The Latest in Cancer News: Screening, Diagnosis, Treatment Trends, Breakthroughs & Milestones

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STEVEN PEACE, CTR

Outline

- Introduction
- The End of Privacy
- Noteworthy Reports & Publications
- The Over-Diagnosis and Over-Treatment of “Cancer”
- “Big Data” & New Directions in Cancer Data Management
- Trends in Cancer Screening and Screening Recommendations
- Next Generation Biomolecular Tumor Markers and Genetic Testing
- The State of Cancer Care in America – 2015
- This & That for $1000
- Wrap Up
Introduction

Source: Life’s Crazy at http://lifesracy.com/game

The End of Privacy

Source: Science Magazine, January 30, 2015 – Special Issue: The End of Privacy
Noteworthy Reports & Publications

- **NCI Cancer Trends Progress Report – 100% Online**

- **2015 Cancer Facts & Figures**
  - Special Section: Breast Carcinoma In Situ

- **2014 Cancer Facts & Figures**
  - Special Section: Childhood and Adolescent Cancers

- **2014-2016 Colorectal Cancer Facts & Figures**

- **2015 Annual Report to the Nation on the Status of Cancer**
  - Feature: Breast Cancer Subtypes – 4 Subtypes by HR/HER2 Status

- **2014 Annual Report to the Nation on the Status of Cancer**
  - Feature: HPV-Associated Cancers and HPV Vaccination Coverage

- **CDC Morbidity and Mortality Weekly Report – 3/13/2015**
  - Cancer Incidence/Mortality and Tracking **Healthy People 2020 Goals**

http://progressreport.cancer.gov/
Noteworthy Reports & Publications

American Cancer Society – Colorectal Cancer Facts & Figures 2014-2016

Noteworthy Reports & Publications

ARTICLE


Source: J Natl Ca Inst. Online March 30, 2015. DOI: 10.1093/jnci/djv048
Noteworthy Reports & Publications

11


Manuscript received August 19, 2012; revised October 18, 2012; accepted October 19, 2012.

Noteworthy Reports & Publications

12

Source: MMWR, March 13, 2015 / Vol. 64 / No. 9 / Pg. 237 - 264; ND 146 - 163

Invasive Cancer Incidence and Survival — United States, 2011

S. Jane Henley, MPH; Simple D. Singh, MDV; Jessica King, MPH; Roch Wilson, MPH; Mary Elizabeth O'Sar, MPH; A. Byche-Byron, PhD

Author affiliations at end of text.

Healthy People 2020
...more publications...

- The Health Consequences of Smoking – 50 Years of Progress
  - Consumer Guide to the Report
  - Executive Summary
  - Full Report

- Clinical Cancer Advances 2015 – ASCO

- The State of Cancer Care in America 2014 - ASCO

- AACR Cancer Progress Report 2014

- 2014 Report on “Medicines in Development” - PhRMA and Cancer

- Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver and Pancreas Cancers in the United States


Noteworthy Reports & Publications

Source: American Association for Cancer Research – AACR.org/Surgeon General
• Tobacco control activities since 1994 have resulted in decreasing lung cancer mortality in the United States.
• Many carcinogens in tobacco products have been identified and the metabolic pathways leading to DNA adduct formation have been elucidated.
• Multiple DNA adducts are present in the lungs of smokers consistent with the thousands of mutations found in critical genes in lung cancer.
• Tobacco carcinogen and toxicant biomarkers provide an objective way to quantify dose, and possibly lung cancer risk, in smokers.
• Screening with helical CT has been shown to reduce lung cancer mortality
• Ongoing research is seeking to refine risk assessment models to focus screening resources to the highest risk populations
• Although no agents are approved for lung cancer prevention, promising agents and new clinical trials models are currently being tested.

Source: American Association for Cancer Research – AACR.org/Surgeon General

Source: Clinical Cancer Advances 2015/ASCO.org
Noteworthy Reports & Publications


Executive Summary

The AACR Cancer Progress Report offers a comprehensive summary of cancer science and potential cancer therapies in current development. The report highlights therapies in development and the regulators and stakeholders who are advancing treatments towards the clinic.

Cancer in 2014

The AACR Cancer Progress Report focuses on advances in cancer and strategies to confront the challenges and opportunities of our ongoing research. The report includes a look at the scientific and societal benefits of the discovery of new treatments and their potential to transform lives.

Medicines in Development By Disease and Phase


Noteworthy Reports & Publications
Noteworthy Reports & Publications

Perspective

Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States

Source: Cancer Res; 1–9, 2014 AACR

Next 20 Years - Projected Incidence

Source: Cancer Res; 1–9, 2014 AACR
Next 20 Years - Projected Mortality

Source: Cancer Res; 1–9, 2014 AACR

National Toxicology Program Report on Carcinogens

Redefining “Cancer” and New Disease Classifications

**NCI Panel: Stop Calling Low-Risk Lesions “Cancer”**

*Overdiagnosis and Overtreatment in Cancer: An Opportunity for Improvement*

Over the past 30 years, awareness and screening have led to an increase in early diagnosis of cancer. Although early detection and treatment is helpful, overdiagnosis and overtreatment have become common. The American Cancer Society estimates that 20% of all cancer diagnoses are overdiagnosed, particularly among breast cancer and prostate cancer, leading to unnecessary treatments and potential harms.

**Fatal Retraction**

Not all cancers are treatable despite the fear the name evokes. Although doctors often can’t tell which individual tumors are destined to be deadly, a growing number of studies suggest that many found at early stages may be too slow growing to be fatal. Some recent estimates of this overdiagnosis rate are:

- Prostate: 60%
- Breast: 50%
- Colon: 90%
- Skin: 90%
- Lung: 18%

Sources: American Cancer Society, National Cancer Institute, and The Wall Street Journal.

**Figure 3. Trends in ductal carcinoma in situ**

Incidence rates* by age, U.S., 1992-2011

*For 100,000 females, two-year moving average, age adjusted to the 2000 U.S. standard population, and adjusted for reporting delay.

**Sources:** Surveillance, Epidemiology, and End Results (SEER) Program, 13 SEER registries, National Cancer Institute, 2014. American Cancer Society, Inc., Surveillance Research, 2015.

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“Big Data” & New Directions in Cancer Data Mgmt.

**FEDERAL HEALTH IT STRATEGIC PLAN**

2015 – 2020

**Collect**
- **Share**
- **Use**

*For the Federal Health IT Strategic Plan 2015-2020—Develops a strategic framework to advance health IT*.

**Source:** Federal Health IT Strategic Plan 2015-2020 – Office of National Coordinator Health IT
ASCO QOPI and ASCO CancerLinQ

CancerLinQ™
The ASCO Institute for Quality, LLC, is leading the development of CancerLinQ™, a cutting-edge health information technology (HIT) platform that will revolutionize how we care for people with cancer. By enabling oncologists from each of the millions of individual patients living with cancer nationwide, CancerLinQ will improve the quality and value of cancer care for all.

CancerLinQ’s development is well under way. Once complete, CancerLinQ will aggregate and analyze a massive web of real-world cancer care data in order to:

- Provide real-time quality feedback to providers: CancerLinQ will enable oncologists to practice more effectively and compare performance with peers based on aggregated data of quality, offering insights that can improve patient outcomes.
- Feed personalized insights to providers: CancerLinQ’s real-time clinical decision support will help other physicians choose the right therapy for their patients, based on clinical guidelines and the experiences of many similar patients.
- Showcase patterns that can improve care: Powerful analytic tools will reveal new, previously unseen patterns in patient characteristics, treatments, and outcomes that can lead to improvements in care.

NCCN Celebrates 20 Years of Guidelines

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

NCCN would like to acknowledge and thank all NCCN Guidelines Panel members and Panel Chairs for their tremendous contribution and dedication in developing the eight original NCCN Guidelines and the ongoing work and dedication of all Guidelines Panel members over the past 20 years to the entire library of NCCN Guidelines.
NCCN/Flatiron Announce Outcomes Database

PRESS RELEASE

NCCN and Flatiron Health Announce Collaboration to Launch Novel Oncology Outcomes Database

A new collaboration between NCCN and Flatiron Health will provide the opportunity to analyze key quality and outcomes metrics and identify trends and patterns in the care of patients with cancer.

FORT WASHINGTON, PA, January 8, 2015 – The National Comprehensive Cancer Network® (NCCN®) is collaborating with Flatiron Health to create a cloud-based data repository of NCCN Member Institution data - the NCCN Outcomes Database.

“The collaboration with Flatiron Health will provide oncology stakeholders the ability to garner critical insights needed to make informed decisions,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “This database will give NCCN a leading edge in determining strategies for optimizing treatment protocols, as well as appropriate goals for oncology policy.”

Through this collaboration, electronic health record (EHR) data will be aggregated for cancer quality and outcomes assessment, as well as identification of key trends and patterns in the care of patients with cancer. Within this database, NCCN Member Institutions will have the opportunity to measure concordance to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) and will be able to access OncoAnalytics™, Flatiron Health’s proprietary, cloud-based analytics tool.

Current Trends in Cancer Screening

<table>
<thead>
<tr>
<th>Breast</th>
<th>Women, ages 20+</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Breast self-examination (BSE)</td>
</tr>
<tr>
<td></td>
<td>Clinical breast examination (CBE)</td>
</tr>
<tr>
<td></td>
<td>Mammography</td>
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<td></td>
<td>It is acceptable for women to choose not to do BSE or to do BSE regularly (monthly) or irregularly. Beginning in their early 20s, women should be told about the benefits and limitations of BSE. Whether or not a woman ever performs BSE, the importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination.</td>
</tr>
<tr>
<td></td>
<td>For women in their 20s and 30s, it is recommended that CBE be part of a periodic health examination, preferably at least every three years. Asymptomatic women ages 40 and over should continue to receive a CBE as part of a periodic health examination, preferably annually.</td>
</tr>
<tr>
<td></td>
<td>Begin annual mammography at age 40.*</td>
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<table>
<thead>
<tr>
<th>Cervix</th>
<th>Women, ages 21–65</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Pap test &amp; HPV DNA test</td>
</tr>
<tr>
<td></td>
<td>Cervical cancer screening should begin at age 21. For women ages 21–29, screening should be done every 3 years with conventional or liquid-based Pap test (LBP). Women ages 30–65: screening should begin at age 30 with a Pap test every 3 years, or every 3 years with the HPV test as opposed to the Pap test as the screening modality for those women who have been found to have a negative Pap test and negative HPV test within the past 10 years, with the most recent test occurring within 5 years, and women who have had a total hysterectomy should stop cervical cancer screening. Women should not be screened annually by any method at any age.</td>
</tr>
</tbody>
</table>

Source: 2015 Cancer Facts & Figures – American Cancer Society
## Current Trends in Cancer Screening

### Colorectal

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal occult blood test (FOBT) with at least 50% test sensitivity for cancer. or Stool DNA test**</td>
<td>Annual, starting at age 50. Testing at home with adherence to manufacturer’s recommendation for collection techniques and number of samples is recommended. FOBT with the single stool sample collected on the client’s finger tip during a digital rectal examination is not recommended. Guaiac-based stool FOBT tests also are not recommended. In comparison with guaiac-based tests for the selection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity. There is no justification for repeating FOBT in response to an initial positive finding.</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy (FSG) or Double-contrast barium enema (DCBE)</td>
<td>Every 5 years, starting at age 50. FSG can be performed alone, or consideration can be given to combining FSG performed every 5 years with a high-sensitivity gFOBT or FIT performed annually.</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>Every 10 years, starting at age 50</td>
</tr>
</tbody>
</table>

Source: 2015 Cancer Facts & Figures – American Cancer Society

### Lung

Clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about lung cancer screening with apparently healthy current or former smokers ages 55-74 who have at least a 30-pack-year smoking history, and who currently smoke or quit smoking within the past 15 years. A process of informed, shared decision making with a clinician balanced by potential benefits, risks, and harms associated with screening for lung cancer with LDCT should occur before any decision is made to initiate lung cancer screening. Smoking cessation counseling remains a high priority for clinical attention in discussions with current smokers, who should be informed of their continuing risk of lung cancer. Screening should not be viewed as an alternative to smoking cessation.

Source: 2015 Cancer Facts & Figures – American Cancer Society

### Prostate

Digital rectal examination (DRE) and prostate-specific antigen test (PSA)

**Men who have at least a 10-year life expectancy should have an opportunity to make an informed decision with their health care provider about whether to be screened for prostate cancer, with counseling information concerning the risks, benefits, and limitations associated with prostate cancer screening. Prostate cancer screening should not occur without an informed decision-making process.**

Source: 2015 Cancer Facts & Figures – American Cancer Society

**Cancer-related checkup**

- **Men and women, ages 21+**
  - On the occasion of a periodic health examination, the cancer-related checkup should include examination for cancers of the thyroid, testicle, ovaries, lymph nodes, oral cavity, and skin, as well as health counseling about tobacco, sun exposure, diet and nutrition, risk factors, sexual practices, and environmental and occupational exposures.

Source: 2015 Cancer Facts & Figures – American Cancer Society
Implementation of the US Preventive Services Task Force Recommendations for low-dose computed tomography (LDCT) lung cancer screening is expected to increase lung cancer diagnoses and increase Medicare expenditure.

Full Implementation (screening offered to all eligible patients in all years) is expected to result in more than 141,000 new lung cancers detected with screening each year at a cost of >$27B to Medicare.

Phased Implementation (a proportion of eligible patients offered screening each year increasing by 20% each year) will result in an additional 100,000 new lung cancers detected by screening each year at a cost of >17.5B.

Both will result in an increased number of Stage I cancers and more cancers of lesser malignant potential (broncho-alveolar carcinoma or BAC).

Current Trends in Cancer Screening - New Methods

- Risk-Based Screening
- 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)
Current Trends in Cancer Screening - New Methods

Targeting High Risk Populations

“Agent Orange Tied to Aggressive Prostate Cancer Risk”

“Study Links HPV to Lung Cancer (20% of NSCLC show HPV)”

“New Report on Radon and Lung Cancer – 2nd leading cause”

Need to Track Radiation Exposures from Screening

Need to Track Radiation Exposure from non-screen CTs

Screening Risk from Radiation Exposure Hypothesis Testing
Common sources of radiation

Where do mobile phones fit?

Radiation exposure: How does it compare?

Exposure measured in mSv

<table>
<thead>
<tr>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000</td>
<td>Fatal within seconds</td>
</tr>
<tr>
<td>6,000</td>
<td>Typical dose recorded in some Chernobyl liquidators who died within months</td>
</tr>
<tr>
<td>5,000</td>
<td>Exposure of Chernobyl liquidators who died within months</td>
</tr>
<tr>
<td>1,000</td>
<td>Exposure of Chernobyl liquidators who were evacuated</td>
</tr>
<tr>
<td>400</td>
<td>100 mrem/min dose in an MRI scan</td>
</tr>
<tr>
<td>350</td>
<td>100 mrem/X-ray examination</td>
</tr>
<tr>
<td>100</td>
<td>50 mrem/week outdoor (12 mrem/month)</td>
</tr>
<tr>
<td>10</td>
<td>5 mrem/week indoor (1 mrem/month)</td>
</tr>
<tr>
<td>2</td>
<td>1 mrem/day (12 mrem/month)</td>
</tr>
<tr>
<td>1.02</td>
<td>0.4 mrem/day (12 mrem/month)</td>
</tr>
<tr>
<td>0.4</td>
<td>0.1 mrem/day (12 mrem/month)</td>
</tr>
<tr>
<td>0.1</td>
<td>Natural radiation</td>
</tr>
<tr>
<td>0.01</td>
<td>Natural radiation</td>
</tr>
</tbody>
</table>

Source: Science Media Centre
New Disease Classifications

WHO/IARC Classification of Tumours - Fourth Edition

- WHO Classification of Tumours of Female Reproductive Organs. Fourth Edition
- WHO Classification of Tumours of Soft Tissue and Bone, Fourth edition
- WHO Classification of Tumours of the Breast, Fourth Edition
- WHO Classification of Tumours of the Digestive System, Fourth Edition
- WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues, Fourth Edition
- WHO Classification of Tumours of the Central Nervous System, Fourth Edition

Pending Review and Revision
- Lung, Pleura, Thymus and Heart
- Head and Neck Tumors
- Tumors of Endocrine Origin
- Urinary System and Male Genital Organs
- Skin Tumors


Misdiagnosis More Frequent Than Believed

- Misdiagnosis can often be attributed to incomplete clinical assessment of a patient prior to treatment and/or tumor tissue exam insufficient to ensure accurate tumor characterization, tumor classification, and targeted prognostic/predictive testing.

- Physicians estimate misdiagnosis or incomplete characterization occurs 10%-20% of the time for all cancers.

- Physicians estimate misdiagnosis or incomplete characterization occurs as much as 44% for certain types of cancer.

- Misdiagnosis or incomplete characterization directly impacts treatment recommendations and treatment planning from pre-surgical neoadjuvant treatment to surgical intervention strategies to post-surgical treatment planning, and treatment for recurrence/progression and end of life care.

- Poor feedback loops to multidisciplinary oncology team are a big part of this problem, particularly when biomarker and genetic testing changes the dx.

Source: Cancer, June 15, 2013 /DOI: 10.1002/cncr.28189
Gene expression profiling is a technique used in molecular biology to query the expression of up to thousands of genes simultaneously.

The unique pattern of gene expression for a given cell or tissue is its “molecular signature” which may have distinct biological properties.

Gene expression profiling can be used to more accurately classify tumors and is used to “personalize” treatment options and follow-up.

Information derived from gene expression profiling may impact tumor-specific treatment options targeted to one or more proteins “active” in the profile or in predicting the patient’s clinical outcome.

TECHNIQUES include Real Time PCR, MicroRNA analysis, DNA Microarray technology or sequenced-based techniques such as Serial Analysis of Gene Expression and DNA or RNA Sequencing.

- RT-PCR is currently the “gold standard” and several commercial products are available such as the Oncotype DX assays which analyze the expression of a panel of 21 genes from a tumor specimen.
- DNA Microarray - DNA “probes” attached to glass to create a “chip” or array of microscopic spots of pre-defined DNA oligonucleotides specifically targeted to identify complementary DNA in a specimen.
- RNA-Sequencing is superior to microarray (no pre-selected “probes”).
- SuperSAGE is highly accurate and can measure any active gene, not just a pre-defined set. Unfortunately, many genes are always active.

FUTURE: Standardized testing that will soon allow registrars to begin to capture standardized results and standardized interpretation of results.
Next Generation: Gene Expression Profiling

- HOWEVER – Few techniques/tests have been standardized, they are expensive but getting cheaper, and the results and interpretation of results varies widely depending upon array, specialty and experience.
  - The size and complexity of gene expression profile testing results in a wide variety of possible interpretations – still “experimental” technique(s).
  - Testing is performed under experimental conditions not real world.
  - Analyzing expression profiling results often takes far more time, effort and specific interpretative expertise than performing available alternate but less accurate proteomic mass spectrometry testing or standard prognostic testing.
  - Few people understand the biological significance of each regulated gene.
- GEP Testing does not replace standard prognostic information.
- Testing is being done and results used incorrectly to “elucidate” treatment options, despite confusion over how to interpret tests and their validity, reproducibility, and application to “inform”.
- GEP Testing does add a new piece to an increasingly complex puzzle.

Current Oncology (2014; doi:10.3747/co.21.1524)

Fast DNA Sequencing Machines Lead to New Tests

“Liquid Biopsy” IDs Cell-Free Tumor DNA Strands in Circulating Blood

- Cancers and DNA Mutations
- Cells Die Leaving Trace DNA
- Trace DNA Acts as Target
- 100s of Mutations Checked
- DNA Composite is Bar-Code
- Target Used for Diagnosis
- Target Used for Treatment
- Target Used for Monitoring
- Mutations Change Over Time
### Proprietary Genetic Assay Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>Oncotype DX</strong></td>
<td>Early stage hormone receptor + invasive Breast Cancer</td>
</tr>
<tr>
<td></td>
<td>Assesses risk for recurrence of DCIS/new primary</td>
</tr>
<tr>
<td></td>
<td>Assesses risk for recurrence</td>
</tr>
<tr>
<td></td>
<td>Examines 21 Genes</td>
</tr>
<tr>
<td></td>
<td>Cost - $4,000</td>
</tr>
<tr>
<td><strong>MammaPrint</strong></td>
<td>Early stage hormone receptor + or – invasive Breast Cancer</td>
</tr>
<tr>
<td></td>
<td>Assesses risk for recurrence</td>
</tr>
<tr>
<td></td>
<td>Examines 70 Genes</td>
</tr>
<tr>
<td><strong>MammoStrat</strong></td>
<td>Early stage hormone receptor + or – invasive Breast Cancer</td>
</tr>
<tr>
<td></td>
<td>Assesses risk for recurrence</td>
</tr>
<tr>
<td></td>
<td>Examines 5 Genes</td>
</tr>
<tr>
<td><strong>Prosigna Breast Cancer Prognostic Gene Signature Assay (PAM50)</strong></td>
<td>Early stage hormone receptor + invasive Breast Cancer</td>
</tr>
<tr>
<td></td>
<td>Assesses risk for recurrence</td>
</tr>
<tr>
<td></td>
<td>Examines 58 Genes</td>
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</table>

### Other Prognostic/Predictive Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Details</th>
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</table>
| **What is HER2 DuaLish Test for Breast Cancer?** | Dual Color CISH HER2 Test  
Dual color chromogenic in situ hybridization test that improves upon the earlier single color CISH test.  
Code as CISH HER2 Test.                                                                                                                                 |
| **What is Urokinase Plasminogen Activator (uPA)?** |                                                                                                                                                                                                           |
| **What is Plasminogen Activator Inhibitor (PAI-1)?** | Both uPA and PAI-1 are tumor markers that may be used as a guide for identifying patients with node-negative breast cancer who might benefit from chemotherapy after surgery. |
Other Prognostic/Predictive Tests

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>ALK Gene Rearrangements</td>
<td>BR/PR</td>
</tr>
<tr>
<td>AFP</td>
<td>Fibrein/Fibrinogen</td>
</tr>
<tr>
<td>Beta-2-microglobulin (B2M)</td>
<td>HE4</td>
</tr>
<tr>
<td>Beta-HCG</td>
<td>HER2/neu</td>
</tr>
<tr>
<td>BCR-ABL Fusion Gene</td>
<td>Immunoglobulins</td>
</tr>
<tr>
<td>BRAF mutation V600E</td>
<td>KIT</td>
</tr>
<tr>
<td>CA15-3/CA27.29</td>
<td>KRAS Mutation</td>
</tr>
<tr>
<td>CA19-9</td>
<td>LDH</td>
</tr>
<tr>
<td>CA125</td>
<td>Nuclear Matrix Protein 22</td>
</tr>
<tr>
<td>Calcitonin</td>
<td>PSA</td>
</tr>
<tr>
<td>CEA</td>
<td>Thyroglobulin</td>
</tr>
<tr>
<td>CD20</td>
<td>Urokinase Plasminogen Activator</td>
</tr>
<tr>
<td>CgA</td>
<td>Plasminogen Activator Inhibitor</td>
</tr>
<tr>
<td>Chromosomes 3,7,17,9p21</td>
<td>5-Protein Signature (Ova1)</td>
</tr>
<tr>
<td>Cytokeratin Fragments 21-1</td>
<td>21-Gene Signature (OncotypeDX)</td>
</tr>
<tr>
<td>EGFR Mutation</td>
<td>70-Gene Signature (Mammaprint)</td>
</tr>
</tbody>
</table>

The State of Cancer Care in America – 2015

- Early-detection via screening identifies early cancers (non-invasive, minimally invasive, in-situ) amenable to treatment.

- Early-treatment should focus on prevention and lifestyle with focus on smoking cessation, weight control, and active lifestyle.

- The 2 biggest risk factors for all cancers: **Smoking & Obesity**

- Obesity is related to diet AND exercise and causes diabetes

- Obesity-related diabetes is linked to increases in occurrence of cancers of the esophagus, thyroid, pancreas, gallbladder, kidney, colon, female breast (post-menopausal) and endometrium.

Source: Cancer Research, American Association for Cancer Research
**The State of Cancer Care in America – 2015**

- **Demand for cancer prevention, screening and treatment services is growing rapidly.** By 2030, the number of new cancer cases in the United States will increase by 45 percent and cancer will become the nation’s leading cause of death, largely as a result of the aging of the nation’s population. At the same time, the number of cancer survivors, now at 13.7 million, will continue to grow. Many of these individuals will require significant, ongoing care.

- **Access to quality cancer care remains uneven.** Millions of people with cancer lack access to quality medical care, and rates of access to care are disproportionately lower for African Americans and Latinos. Today, one quarter of uninsured individuals forego care because of cost, and those without a regular source of care are less likely to receive cancer screening. The Patient Protection and Affordable Care Act (referred to hereafter as ACA) is expected to provide millions more Americans with health insurance coverage in the coming years. However, the ACA alone may not solve disparities in cancer care—in part because it places significant emphasis on expanding Medicaid coverage, which has been associated with poor outcomes for patients with cancer. In addition, millions of Americans are expected to remain uninsured even after the ACA is implemented.

  Source: American Society of Clinical Oncology – ASCO.org

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**The State of Cancer Care in America – 2015**

- **Soaring costs have created an urgent need to improve the value of patient care.** While costs are rising throughout the healthcare system, the trend is especially pronounced in cancer care—annual costs are projected to rise from $104 billion in 2006 to more than $173 billion in 2020. This increase is a result of many factors, including the cost of many new cancer therapies. Access to high-quality cancer care will be sustained and expanded only if we address these rising costs, including the use of unnecessary or ineffective tests and treatments.

- **Potential workforce shortages.** ASCO estimates that, by 2025, demand for oncology services will grow by 42 percent or more, while the supply of oncologists will grow by only 28 percent. In this scenario, there could be a shortage of more than 1,487 oncologists in 2025. Furthermore, ASCO’s research indicates that the shortfalls may be further exacerbated by high levels of burnout, potentially leading to reduced clinical load or early retirement.

  Source: American Society of Clinical Oncology – ASCO.org
• **Practice size increasing.** The median size of practices increased substantially between those reporting in 2012 and 2013, from nine physicians per practice to 15. These results are consistent with other qualitative information about practice consolidation and mergers over the past year.

• **Financial instability for oncology practices.** Practices cited financial pressures as the greatest threat to their ability to continue providing high-quality care. As a result of cost pressures, significant numbers say they are cutting back on support staff or clinical research, or are sending patients to hospitals to receive chemotherapy.

• **Greatest threats faced by small community-based practices.** The 2013 ASCO census suggests that smaller community practices handle a disproportionate share of patient care, particularly in the southern and western United States, yet are under far greater economic pressure than larger practices. Nearly two-thirds of small practices (63 percent) reported that they were likely to merge, sell or close operations in the next year.

Source: American Society of Clinical Oncology – ASCO.org

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• **Physician-led quality initiatives show potential to improve care.** A number of different quality improvement efforts are being implemented in oncology with physician leadership and participation.

• **Medicare and private insurers working with physicians to test payment or care delivery approaches that reward high quality care.** These range from clinical pathways to patient-centered medical homes, which promote aggressive disease management, care coordination and strong patient/physician communication.

• **“Big data” arrives in cancer care.** The adoption of health information technology is already transforming many aspects of cancer care, but more dramatic change is on the horizon. Within years, big data initiatives will unlock and analyze data from large numbers of patients—and feed conclusions back to doctors in the form of personalized guidance for each patient. Such guidance will be vital in an area of increasingly complex treatments tailored to the genetics of each patient’s tumor.

Source: American Society of Clinical Oncology – ASCO.org
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

Robotic Surgery has increased in practice nationwide but is it worth the cost with payoff in reduced aftercare and recovery.

This and That: New Surgical Techniques

Vascularized Lymph Node Transfer (VLNTx) is a microsurgical procedure where normal lymph nodes and their associated adipose tissue are transferred to a region of the body that suffers from lymphedema.
This and That: FDA New Drugs Approved

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Approved Use</th>
<th>Prescribed or Targeted Therapy?</th>
<th>Oral or Injection</th>
</tr>
</thead>
</table>
| Daratumumab | X版权声明 | Multiple myeloma and related monotypic plasmacytoma | Y | Inh.
| Gilopsis | Gippeity | Myelodysplastic syndrome | Y | Inh.
| Alemtuzumab | MYAPMA | Chronic lymphocytic leukemia | Y | Inh.
| Pomalidomide injection | POMALYST | Multiple myeloma | Y | Injection
| Panitumumab (prescription required; patient-locked vial) | ZYRISTA | Advanced colorectal cancer | Y | Injection
| Alemtuzumab | Cladribine tablets | Non-Hodgkin lymphoma | Y | Oral
| Daratumumab | Xagement injection | Light chain amyloidosis | Y | Injection
| Alemtuzumab | VELCADE capsules | Non-Hodgkin lymphoma | Y | Oral
| Tramavale | MEDI5517 tablets | Non-small cell lung cancer with EGRF mutation | Y | Oral
| Efudex | TUM AND CAPSULE | Malignant melanoma | Y | Oral
| Ralston | TE-222 Clomipamide | Multiple myeloma | Y | Injection
| Melphalan | TACOSA | Multiple myeloma | Y | Injection
| Adenocarcinoma and melanoma | RETINOX injection | NSCLC resistance | Y | Injection
| Prednisone | FIORMIST VAP CUP | Multiple myeloma | Y | Injection
| Decamethylcoproporphyrin derivative injection | DCP DERIVATIVE INJECTION | Multiple myeloma | Y | Injection
| Decamethylcoproporphyrin derivative | DCP DERIVATIVE INJECTION | Multiple myeloma | Y | Injection
| Pomalidomide | ANAETH injection | Multiple myeloma | Y | Injection

This and That: 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 helps 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
This and That: 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 mesothelioma

- **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)
  - Ytrium-90 Microsphere Therapy – administration of spheres with low levels of radio-isotope Ytrium-90 attached – direct radiation to liver
    - Code as brachytherapy not radio-isotope per CoC

This and That: Ablation or Embolization

- “Ablation” is destruction of tumor by vaporization, chipping away (like chipping ice) or various other erosive processes.

- Tumor ablation is coded as surgery.

- Types of Ablation Include:
  - Cryo-Ablation – Uses Cold
  - Laser-Ablation – Uses Light
  - Microwave-Ablation – Uses Heat
  - PDT – photodynamic therapy is a type of laser ablation
  - High-Intensity Ultrasound – Uses Sound Waves to create heat
**This and That: Ablation or Embolization**

- "Embolization" is a procedure performed to create an embolus, a blocked or hardened blood vessel, and is used to shut down blood flow and blood supply to the primary tumor or to metastasis.

- Embolization can include injection of a chemical like alcohol or a chemo agent to sclerose or harden key blood vessel(s) and may even trap chemo behind the embolus; or can be performed by injecting a foreign material or substance like coils or radioactive beads to block the artery and prevent any blood flow to the tumor.

- Types of Embolization Include:
  - Chemo-Embolization – Uses Chemotherapy Agent(s) - TACE
  - Alcohol-Embolization – Uses Alcohol
  - Radioactive Beads/Spheres – Combines Radioisotopes / Mechanical Block
  - Artificial Embolus – plastic or metal coils, foam, other plugs to Block

- Treatment Code Will Depend on Type of Embolization

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**This and That: New Treatment Delivery Methods**

- HIPEC Chemotherapy – Heated Intra-peritoneal 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)
This and That: Radioimmunotherapy + Chemo

- PANCREAS: Small doses of an investigational radioimmunotherapy combined with small doses of the chemotherapy drug gemcitabine shown to provide “superior outcomes” over radioimmunotherapy alone for metastatic pancreatic cancer.

- Regimen: $^{90}$Y-clivatuzumab tetraxetan + gemcitabine (radiosensitizer)

- yttrium-90 or $^{90}$Y is a decay product of strontium-90, a fission product of uranium in nuclear reactors. It is used as a high-dose radio-isotope most often used as injectable beads or microspheres which deliver radiation directly to a tumor (high-dose brachytherapy) and is used to embolize liver tumors (radio-embolization).

- In this case $^{90}$Y is attached to the drug clivatuzumab tetraxetan, a monoclonal antibody that also targets/treats pancreatic cancer. The combination, a radioimmunoconjugate, selectively delivers a cytotoxic dose of beta radiation.

- How to code the complete regimen:
  - Radiation Therapy – yttrium-90 – high-dose intracavitary brachytherapy (code = 52)
  - Immunotherapy/BRM – clivatuzumab tetraxetan – immunotherapy (code = 01)
  - Chemotherapy – gemcitabine – single agent (code = 02)

Picozzi VJ. #89. AACR Pancreatic Cancer: Innovations in Research and Treatment; New Orleans; May 2014.

This and That: Glioblastoma, CMV & Tetanus

Diagram showing the process of vaccination with DC vaccine and the migration of pp65-Specific CD4+ T cell and CCL3, CCL21.

Diagram showing the process of vaccination with pre-conditioned site and the migration of pp65-Specific CD8+ T cell and CCL3, CCL21.
This and That: New Quality Indicators

**Risk Stratification TX Early Stage Bladder Cancer**

- **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)

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This and That: Registry Data Limitations

**Completeness of American Cancer Registry Treatment Data: Implications for Quality of Care Research**

Katherine Mallin, PhD, Bryan E Palis, MA, Nancy Watroba, MPA, Andrew K Stewart, MA, Daniel Walczak, MSc, Joseph Singer, MD, John Barron, PharmD, Wendy Blumenthal, MPH, Georgette Haydu, MA, Stephen B Edge, MD, FACS

**CONCLUSIONS**: Hospital-based registries for breast and colon cancer diagnosed in 2004–2006 captured about 85% of radiation and chemotherapy data compared with claims data, a higher percentage than earlier reports. These findings provide direction and a cautionary note to those using registry data for study of patterns and quality of systemic and radiation therapy care. (J Am Coll Surg 2013;216:428–437. © 2013 by the American College of Surgeons)
This and That: Expectations for the Registry

COMMENTARY

Leveraging State Cancer Registries to Measure and Improve the Quality of Cancer Care: A Potential Strategy for California and Beyond


Cancer Registries:
Data Strengths and Weaknesses

- Diagnosis
- First round of treatment/surgery
- Recurrence
- Subsequent treatments/surgery
- Survival
### This and That: Expectations for the Registry

- Increased Research Capacity
- Improved Healthcare Metrics
  - Quality of Care Monitoring
  - Performance Monitoring
- Rapid Reporting
- Direct Access to EHR/EMR
- Meaningful Use Data
- E-Claims
- E-Path
- E-Labs
- E-Tumor Markers
- E-Genetics Testing
- E-Specialty Testing
- Recurrence/Progression
- Subsequent Treatment(s)
- Ensure Patient Privacy
- Ensure Data Security

- Expanded use of the registry’s data to include quality measurement and public reporting, including provider identification
- Linkage of the registry to administrative claims and utilization data, in order to supply information not currently captured by the registry
- Linkage of the registry to systems of electronic health records (EHR), in order to further supplement registry data.

### Wrap Up

Source: ASCO.org/The State of Cancer Care in America - 2014