WHAT’S NEW IN CANCER CARE?

- Targeting At Risk and High Risk Populations
  - Cancer Screening Guidelines
  - New Screening Methods
- Profiling Individual and Tumor Characteristics
  - Prognostic Indicators
  - Molecular Testing
  - Genetic Testing
  - Staging Factors
- Targeting Treatment
  - Patient/Tumor Profile
  - Treatment Guidelines
  - Quality of Life and End of Life Care
  - New Methods for Drug Delivery

IDENTIFYING HIGH RISK POPULATIONS

- Population Characteristics
  - Clearly Define the Population
  - Family History of Cancer
  - Geographic Location
  - Education Level
  - Employment
  - Lifestyle
  - Income
  - Race
  - Sex
  - Age
  - Performance Status

TARGETING HIGH RISK POPULATIONS

- Current/Former Smokers Age 55-74 with 30+ pack-year
- Broward County Women Age 50+ Without Colonoscopy
- Women Age 40-85 with Triple Negative Breast Cancer
- Patients with Neoplasm Never Seen in Hospital
- Women with BRCA1/BRCA2 Gene Expression
- Vietnam Veterans exposed to Agent Orange
- Children with BCR/ABL1+ CML
- Black Men Age 55-75
- Children Age 0-15
- Migrant Farmer
- Other

IDENTIFYING HIGH RISK POPULATIONS

- Workplace/Occupation/Industry
  - Painters
  - Construction
  - Ship building
- Exposure to Cancer Causing Agent(s)
  - Agent Orange
  - Solvents
  - Ionizing Radiation
- Genetic Predisposition(s) to Cancer(s)
  - BRCA1 and BRCA2
  - Lynch Syndrome
  - Li-Fraumeni Syndrome
  - Von Hippel-Lindau Disease
- Viral or Bacterial Infection – HIV1, HIV3, EBV, HPV, HHV, Merkel

TARGETING HIGH RISK POPULATIONS

- HIPAA Privacy and Outreach to High Risk Populations
- HIPAA Security and Outreach to High Risk Populations
- 1st HIPAA Breach Settlement
- Other HIPAA News
CANCER DEATH RATES* AMONG MEN, US, 1930-2009

CANCER DEATH RATES* AMONG WOMEN, US, 1930-2009

TRENDS IN TOBACCO USE AND LUNG CANCER DEATH RATES* IN THE US

- August 2011 - National Lung Screening Trial (NLST) Results
- Screening with low-dose spiral CT compared to CXR reduced lung cancer deaths among older heavy smokers by 20%.
- Improved detection of lung cancer at earlier stages is key to increased survival and improved mortality due to lung cancer.
- Weigh Benefits/Risk of lung cancer screening using CT scan
- Recommend Screening in High Risk Population:
  - Current/Former Smoker
  - Age 55-74 Years
  - Smoking History of at least 20-30 pack-years (varies by organization)
  - No personal history of lung cancer
- Frequency of Screening not included in All Recommendations
  - Annual
  - Once Every 3 Years
  - Other

CANCER SCREENING GUIDELINES - LUNG

- Endorsement/Adoption of Guideline
  - American Cancer Society (ACS)
  - American Lung Association (ALA)
  - American College of Chest Physicians (ACCP)
  - American Association for Thoracic Surgery (AATS)
  - ASCO/NCCN Clinical Practice Guidelines (ASCO/NCCN)
- Pending Endorsement
  - United States Preventative Services Task Force
  - 2004 - Last update to USPS TF Lung Cancer Screening

American Lung Association Recommendations
- The best way to prevent lung cancer caused by tobacco use is to never start smoking or to quit smoking.
- Low-dose CT screening should be recommended for those people who meet NLST criteria:
  - Current or former smokers aged 55 to 74 years
  - A smoking history of at least 20-30 pack-years
  - No history of lung cancer
- Individuals should not receive a chest X-ray for lung cancer screening
- Low-dose CT screening should NOT be recommended for everyone
- Patients should be referred to a facility that uses "best practices" for CT screening

The complete report can be found at www.Lung.org.
ALA Developing an Educational Portfolio for Patients to Explain:
- The difference between a screening process and a diagnostic test
- Cancer screening is testing for cancer before there are any symptoms
- The benefits, risks and costs (emotional, physical and economic)
- That not all lung cancers will be detected through use of low dose CT scanning

ALA issued a Call to Action for Hospitals and Screening Centers to:
- Establish ethical policies for advertising/promoting lung cancer screening services
- Develop educational materials to assist patients in having thoughtful discussions between patients and physicians regarding lung cancer screening
- Provide lung cancer screening services with access to multidisciplinary teams that can deliver the needed follow-up for evaluation of nodules.

PSA screening in men under age 40 years is not recommended.
Routine screening in men between ages 40 to 54 years at average risk is not recommended.
For men ages 55 to 69 years, the decision to undergo PSA screening involves weighing the benefits of preventing prostate cancer mortality in 1 man for every 1,000 men screened over a decade against the known potential harms associated with screening and treatment. For this reason, shared decision-making is recommended for men age 55 to 69 years that are considering PSA screening, and proceeding based on patients' values and preferences.
To reduce the harms of screening, a routine screening interval of two years or more may be preferred over annual screening in those men who have participated in shared decision-making and decided on screening. As compared to annual screening, it is expected that screening intervals of two years preserve the majority of the benefits and reduce over diagnosis and false positives.
Routine PSA screening is not recommended in men over age 70 or any man with less than a 10-15 year life expectancy.
CANCER SCREENING GUIDELINES - PROSTATE

- What do the guidelines actually mean?
  - Men of any age should not be routinely screened using PSA until evidence demonstrates mortality benefit of screening.
  - Men ages 55 to 69 are urged to talk with their doctors about benefits and harms of testing and treatment.
  - The best available evidence suggests that following these guidelines will lead to an improved benefit-to-harm ratio.
- What will this mean for cancer registry programs?
- What will this mean for cancer treatment centers?

CANCER SCREENING GUIDELINES - PROSTATE

- Endorsement/Adoption of Guideline
  - American Cancer Society (ACS)
  - American College of Physicians (ACP)
  - American Urological Association (AUA)
  - American Society for Radiation Oncology (ASTRO)
  - ASCO/NCCN Clinical Practice Guidelines (ASCO/NCCN)
  - United States Preventative Services Task Force (USPSTF)

CANCER SCREENING GUIDELINES - COLON

- Starting at age 50, men and women should follow one of the following examination schedules:

<table>
<thead>
<tr>
<th>Test</th>
<th>Time Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal Occult Blood Test</td>
<td>Annual</td>
</tr>
<tr>
<td>Flexible Sigmoidoscopy</td>
<td>5 Years</td>
</tr>
<tr>
<td>Double Contrast Barium Enema</td>
<td>5 Years</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>10 Years</td>
</tr>
<tr>
<td>CT Colonography</td>
<td>5 Years</td>
</tr>
</tbody>
</table>

NEW CANCER SCREENING METHODS

- Personal Genetic Profile
- Low-Dose Imaging Techniques
- Virus Exposure Testing – HPV (oral)
- MicroRNA-Based Diagnostic Assays
- Immunological Stool Testing for Blood and Antibodies – Colon
  - Significantly Superior to Enzymatic Stool Testing
- Laser-Induced Fluorescence (new imaging technique)

NEW CANCER SCREENING METHODS

- Need to Track Radiation Exposures from Screening
- Need to Track Radiation Exposure from non-screen CTs
- Screening Risk from Radiation Exposure Hypothesis Testing
NEW TREATMENT DELIVERY METHODS

- Transition from infusion chemotherapy to oral administration
- New inhalable chemotherapeutic agents using “nanostructured lipid nanocarriers” can transport antineoplastic agents at full strength directly into lungs or other organs – highly efficient.
- Nanoparticles also carry small interfering RNA (siRNA) molecules which help control and repress certain genes to eliminate “pump” resistance (when tumor cells actively expel chemo agent(s) before the chemo can work) and “non-pump” resistance, which keeps cancer cell from dying.
- MRI-Guided Focused/Concentrated Ultrasound Therapy

NEW TREATMENT DELIVERY METHODS

- Photo-Dynamic Therapy (PDT)
  - Approved for airway malignancy, Barrett’s esophagus with high grade dysplasia and non-melanoma skin cancers
  - Investigational for high-grade glioma, oral and laryngeal neoplasms, inoperable cholangiocarcinoma, and mesotheliomas
- New Embolization Techniques
  - Code as Chemo or Radiation plus Other Therapy
  - Trans-Arterial Chemo Embolization (TACE) – direct administration of chemo into liver or other organ then embolization of artery
  - Drug Eluting Bead Therapy – administration of beads impregnated with chemo agent(s) through catheter with timed release of agent(s)
  - Yttrium-90 Microsphere Therapy – administration of spheres with low levels of radio-isotope Yttrium-90 attached – direct radiation to liver
    - Code as brachytherapy not radio-isotope per CoC

NEW TREATMENT DELIVERY METHODS

- HIPEC Chemotherapy – Heated Intraperitoneal Chemotherapy
  - Chemotherapy solution heated to 107.6 degrees before administration
  - Chemotherapy solution kept at 107.6 degrees and recirculated throughout peritoneal cavity for at least two hours by going through a heating chamber
  - Proton Therapy Increases Precision and Reduces Side Effects
    - Focusing not only on direct treatment to tumor burden but also reducing side effects from treatment and collateral tissue damage
    - Also focusing on long-term/secondary effects from treatment(s)

TREATMENT RECONSIDERED

- Knowing When No Treatment is the Best Treatment
- Risk Stratification for Treatment of Solid Tumors
  - Neo-adjuvant therapy
  - Primary treatment
  - Adjuvant and Consolidation therapy
  - Maintenance therapy
  - Therapy for recurrent/progressive disease
  - Salvage therapy
- IMRT – Intensity-Modulated Radiotherapy is more expensive and not as effective or at least equally effective to conventional CRT – Conformal Radiotherapy for treatment of prostate cancer

CLINICAL CANCER ADVANCES
2012

ASCO's Annual Report on Progress Against Cancer
FOCUS AREAS IN CANCER RESEARCH

- Cancer Screening Risks and Benefits
- No Two Tumors Are Alike
- Precision Medicine – Personalized Medicine
- Targeting Molecular Pathways
- Targeting Genetic Alterations
- FDA and New Drug Approvals
- Management of Clinical Trials
- Overcoming Treatment Resistance
- Quality of Life and Survivorship Issues
- End of Life Care

FDA APPROVALS OF ANTICANCER AGENTS

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Trade Name</th>
<th>Indication</th>
<th>Date of Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alectinib</td>
<td>Wireliss</td>
<td>For advanced stage non-small cell lung cancer patients who are anaplastic lymphoma kinase (ALK) positive</td>
<td>January 28, 2017</td>
</tr>
<tr>
<td>Crizotinib</td>
<td>Xalkori</td>
<td>For advanced stage non-small cell lung cancer patients who are ALK positive</td>
<td>January 28, 2017</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>Keytruda</td>
<td>For use in patients with advanced melanoma, non-small cell lung cancer, renal cell carcinoma, and other tumors</td>
<td>June 28, 2017</td>
</tr>
<tr>
<td>Naxitamab</td>
<td>Zaltrap</td>
<td>For use in patients with metastatic colorectal carcinoma</td>
<td>August 30, 2017</td>
</tr>
<tr>
<td>Vandetanib</td>
<td>Zelboraf</td>
<td>For treatment of patients with advanced melanoma</td>
<td>August 30, 2017</td>
</tr>
<tr>
<td>Ramucirumab</td>
<td>Onyx</td>
<td>For treatment of patients with metastatic colorectal carcinoma</td>
<td>September 27, 2017</td>
</tr>
</tbody>
</table>

“Advances in breast cancer research over the past year were especially exciting. They provided evidence that several new targeted therapies benefit patients with metastatic breast cancer. The studies also allowed a glimpse into the future, in which the power of genomic technologies is used to define the molecular underpinnings of breast cancer, opening avenues for better understanding of drug resistance and the discovery of new therapeutic targets.”

“An increasing number of targeted therapies are being evaluated in clinical trials and are becoming available for our patients. Clinicians will need to select therapeutic approaches using these novel agents, standard chemotherapeutic regimens, and combinations of the two based on their knowledge of their patients and the specific features of their diseases.”

HARRY J. FISKE, MD, FACP
MAJOR CLINICAL ADVANCES IN YEAR 2012

Breast Cancer
- Chemo - Everolimus (Afinitor) for hormone-receptor + breast
- Chemo - Trastuzumab-DM1 for HER2-positive metastatic breast
- BRM - Pertuzumab (Perjeta) for HER2-positive metastatic breast

Lung Cancer
- Combination Chemo - Carboplatin and Pemetrexed for non-small cell lung cancer

MAJOR CLINICAL ADVANCES IN YEAR 2012

Prostate Cancer
- Hormone - Enzalutamide (Xtandi) for late stage prostate cancer

Esophageal Cancer
- Neoadjuvant chemo plus XRT then surgery for esophagus and gastroesophageal junction tumors

MAJOR CLINICAL ADVANCES IN YEAR 2012

Multiple Myeloma
- BRM - Lenalidomide (Revlimid) maintenance delays relapse after stem cell transplant
- BRM Agents for MM – Thalidomide, Velcade, Kyprolis, Pomalyst

Soft Tissue Sarcoma
- Chemo - Pazopanib (Votrient) for soft tissue sarcoma – 1st new drug in decades for soft tissue sarcoma

MAJOR CLINICAL ADVANCES IN YEAR 2012

Thyroid Cancer
- Chemo - Cabozantinib (Cometriq) in medullary thyroid cancer

Colorectal Cancer
- Chemo - Regorafenib (Stivarga) in metastatic colorectal cancer

Ovarian Cancer
- BRM - Bevacizumab (Avastin) in recurrent ovarian cancer

MAJOR CLINICAL ADVANCES IN YEAR 2012

Colorectal Cancer Screening
- Flexible sigmoidoscopy reduces colorectal cancer incidence and deaths – where does it fit into screening paradigm?
- Flexible sigmoidoscopy results are comparable to colonoscopy

Factors increase risk of death in elderly chemo population
- Geriatric assessment for patients > 70 yrs of age
- Advanced disease
- Low nutritional assessment score
- Poor mobility

Chemo-induced Nausea and Vomiting
- Ancillary - Olanzapine (Zyprexa) for breakthrough nausea/vomiting
MAJOR CLINICAL ADVANCES IN YEAR 2012

- Predicting risk for adverse effects of chemo in elderly
  - New model introduced scoring system and risk-stratification
  - Low-Risk / Intermediate-Risk / High-Risk
- Chemo-induced Peripheral Neuropathy
  - Ancillary - Duloxetine (Cymbalta) for alleviating pain from chemo-induced neuropathy

QUALITY INDICATORS

- Risk Stratification TX Early Stage Bladder Cancer (example):
  - Low-Risk Group: Ta Low Grade/Low Volume Non-Muscle Invasive Bladder Cancer – single dose Intravesical Chemotherapy using Epirubicin or Mitomycin
  - High-Risk Group: Ta High Grade/High Volume Non-Muscle Invasive and T1 Bladder Cancer – Intravesical BCG (Bacillus Calmette-Guerin – Tuberculosis)

QUESTIONS