAdPrO
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Full Disclosure:
BMS. Speaker honorarium
Amgen. Speaker honorarium
Merck. Speaker honorarium
Novartis. Speaker honorarium
Meniscus. Speaker, ad board

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this open session.

Speaker:
Susan Moore, RN, MSN, ANP, AOCNP®
Oncology Nurse Practitioner and Consultant
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Chicago, IL
smoore46@sbcglobal.net

Full Disclosure:
Genentech. Non-CE speakers bureau

Speaker has indicated that he/she intends to discuss unapproved/investigational use of a commercial product/device during this open session.

Objectives:
By the end of this presentation, participants will be able to:
1. Define relevant changes in staging for colorectal cancer.
2. Describe the current therapeutic approaches for colon cancer using national guidelines.
3. Identify current strategies for management of CRC treatment-related toxicities.

Content Outline:
I. Colorectal cancer
   A. Current American Cancer Society statistics
   B. Risks for developing disease
   C. Changes in staging for CRC
   D. Update in clinical trial endpoints
II. Current treatment approaches
   A. National Comprehensive Cancer Network (NCCN) guidelines for colon cancer
   B. Therapeutic regimens for adjuvant and metastatic disease
   C. Role of the oncology nurse
III. Using genomics to tailor therapy
   A. KRAS
   B. BRAF
   C. Markers under study
IV. Toxicity management
   A. Hypersensitivity
   B. Neurologic
      1. Peripheral neuropathy
      2. Management of PN
   C. Gastrointestinal
   D. Dermatologic
      1. EGFR rash
      2. Hand-foot syndrome
   E. Cardiovascular
V. Evidence-based practice
   1. NCCN
   2. ONS Putting Evidence Into Practice
   3. Agency for Healthcare Research and Quality (AHQR)
VI. Effect of toxicities on patients
VII. Implications for nursing research

Bibliography:


**Alarming Trend in Incidence of CRC**

- Cancer prevention efforts have contributed to CRC rates declining, however:
  - a study reported in 2009 that the overall incidence rate of CRC has been **INCREASING** since 1992 among adults aged 20-49 (by 1.5% per year in men and 1.5% per year in women)
- The authors propose diet, physical activity and weight trends (and possibly tobacco use in some geographic areas) are the likely factors responsible

*Siegel, Jamal & Ward 2009*

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**Risk Factors for Developing CRC**

- **Risk Factors That Cannot be Changed**
  - Age (more than 9 out of 10 people with CRC are older than 50)
  - Personal history of colorectal polyps or CRC
  - Personal history of IBD
  - Family history of CRC
  - Genetic disposition (5-10% are caused by inherited syndromes)
  - Ethnicity

- **Life-style Related Factors**
  - Diet (red meats, processed meats, cooking styles)
  - Physical inactivity
  - Obesity
  - Smoking
  - Heavy alcohol use
  - Diabetes (type 2)

*American Cancer Society 2010; Cancer facts & figures 2009*

---

**Screening For Colorectal Cancer**

<table>
<thead>
<tr>
<th>Tests that find polyps and cancer</th>
<th>Tests that primarily find cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexible sigmoidoscopy every five years or</td>
<td></td>
</tr>
<tr>
<td>Double contrast barium enema every five years or</td>
<td></td>
</tr>
<tr>
<td>CT colonography (virtual colonoscopy) every five years</td>
<td></td>
</tr>
</tbody>
</table>

*American Cancer Society 2010; NCCN, 2010*

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**How Does CRC Present? Presenting Symptoms and Signs**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Percentage of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal occult blood test</td>
<td>77</td>
</tr>
<tr>
<td>Rectal bleeding</td>
<td>58</td>
</tr>
<tr>
<td>Anemia</td>
<td>57</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>52</td>
</tr>
<tr>
<td>Weight loss</td>
<td>30</td>
</tr>
<tr>
<td>Anorexia</td>
<td>27</td>
</tr>
<tr>
<td>Constipation</td>
<td>27</td>
</tr>
<tr>
<td>Abdominal cramps</td>
<td>25</td>
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<tr>
<td>Fatigue</td>
<td>25</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>22</td>
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<tr>
<td>Nausea and vomiting</td>
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<tr>
<td>Tenderness</td>
<td>8</td>
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<tr>
<td>Muscle in stools</td>
<td>6</td>
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<tr>
<td>Rectal pain</td>
<td>5</td>
</tr>
<tr>
<td>Obstruction</td>
<td>4</td>
</tr>
</tbody>
</table>

*Fletcher 2009; Major, Fletcher, & Evans, 1999*
What's New in NCCN, October 12–14, 2010

Stage IIIA
T3, T2, N1, M0: Tumor has grown through the muscularis mucosa into the submucosa (T1) or it may also have grown into the muscularis propria (T2), but it was not found in areas beyond the muscularis propria (T3) and spread to 4-6 LN: T1-2, N2b, M0. Tumor is through outermost layers of colon or rectum (T3) or through visceral peritoneum (T4a) but not into nearby organs. Spread to 1-3 LN (N1a/N1b) or into areas of fat near LN (N1c); T3-3, N2a, M0: tumor is into muscularis propria (T2) or into outermost layers (T3) and spread to 4-6 LN: T1-2, N2b, M0: Tumor is through mucosa into submucosa (T1) or into muscularis propria (T2) and spread to 2 or more LN.

Stage IIIB
T4a, N2a, M0: Tumor is through wall of colon or rectum, including visceral peritoneum and spread to 4-6 LN: T1-4a, N2b, M0: Tumor is through outermost layers of colon or rectum (T3) or through visceral peritoneum (T4a) and spread to 7 or more LN; T4b, N2, M0: Tumor is through wall of colon or rectum and attached to or into nearby tissues or organs and spread to 1 or more LN or into areas of fat near LN.

Stage IIC
T4a, N2, M0: Tumor is through wall of colon or rectum, including visceral peritoneum and spread to 4-6 LN: T1-4a, N2b, M0: Tumor is through outermost layers of colon or rectum (T3) or through visceral peritoneum (T4a) and spread to 7 or more LN; T4b, N2, M0: Tumor is through wall of colon or rectum and attached to or into nearby tissues or organs and spread to 1 or more LN or into areas of fat near LN.

Reasons for Practitioner-Delay
- Misdiagnosis, leading to delayed referral
- Failure to fully or accurately examine patients
- Use of inappropriate or inadequate tests or receiving or failing to follow-up inconclusive, negative or false-negative test results
- Prescribing treatment for benign conditions such as acid suppression (seen in UGI cancers) increased time to referral
- Time to referral was increased in patients who frequently consulted their general practitioner

Macleod, et al., 2009
What Are the High-Risk Factors for Recurrent CRC?

- Grade 3/4 histology
- Lymphatic or vascular invasion
- Presents with bowel obstruction
- Stage IIb (T4 N0 M0)—large mass
- Stage IIA with localized perforation or close, indeterminate, or positive margins
- < 12 LNs examined (inadequate sample)

Benson et al., 2004
NCCN, 2010

How Has the Evidence Optimized Therapeutic Outcomes and Practice?

![Graph showing therapeutic outcomes](image)

Commonly Used Antineoplastic Agents in CRC Management

<table>
<thead>
<tr>
<th>Agent Class</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoropyrimidines</td>
<td>5-Fluorouracil, Capecitabine</td>
</tr>
<tr>
<td>Platinum analogues</td>
<td>Oxaliplatin</td>
</tr>
<tr>
<td>Topoisomerase inhibitors</td>
<td>Irinotecan</td>
</tr>
<tr>
<td>VEGF inhibitors</td>
<td>Bevacizumab</td>
</tr>
<tr>
<td>EGFR inhibitors</td>
<td>Cetuximab, Panitumumab</td>
</tr>
</tbody>
</table>

NCCN, 2010

NCCN Treatment Guidelines Summary: Adjuvant Therapy, Nonmetastatic Colon Cancer

For patients with node-negative (stage I) disease:
- T1, N0, M0 (no high risk features) consider:
  - 5-FU/LV or capcitabine
  - Clinical trial
  - Observation
- T3-4 N0, M0 (with high risk: grade 3-4, lymphatic/vascular invasion, bowel obstruction; < 12 LN examined) or T4, N0, M0 or T3 with localized perforation or close, indeterminate or positive margins
  - 5-FU/LV/oxaliplatin or 5-FU/LV or irinotecan or cetuximab
  - Clinical trial
  - Observation

For patients with node-positive (stage III) disease:
- T1-4, N1-2, M0
  - FOLFOX (category 1)
  - Cetuximab
  - 5-FU/LV

NCCN, 2010

NCCN Treatment Guideline Summary: Continuum of Care*: Chemotherapy for Advanced or Metastatic Disease

Appropriate for Intensive Therapy
- **Initial therapy**
  - FOLFOX ± bevacizumab or
  - CapeOX ± bevacizumab or
  - FOLFIRI ± cetuximab or panitumumab (KRAS wild-type WT gene only) or
  - FOLFIRI ± bevacizumab or
  - FOLFIRI ± cetuximab or panitumumab (KRAS WT gene only) or
  - 5-FU/LV ± bevacizumab or
  - FOLFOXIRI (category 2a) or

*Continuum of care approach attempts to use all active agents in armamentarium for advanced or metastatic CRC. Initial therapy choices will drive choices for therapy after first progression.

NCCN, 2010.

NCCN Treatment Guideline Summary: Continuum of Care*: Chemotherapy for Advanced or Metastatic Disease

Appropriate for Intensive Therapy
- **Therapy after First Progression**
  - FOLFIRI or
  - Irinotecan alone or
  - FOLFIRI ± cetuximab or panitumumab (KRAS WT gene only) or
  - Cetuximab (KRAS WT gene only) + irinotecan (category 2b) or
  - FOLFOX or CapeOX or
  - Cetuximab (KRAS WT gene only) + irinotecan, patients not able to tolerate combination, consider single agent cetuximab or panitumumab (KRAS WT gene only) or
  - FOLFOX or CapeOX or
  - Irinotecan or
  - FOLFIRI

*Continuum of care approach attempts to use all active agents in armamentarium for advanced or metastatic CRC. Therapy choices as initial therapy will drive choices for therapy after first progression.

NCCN, 2010.
NCCN Treatment Guideline Summary: Continuum of Care*•: Chemotherapy for Advanced or Metastatic Disease

Appropriate for Intensive Therapy
• Therapy after Second Progression
  – Cetuximab (KRAS WT gene only) + irinotecan, patients not able to tolerate combination, consider single agent cetuximab or panitumumab (KRAS WT gene only)
  – Clinical trial or best supportive care
  – Cetuximab (KRAS WT gene only) + irinotecan, patients not able to tolerate combination, consider single agent cetuximab or panitumumab (KRAS WT gene only)
  – FOLFOX or CapeOX
  – Irinotecan (followed by cetuximab (KRAS WT gene only) + irinotecan, patients not able to tolerate combination, consider single agent cetuximab or panitumumab (KRAS WT gene only)
  – Cetuximab (KRAS WT gene only) + irinotecan, patients not able to tolerate combination, consider single agent cetuximab or panitumumab (KRAS WT gene only)

*Continuum of care approach attempts to use all active agents in ornamentalism for advanced or metastatic CRC. Therapy choices as initial therapy will drive choices for therapy after first progression.

NCCN, 2010.

Additional Considerations With Chemotherapy for Advanced or Metastatic Disease

• Discontinuation of oxaliplatin should be strongly considered from FOLFOX or CapeOX after 3-4 months of therapy (or sooner if significant neurotoxicity with other drugs maintained–fluoropyrimidine and bevacizumab) until tumor progression
• No prospective data to support continuation of bevacizumab in second line setting after progression on a bevacizumab regimen
• Combination therapy with cytotoxics, EGFRI monoclonal antibodies, and anti-VEGF agents is not recommended
• If cetuximab or panitumumab are used as initial therapy, then those agents should not be used in second or subsequent lines of therapy

Tournigand et al. 2006; NCCN, 2010; Hecht et al. 2009

Predicting Response to Therapy

• KRAS is a gene essential to the growth and differentiation of extracellular signaling
  – In CRC, approximately 40% of patients have a mutation in the K-ras gene linked to increased risk of nodal metastasis and possibly more aggressive tumor behavior for this subset of patients
  – When KRAS is mutated, it is permanently “turned on” and downstream events can occur

Allen & Johnston, 2005

KRAS

• Results from phase II and III clinical trials have shown that select patients with mCRC benefit from treatment with EGFRI mo Abs as monotherapy or combined with chemotherapy
• Retrospective subset analyses of the data from these pivotal trial strongly suggest that patients with KRAS mutations in codon 12 or 13 do not benefit from therapy (approximately 35-45% of patients)
• Patients with wild-type KRAS (WT KRAS) are appropriate candidates for treatment with EGFRI Ab therapy

Allegra et al 2009
Predictive Biomarkers for Selection of Treatment: EGFR Monoclonal Antibodies

- Current standard practice:
  - Selection of patients for treatment with epidermal growth factor receptor inhibitor monoclonal antibodies (panitumumab and cetuximab)
  - Dependent on KRAS status of tumor
  - Both NCCN guidelines and ASCO provisional clinical opinion call for KRAS testing prior to initiation of therapy with EGFR mo Abs
  - NCCN states that mutations in codons 12 and 13 of KRAS gene predict lack of response to EGFR agents
  - Testing can be on primary or metastatic tissue
- ASCO states that patients with CRC and mutations should be spared the toxicity and economic cost of an ineffective therapy

Testing for K-ras Mutation Is the New Standard for CRC

- NCCN recommends cetuximab and panitumumab be given, either as single agents, or in the case of cetuximab, in combination with chemotherapy
  - ONLY in patients with wild-type (normal) K-ras
  - This prevents toxicity without benefit in those patients whose tumors will not respond (mutated K-ras gene)
  - Patients with a known V600E BRAF mutation are unlikely to benefit from EGFR therapy although data are more inconsistent compared to KRAS data; NCCN currently calls for BRAF testing as an option to KRAS testing if KRAS is WT

Today’s Focus: What’s New?

- Hypersensitivity Reactions (HSRs)
- Dermatologic Effects
- Chemotherapy-induced Peripheral Neuropathy

Hypersensitivity Reactions: Terminology

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylactic</td>
<td>Acute, inflammatory reaction with allergic nature</td>
</tr>
<tr>
<td></td>
<td>Typically mediated by immunoglobulin E (IgE)</td>
</tr>
<tr>
<td></td>
<td>Symptoms produced by reaction to histamine release</td>
</tr>
<tr>
<td>Anaphylactoid</td>
<td>Not true allergic reactions</td>
</tr>
<tr>
<td></td>
<td>Not mediated by IgE</td>
</tr>
<tr>
<td>Uniphasic</td>
<td>Occur during or immediately after drug administration</td>
</tr>
<tr>
<td></td>
<td>Usually easily managed or interrupted</td>
</tr>
<tr>
<td>Biphasic</td>
<td>Symptoms re-develop 30 minutes to hours or cycles after the initial HSR</td>
</tr>
<tr>
<td></td>
<td>May occur during subsequent cycles</td>
</tr>
</tbody>
</table>

Based on information from: Viale & Tamamato, 2010

HSRs with CRC Agents

<table>
<thead>
<tr>
<th>Agent</th>
<th>Overall Incidence</th>
<th>Grade 3-4 Events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monoclonal Antibodies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Cetuximab</td>
<td>15% - 20%</td>
<td>3%</td>
</tr>
<tr>
<td>- Panitumumab</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>- Bevacizumab</td>
<td>&lt; 3%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Platinum compounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Oxaliplatin</td>
<td>5% - 12%</td>
<td>2% - 3%</td>
</tr>
</tbody>
</table>

Based on information from: Bristol-Myers Squibb, 2010; Genentech, 2009; sanofi-aventis, 2009; Amgen, 2010
**HSRs: Signs & Symptoms**

<table>
<thead>
<tr>
<th>Body System</th>
<th>Signs/Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>Chest pain, palpitations</td>
</tr>
<tr>
<td></td>
<td>Hypotension, hypertension</td>
</tr>
<tr>
<td></td>
<td>Cardiac arrest</td>
</tr>
<tr>
<td>Neurological</td>
<td>Headache, especially throbbing</td>
</tr>
<tr>
<td></td>
<td>Dizziness</td>
</tr>
<tr>
<td>Dermatologic</td>
<td>Rash</td>
</tr>
<tr>
<td></td>
<td>Itching</td>
</tr>
<tr>
<td></td>
<td>Flushing</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Cough</td>
</tr>
<tr>
<td></td>
<td>Nasal congestion, rhinitis</td>
</tr>
<tr>
<td></td>
<td>Wheezing</td>
</tr>
<tr>
<td></td>
<td>Acute respiratory distress syndrome (ARDS)</td>
</tr>
</tbody>
</table>

**Preventing HSRs**

- **Pre-medication**
  - Cetuximab
  - H₁ antagonist
- Panitumumab
  - PI has no specific recommendations
- Bevacizumab
  - None required
- Oxaliplatin
  - PI has no specific recommendations

Based on information from: Bristol-Myers Squibb, 2010; Genentech, 2006; sanofi-aventis, 2009; Amgen, 2010

**HSR Management**

- HSRs are usually managed with
  - Epinephrine
  - Corticosteroids
  - Antihistamine therapy
- Re-challenge with pre-medication should be approached with caution in patients with a history of an anaphylactic reaction
  - Re-challenge after severe reactions is not recommended
  - Conduct re-challenge administrations in settings where optimal administration support is present, such as inpatient settings
- May require discontinuation of therapy

Vogel, 2010; Viale & Yamamoto, 2010

**EGFRI Skin Rash: STEPP* Trial**

- **Primary Objective**
  - Estimate the difference in incidence of specific grade ≥ 2 skin toxicities between patients in pre-emptive and reactive skin treatment groups during the 6-week skin treatment period
- **Patients & Methods**
  - N=95, randomly assigned 1:1 to pre-emptive (n=48) or reactive (n=47) treatment arms
  - Phase II, open-label, randomized
  - Patient-reported quality of life assessed with the Dermatology Life Quality Index (DLQI)

* Skin Toxicity Evaluation Protocol With Panitumumab (STEPP)
LaCouture et al., 2010

**EGFRI Skin Rash: STEPP Trial**

- **Chemotherapy regimen**
  - Panitumumab
  - 6 mg/kg every 2 weeks with FOLFIRI chemotherapy
  - 9 mg/kg every 3 weeks with irinotecan chemotherapy
  - Chemotherapy regimen was chosen by treating oncologist
- **Tumor assessment by RECIST criteria**
  - Assures that anti-toxicity treatment does not affect efficacy of EGFRI

LaCouture et al., 2010

**Pre-emptive arm**

- Treatment began day -1, continued weeks 1-6
- Skin moisturizers applied q AM
- Sunscreen SPF ≥ 15, UVA and UVB protective, applied before going outdoors
- 1% hydrocortisone cream, applied q HS
- Doxycycline 100mg PO BID

LaCouture et al., 2010

**Reactive arm**

- Treatment began on presentation of rash
- Not prohibited from using skin moisturizers or sunscreen
- Rash treatment was determined by treating physician
EGFRI Skin Rash: STEPP Trial

- Results
  - Incidence of protocol-specified ≥ grade 2 skin toxicities during the 6-week skin treatment period
    - 29% for the pre-emptive group
    - 62% for the reactive group
  - QOL was less impaired in the pre-emptive group compared with the reactive group
  - Stable disease rate was similar in the pre-emptive (50%) and reactive groups (53%)
  - Disease control and disease progression were also similar between groups

LaCouture et al., 2010

EGFRI Skin Rash: STEPP Trial

- Conclusions
  - Findings underscore the importance of establishing a pre-emptive, comprehensive skin toxicity program in patients treated with panitumumab
  - Toxicities are considered a class-based effect
    - Results may be generalized to other EGFRIIs
  - The reduction in ≥ grade 2 skin toxicities, especially rash, paronychia, and pruritus, improvements in QOL, lack of interference on antitumor effect, and decreased need for dose modification justify this therapeutic rationale

LaCouture et al., 2010

EGFRI Rash: Management

- Begin treatment day prior to first EGFRI treatment and continue through therapy
  - Skin moisturizers applied to face, hands, feet, neck, back, and chest daily in the morning on rising
  - Sunscreen SPF ≥ 15, PABA-free, UVA and UVB protective, applied to exposed skin areas before going outdoors
  - 1% hydrocortisone cream, applied to face, hands, feet, neck, back, and chest at bedtime
  - Doxycycline 100mg PO BID

LaCouture et al., 2010

Chemotherapy-induced Peripheral Neuropathy

- Sensory
  - Numbness, tingling, painful dysesthesias, sensitivity to cold, diminished reflexes
- Motor
  - Muscle weakness, gait disturbances
- Peripheral sensory neuropathy (PSN) 2° oxaliplatin
  - Cold allodynia
    - Hyperalgesia due to cold stimulus
  - Chronic PSN
    - Can be dose-limiting toxicity

Visocky, 2010

The Calcium-Magnesium Controversy

  - Ca/Mg infusion significantly reduced the incidence and severity of PSN secondary to oxaliplatin
- 2007: CONcePT (Combined Oxaliplatin Neurotoxicity Prevention Trial) study (N=160)
  - Report by independent monitoring committee indicated Ca/Mg infusion negatively affected clinical outcome
  - Reduction in oxaliplatin response by 52%
- 2008: Central, blinded review of CONcePT data
  - Slightly favored Ca/Mg infusion but not statistically significant (P=0.70)
- 2008: French Neuroxa study (N=144)
  - Reduction in PSN, no reduction in chemotherapy efficacy

Korneli, Luo & Weitberg, 2010

And the Answer is...

- Central blinded reviews of clinical outcomes in Ca/Mg anti-toxicity trials indicate Ca/Mg infusions are safe, reduce the incidence and severity of PSN, and do not reduce clinical efficacy of oxaliplatin for CRC in the adjuvant or metastatic setting

1 gram each calcium gluconate and magnesium sulfate over 30 min pre- and post-oxaliplatin

Hochster et al., 2008
PSN: Patients with Concomitant Diabetes

- Ramanathan, et al. (2010) study details
  - Determine if pre-existing DM influences incidence, severity or course of PN after FOLFOX in patients with CRC
  - Pooled analysis of 3 phase III studies, N=135
  - Ineligibility: pre-existing PN

- Results
  - Incidence of PN (non-DM/DM) was 45.0%/46.7% (grade 1), 28.6%/26.7% (grade 2), and 13.0%/12.6% (grade 3)
  - The probability of PN by cumulative dose of oxaliplatin was similar in DM and non-DM patients
  - Conclusions: Oxaliplatin-based therapy does not influence the incidence, severity, or time to onset of PN in asymptomatic DM patients with CRC who meet eligibility criteria for clinical trials

Evidence-based Practice

- National Comprehensive Cancer Network Clinical Guidelines
- ONS Putting Evidence into Practice
- Agency for Healthcare Research and Quality (AHRQ)
  - Evidence-based Practice Centers (EPC) Reports
  - Clinical Practice Guidelines Archive
  - National Guideline Clearinghouse™

Implications for Nursing Practice

- Evaluation of clinical trial results
- Nursing research
  - Side effect management strategies
  - Quality of life
  - Adherence
  - Further evaluation of non-malignant supportive care agents
  - Policies & procedures based on EBP

Ramanathan, Rothenberg & de Gramont, 2010
Session Description: Just as health is more than the absence of physical illness, so too is palliative care more than the absence of disturbing physical symptoms. Healing involves the transition from hopelessness to wholeness. Healing can occur in the context of compassionate relationships. This lecture will focus on the definition of healing, how it may occur and how nurses and any healthcare provider may be able to help the patient with healing presence heal.

Target Audience: Nurses, advanced practice nurses, nursing assistants, and other healthcare professionals

Level of Content: Introductory

Content Area: Clinical Practice

Continuing Nursing Education: Participants will receive 1.5 continuing nursing education credits for successful evaluation completion of this special session.

Coordinator/Speaker:
Ann Berger, MSN, MD
Chief of Pain and Palliative Care
National Institutes of Health Clinical Center
Bethesda, MD
aberger@cc.nih.gov

Full Disclosure:
Nothing to Disclose

Speaker has indicated that he/she does not intend to discuss unapproved/investigational use of a commercial product/device during this special session.

Objectives:
By the end of this presentation, participants will be able to:
1. Define what healing is.
2. Describe how healing may occur.
3. Describe the importance of healing presence.

Content Outline:
I. Define what healing is
   A. Psychosocial and spiritual dimensions—patient reported outcome
II. Describe how healing may occur
   A. Coping occurs first
   B. New ways of functioning occur second
   C. Finding new personal values and meaning occurs third
   D. Integration
III. Healing presence
   A. Out-of-the-box creativity
Palliative/Supportive Care

- Serves to relieve or alleviate suffering without curing
- Not limited to end of life care
- Parallels aggressive curative treatment modalities
- Optimized thru early initiation and comprehensive implementation throughout the disease trajectory
- Involves comprehensive management of any symptom which affects quality of life

Palliative/Supportive Care

- Involves a combination of active and compassionate therapies that is focused on the physical, psychological, social and spiritual suffering of the patient, family and caregiver.
- Major aim is to relieve suffering and heal the patient with cancer.

The interrelationship of therapies with curative and palliative intent

Curative / life-prolonging therapy

Presentation → Disease → Death

Relieve suffering (palliative care)

It takes a nurturing interdisciplinary team to practice the nature of palliative care

Symptoms

Individual’s Quality of Life

Suffering

It’s Not Just About Curing the Illness But About Healing

- Female subject was in 30s with young child when cancer diagnosed, poor prognosis
- Survived >5yrs
- Subject reports multiple positive psycho-socio-spiritual outcomes
  - began early in treatment, extended beyond crisis

“...You can’t die cured, but you can die healed. Healing is about a sense of wholeness as a person, and that wholeness includes understanding our mortality, our place in the world—death is not a betrayal of life, but a part of it.”

- Dan Frimmer M.D.
- TIME Magazine, 2000
“IT WENT TO TECHNICOLOR”

- 1st color: Coping with current crisis – cancer
- 2nd color: Healing childhood wound – loss of father
- 3rd color: Exploring new experiences, new understanding of life, clearer and stronger values, more satisfying ways of living
- More than just saving her life from cancer

COPING AND PERSONAL CHANGE

- Both precipitated by event or situation
- Can be positive (adaptive) or negative (maladaptive)
- When situation is over:
  - Coping is over (e.g., crisis management)
  - Personal change is maintained

1: COPING WITH CURRENT CRISIS

- Threat of dying, social and spiritual losses
- Treatment debilitation, logistics, etc.
- Change of lifestyle
- Chronic conditions in survivorship
- When problem ends then coping ends, too

2: HEALING OF WOUNDS

- Healing = positive change in psycho-socio-spiritual function related to wound
- Wound = loss of adaptive psycho-socio-spiritual function (pre-crisis or during crisis)
  - If no wound, there is nothing to heal
- When problem ends, healing is maintained

ALL THREE WORK TOGETHER

- Coping Ends when problem ends
- Healing Maintained after problem ends
- Growth, explore

There is life During Treatment

- Female double-cancer survivor
- Subject discusses:
  - Building a kind of inner strength
  - Importance of choosing your perspective:
    “treatment is misery” vs “There is life during treatment…”
  - Value of hearing from other cancer survivors – their experience proves which perspective is real
Barriers to Palliative Care

- Misconceptions/fear of addiction and adverse treatment effects
- Lack of integration into most health care systems
- Disease-oriented approach to patient care
- Limited medical and clinical expertise in palliative care
- Differences in ethical, cultural, and religious beliefs
- Paternalistic/maternalistic decision-making process
- Patient/family reluctance to report signs of adverse events that impair quality of life
- Financial and regulatory obstacles

Obstacles to the relief of suffering in modern medicine

- **Science without humanism**
  - Specialization
  - Fragmentation
  - Depersonalization
  - Focus on disease
  - Success determined by “cure” rates

“**It is not the suffering that is most important but the growth and transformation that result from it.**”

• Suffering is the catalyst for change

“**We are often more comfortable in dealing with the physical ailments than in the underlying emotional issues which are the root cause!**”

John Sarno, MD
Healing Back Pain

Emotional/Spiritual Pain

“**Suffering**” Profile

“I hurt all over and nothing helps the pain”
“I just want to go to sleep & when I wake up all of this will be better”

**Where does the suffering come from?**

- Unrealistic expectations for a cure
- Multifaceted needs of the family/caregiver
- Desire for normalcy
- Cultural influences
- Misunderstanding, denial or limited disclosure of clinical information

Emotional Pain

**Psychosocial assessment:**

- Identify psychiatric history, ETOH/drug abuse, past experiences, coping skills, social role, financial status, coping style, support system, cultural impact, recreational interests
- Discuss fears, anxiety, agitation...do you feel depressed
- Review pharmacological & supportive treatment modalities
Emotional Pain

Psyclhosocial assessment:

- Determine patient understanding of disease / treatment process
- Explore preferences, concerns, expectations, goals & patient/clinician responsibility

Emotional Pain

Emotional care treatment plan:

- Determine differential diagnosis
- Treat pathophysiology with appropriate pharmacological agents
- Utilize supportive counseling, coping skill development & complementary modalities for emotional suffering

Introduction

- Male cancer survivor
- Discusses sharing news of relapse with his adult, career-oriented daughter
- Example of the importance of healing relationships
- Loved ones are essential interconnected partners in the healing journey

Summary

- It took just one spur-of-the-moment decision and three words start profoundly healing a relationship between a father and daughter
- When family members are given medical information, it can be a strong opportunity for them to initiate healing with the patient

Introduction

- Male cancer survivor
- Subject is responding to 1 of 67 healing-related sentences presented for comment during interview
- Subject strongly endorses one of the most frequently reported changes from subjects in this study: “less bothered by little things”

“Just as you ought not to attempt to cure eyes without head or head without body, so you should not treat body without soul.”

Socrates
(approx. 500 BC)
Spiritual Pain

Spiritual assessment:

- Clarify distinction between religion & spirituality
- Identify part of “self” where search for meaning takes place for the patient
- Explore the intimate connection with life through family, home, friends & work

Introduction

- Female subject was in 30s with young child when cancer diagnosed, poor prognosis
- Survived >5yrs, reports multiple positive psycho-socio-spiritual outcomes that began early in treatment
- She discusses growing as a spiritual being

Is it coping? Healing? Growth?

- “… learning something from it or growing as a spiritual being, that’s what I wanted.”
- Coping – ends when the crisis is over
- Healing and growth – change is maintained after crisis is over
- All three are valuable

SUCCESSFUL COPING


Healing And Growth

“Better than before”

“Before”

Thriving

Resilience (recovery)

Survival with Impairment

Succumbing

Time

Healing And Growth

The word “Patient”

Latin Patients; meaning endure, bear, suffer, an acquired vulnerability, dependency imposed by changes in health circumstances

H. Chochinov ’07
Construct: “Presence” *in a clinical application*

- Respite from fear of abandonment, live beyond the usual or common place. 
  
  *Stanley, K. 2002*

- An interpersonal process, sensitive, holistic, intimate.
- Patients demonstrate a need for and an openness to.
- Clinicians enact it, and follow moral principles.

**Attributes of Presence**

- Purposeful, interactive
- Shared, available
- Patient centeredness; here and now, suspension of own agenda
- Attentiveness; listen, touch, share expertise, mindfulness
- Individual; authentic

**Summary**

- Cancer and its treatment regimens can naturally cause a patient to think more “in the present”
- Presence and just being in the present reduces uncertainties in friendships of cancer patients

**Introduction**

- Young female cancer survivor
- Discusses how fortunate she was to have a very positive and empowering relationship with her medical team
- Discusses a contrasting experience she had at another hospital

**Actualize**

- How do we best provide care for “support” at this dove-tail juncture?
- Re-negotiating goals of care, Presence
  
  "There is nothing more we can do"

**Introduction**

- Female cancer survivor
  
  (too embarrassed to say how young she was, saying “cancer stole my youth”)
- Subject reported excellent support from her medical team
- Subject is discussing how she felt after treatment ended
Summary

- End of treatment may come long before the patient feels physically well
- Transition to support after treatment can make a critical difference for a patient who is not fully recovered physically
- Treatment providers are in a uniquely strong position to partner with a wide variety of post-treatment support providers

Patients often need to tell their story.

When offered options that are unlikely to change outcomes, patients will usually select to stay the course.

Medical Paradox Still Exists

Majority of health care providers do not know how to help patients make transitions from curative to palliative care.

Guide

In Palliative Care we need to do modeling/imprinting on our colleagues
Attentive to shift in psycho-social, spiritual issues
Minimize areas of distress

Transition Points

- Present in appropriate environment
- Objective / succinct information
- Avoid medical jargon

Transition Points

- Assure clinical care is intact within the redefinition of goals of care
- Allow time to absorb
- Expect repeat messaging

Patients often need to tell their story.

When offered options that are unlikely to change outcomes, patients will usually select to stay the course.

Summary

- End of treatment may come long before the patient feels physically well
- Transition to support after treatment can make a critical difference for a patient who is not fully recovered physically
- Treatment providers are in a uniquely strong position to partner with a wide variety of post-treatment support providers

Patients often need to tell their story.

When offered options that are unlikely to change outcomes, patients will usually select to stay the course.

Medical Paradox Still Exists

Majority of health care providers do not know how to help patients make transitions from curative to palliative care.

Guide

In Palliative Care we need to do modeling/imprinting on our colleagues
Attentive to shift in psycho-social, spiritual issues
Minimize areas of distress

Transition Points

- Present in appropriate environment
- Objective / succinct information
- Avoid medical jargon

Transition Points

- Assure clinical care is intact within the redefinition of goals of care
- Allow time to absorb
- Expect repeat messaging
Palliative Care Clinicians can feel yet respond

Anger / Frustration; address by

Turning energy around, focus on “here and now” with patient.

Respect patient choices, they may be the antithesis of your own.

Palliative Care Clinicians

Have real conversations toward meaning, affirming, take clues from family, be reflective. Ask

“What are you most concerned about?”

“What is the greatest surprise surrounding your illness experience?”

Introduction

• Young female cancer survivor
• Discusses how fortunate she was to have a very positive and empowering relationship with her medical team
• Discusses a contrasting experience she had at another hospital

Take Back to Practice

Palliative Intervention
• Early
• Available
• Integrative
• Reassurance

To our patient-Heroes disguised as ordinary people going on an extraordinary journey!

...and they lived at peace each day they had.........