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

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FCDS ANNUAL CONFERENCE
ST PETERSBURG, FLORIDA
JULY 30, 2015

STEVEN PEACE, CTR

Prevention → Diagnosis → Treatment → Recovery → Palliation

Outline

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- Next Generation Biomolecular Tumor Markers and Genetic Testing
- The State of Cancer Care in America – 2015
- This & That for $1000
- Wrap Up

Introduction

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Source: Life's Crazy at http://lifescrazy.com/game-7

The End of Privacy

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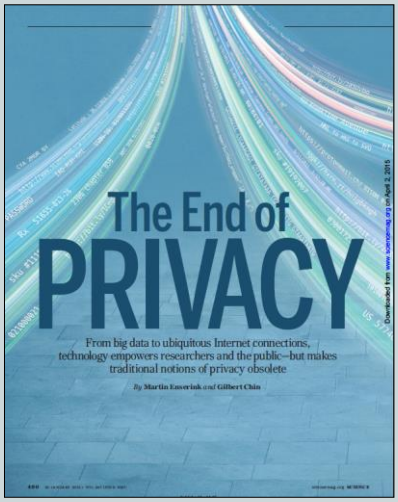

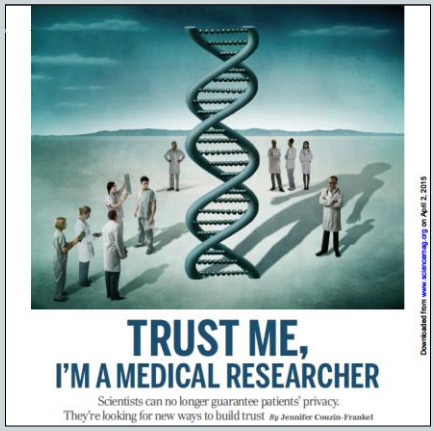

Source: Science Magazine, January 30, 2015 – Special Issue: The End of Privacy

Noteworthy Reports & Publications

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- 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

Noteworthy Reports & Publications

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http://progressreport.cancer.gov/

Noteworthy Reports & Publications

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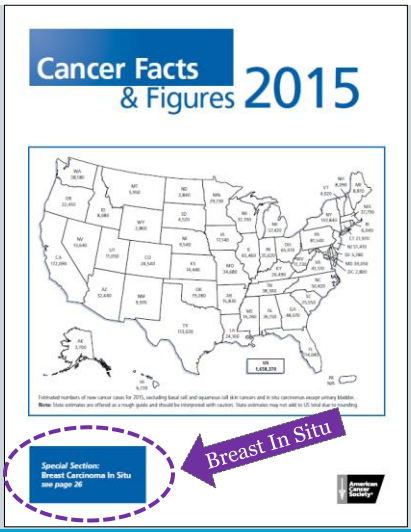

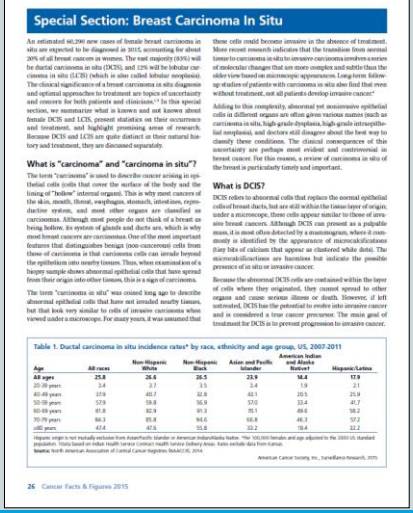

Special Section: Breast Carcinoma In Situ

An estimated 60,290 new cases of female breast carcinoma in situ are expected to be diagnosed in 2015, accounting for about 20% of all breast cancers in women. The vast majority (83%) will be ductal carcinoma in situ (DCIS), and 12% will be lobular carcinoma in situ (LCIS) (which is also called lobular neoplasia). The clinical significance of a breast carcinoma in situ diagnosis and optimal approaches to treatment are topics of uncertainty and concern for both patients and clinicians.[1,2] In this special section, we summarize what is known and not known about female DCIS and LCIS, present statistics on their occurrence and treatment, and highlight promising areas of research. Because DCIS and LCIS are quite distinct in their natural history and treatment, they are discussed separately.

What is "carcinoma" and "carcinoma in situ"?

The term "carcinoma" is used to describe cancer arising in epithelial cells (cells that cover the surface of the body and the lining of "hollow" internal organs). This is why most cancers of the skin, mouth, throat, esophagus, stomach, intestines, reproductive system, and most other organs are classified as carcinomas. Although most people do not think of a breast as being hollow, its system of glands and ducts are, which is why most breast cancers are carcinomas. One of the most important features that distinguishes benign (non-cancerous) cells from those of carcinoma is that carcinoma cells can invade beyond the epithelium into nearby tissues. Thus, when examination of a biopsy sample shows abnormal epithelial cells that have spread from their origin into other tissues, this is a sign of carcinoma.

The term "carcinoma in situ" was coined long ago to describe abnormal epithelial cells that have not invaded nearby tissues, but that look very similar to cells of invasive carcinoma when viewed under a microscope. For many years, it was assumed that these cells could become invasive in the absence of treatment. More recent research indicates that the transition from normal tissue to carcinoma in situ to invasive carcinoma involves a series of molecular changes that are more complex and subtle than the older view based on microscopic appearances. Long-term follow-up studies of patients with carcinoma in situ also find that even without treatment, not all patients develop invasive cancer.[3]

Adding to this complexity, abnormal yet noninvasive epithelial cells in different organs are often given various names (such as carcinoma in situ, high-grade dysplasia, high-grade intraepithelial neoplasia), and doctors still disagree about the best way to classify these conditions. The clinical consequences of this uncertainty are perhaps most evident and controversial in breast cancer. For this reason, a review of carcinoma in situ of the breast is particularly timely and important.

What is DCIS?

DCIS refers to abnormal cells that replace the normal epithelial cells of breast ducts, but are still within the tissue layer of origin; under a microscope, these cells appear similar to those of invasive breast cancers. Although DCIS can present as a palpable mass, it is most often detected by a mammogram, where it commonly is identified by the appearance of microcalcifications (tiny bits of calcium that appear as clustered white dots). The microcalcifications are harmless but indicate the possible presence of in situ or invasive cancer.

Because the abnormal DCIS cells are contained within the layer of cells where they originated, they cannot spread to other organs and cause serious illness or death. However, if left untreated, DCIS has the potential to evolve into invasive cancer and is considered a true cancer precursor. The main goal of treatment for DCIS is to prevent progression to invasive cancer.

Table 1. Ductal carcinoma in situ incidence rates* by race, ethnicity and age group, US, 2007-2011

Age	All races	Non-Hispanic White	Non-Hispanic Black	Asian and Pacific Islander	American Indian and Alaska Native†	Hispanic/Latina
All ages	25.8	26.6	26.5	23.9	14.4	17.9
20-39 years:	3.4	3.7	3.5	3.4	1.9	2.1
40-49 years:	37.9	40.7	32.8	42.1	20.5	25.9
50-59 years:	57.9	59.8	56.9	57.0	33.4	41.7
60-69 years:	81.8	82.9	91.3	70.1	49.6	58.2
70-79 years:	84.3	85.8	94.6	66.8	48.3	57.2
≥80 years:	47.4	47.6	55.8	33.2	19.4	32.2

*Hispanic origin is not mutually exclusive from Asian/Pacific Islander or American Indian/Alaska Native. †Per 100,000 females and age adjusted to the 2000 US standard population. ‡Data based on Indian Health Service Contract Health Service Delivery Areas. §Rates exclude data from Kansas.
Source: North American Association of Central Cancer Registries (NAACCR), 2014.
American Cancer Society, Inc., Surveillance Research, 2015

Source: 2015 Cancer Facts & Figures – American Cancer Society

Noteworthy Reports & Publications

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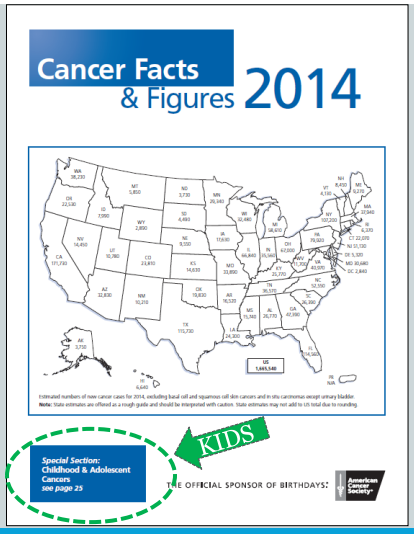

Special Section:
Cancer in Children & Adolescents

Overview

The news of a cancer diagnosis is never welcome, but may be even more unexpected and difficult when the disease is diagnosed in a child or adolescent. Although cancer is much less common among children compared to older adults, approximately 1 in 285 children in the US will be diagnosed with the disease before the age of 20. While advances in treatment have increased the survival rate for many childhood cancers, the disease is still the second leading cause of death (following accidents) in children ages 5-14.[1]

The types of cancers that develop in children and adolescents differ from those that develop in adults. The predominant types of pediatric cancers (ages 0-19) are leukemia (26%), cancers of the brain and central nervous system (CNS) (18%), and lymphoma (14%). Some of the cancers that develop in children are rarely seen in older individuals, notably those cancers that arise from embryonic cells and originate in developing tissues and organ systems. Embryonal cancers include neuroblastoma (sympathetic peripheral nervous system), Wilms tumor or nephroblastoma (developing kidney), medulloblastomas (brain), rhabdomyosarcomas (muscle), and retinoblastoma (retina of the eye). Some pediatric cancers, particularly those that are more common in adolescents, are more similar to those that arise in adults (e.g., acute myeloid leukemia, Hodgkin lymphoma, thyroid cancer, and melanoma).

Pediatric cancers represent 1% of all new cancers diagnosed in the US. Because these cancers occur in the context of rapid growth and development, most experts strongly recommend that they be treated at medical centers specialized in childhood cancer by multidisciplinary teams including pediatric oncologists, surgeons, radiation oncologists, and other specialists. At pediatric cancer centers, treatment protocols are available for most types of cancer that occur in children and adolescents, and the opportunity to participate in clinical trials is offered to most patients and their families. Clinical trials are generally designed to compare a potential improvement in therapy with therapy that is currently accepted as standard; improvements may result in an increase in cure rates or a reduction in acute or long-term complications. Member institutions of the Children's Oncology Group (COG), a National Cancer Institute-supported clinical trials group, care for more than 90% of US children and adolescents diagnosed with cancer (childrensoncologygroup.org). The COG has nearly 100 active clinical trials open at any given time, which include studies to test the efficacy of new treatments for many types of childhood cancers at diagnosis or recurrent diseases, improve understanding of the underlying biology of these diseases, and improve supportive care and survivorship. Children and adolescents diagnosed with types of cancer more commonly seen in adults also benefit from treatment in pediatric cancer centers.

In this special section, we provide an overview of trends in incidence, mortality, and survival for cancers commonly diagnosed in children and adolescents. We also provide more detailed information on risk factors, symptoms, treatment, and important long-term and late effects for these cancers. The major types of cancers included are leukemias and lymphomas, brain and CNS tumors, embryonal tumors, sarcomas of bone and soft tissue, and gonadal germ cell tumors.

How Many Cases and Deaths Are Expected to Occur in 2014?

An estimated 10,450 new cases and 1,350 cancer deaths are expected to occur among children (ages 0-14) in 2014. The corresponding figures among adolescents (ages 15-19) are 5,330 new cases and 610 cancer deaths.

What Are the Most Common Cancers in Children and Adolescents?

The most common cancers among children and adolescents vary by age and are shown in Figure 1 (page 26).

- Cancers that are most common in children ages 0-14 are acute lymphocytic leukemia (26%), brain and CNS (21%), neuroblastoma (7%), and non-Hodgkin lymphoma (6%).
- The most common cancers among adolescents ages 15-19 are Hodgkin lymphoma (15%), thyroid carcinoma (11%), brain and CNS (10%), and testicular germ cell tumors (8%).

While cancers occurring in adults are classified by the anatomical site of the primary tumor, cancers in children and younger adolescents are classified by histology (tissue type) into 12 major groups using the International Classification of Childhood Cancers (ICCC)[2] Figure 1 (page 26) shows the distribution of the most common cancers in children and adolescents by ICCC group.

Source: 2014 Cancer Facts & Figures – American Cancer Society

Noteworthy Reports & Publications

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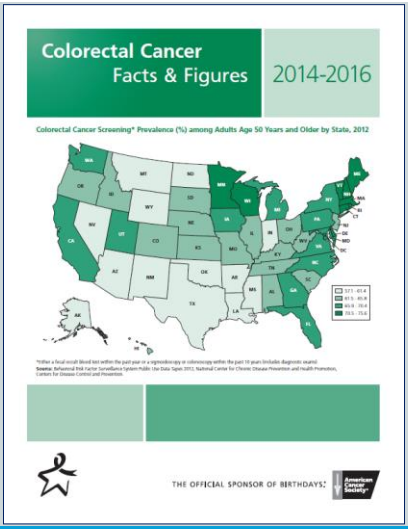

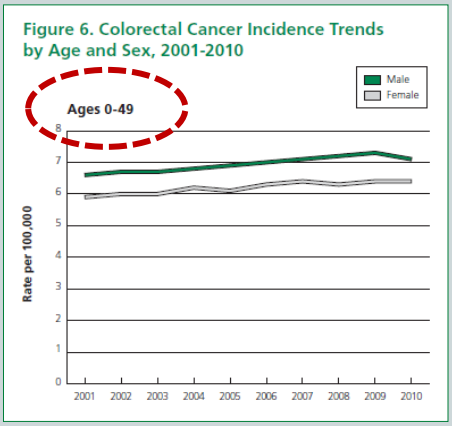

American Cancer Society – Colorectal Cancer Facts & Figures 2014-2016

Noteworthy Reports & Publications

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OXFORD

JNCI J Natl Cancer Inst (2015) 107(6): djv048

doi:10.1093/jnci/djv048
First published online March 14, 2015
Article

ARTICLE

Annual Report to the Nation on the Status of Cancer, 1975-2011, Featuring Incidence of Breast Cancer Subtypes by Race/Ethnicity, Poverty, and State

HR/HER2

Betsy A. Kohler, Recinda L. Sherman, Nadia Howlader, Ahmedin Jemal, A. Blythe Ryerson, Kevin A. Henry, Francis P. Boscoe, Kathleen A. Cronin, Andrew Lake, Anne-Michelle Noone, S. Jane Henley, Christie R. Eheman, Robert N. Anderson, Lynne Penberthy

Source: *J Natl Ca Inst. Online March 30, 2015. DOI: 10.1093/jnci.j/djv048*

Noteworthy Reports & Publications

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JNCI Journal of the National Cancer Institute Advance Access published January 7, 2013

ARTICLE

HPV

Annual Report to the Nation on the Status of Cancer, 1975–2009, Featuring the Burden and Trends in Human Papillomavirus (HPV)–Associated Cancers and HPV Vaccination Coverage Levels

Ahmedin Jemal, Edgar P. Simard, Christina Dorell, Anne-Michelle Noone, Lauri E. Markowitz, Betsy Kohler, Christie Eheman, Mona Saraiya, Priti Bandi, Debbie Saslow, Kathleen A. Cronin, Meg Watson, Mark Schiffman, S. Jane Henley, Maria J. Schymura, Robert N. Anderson, David Yankey, Brenda K. Edwards

Manuscript received August 15, 2012; revised October 18, 2012; accepted October 19, 2012.

Source: *JNCI J Natl Cancer Inst (2013) djs491 doi: 10.1093/jnci/djs491*

Noteworthy Reports & Publications

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Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Weekly / Vol. 64 / No. 9 March 13, 2015

Invasive Cancer Incidence and Survival — United States, 2011

S. Jane Henley, MSPH[1], Simple D. Singh, MD[1], Jessica King, MPH[1], Reda Wilson, MPH[1], Mary Elizabeth O'Neil, MPH[1], A. Blythe Ryerson, PhD[1]
(Author affiliations at end of text)

Healthy People 2020

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

…more publications…

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- 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" - P*h*RMA and *Cancer*
- Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver and Pancreas Cancers in the United States
- 2014 "Report on Carcinogens" – National Toxicology Program, 13th edition

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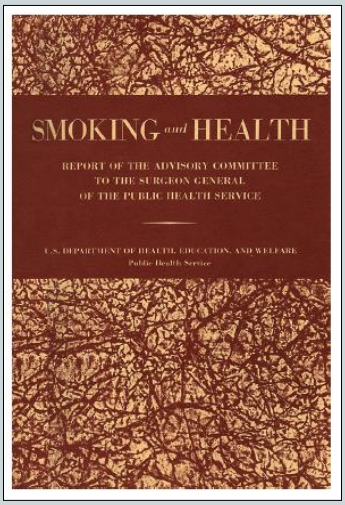

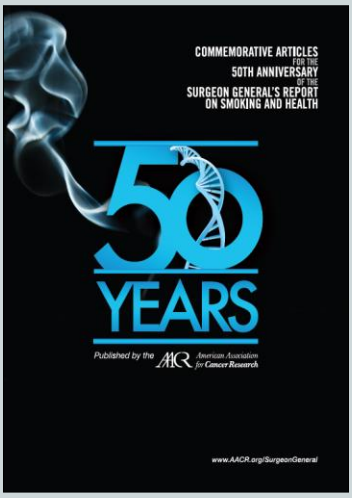

Source: American Association for Cancer Research – AACR.org/Surgeon General

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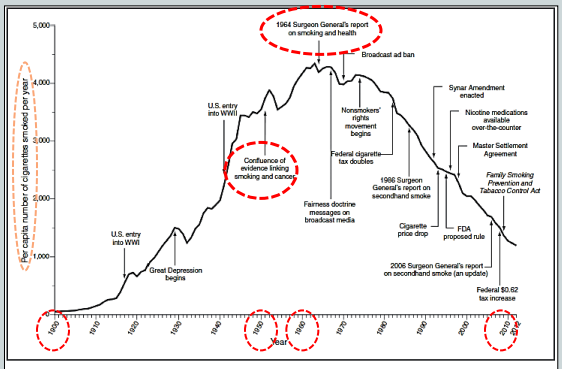

Figure 1. Adult per capita cigarette consumption and major smoking and health events, United States, 1900 to 2012. Source: U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress*. A Report of the Surgeon General. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

- Tobacco control activities since 1964 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

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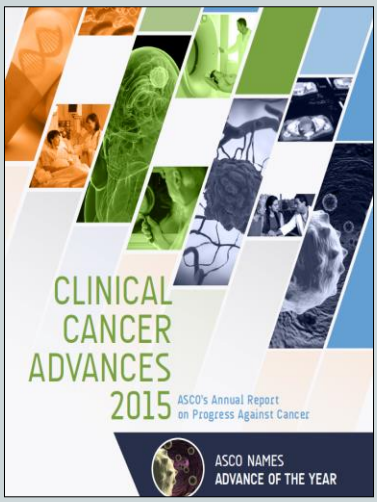

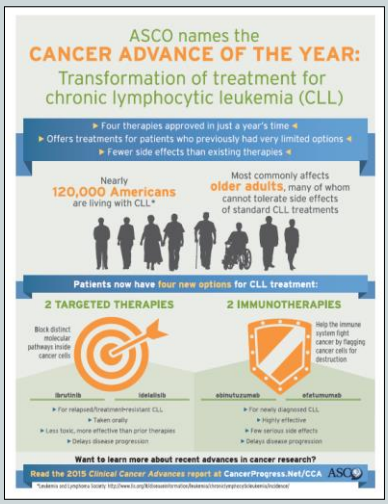

Source: Clinical Cancer Advances 2015/ASCO.org

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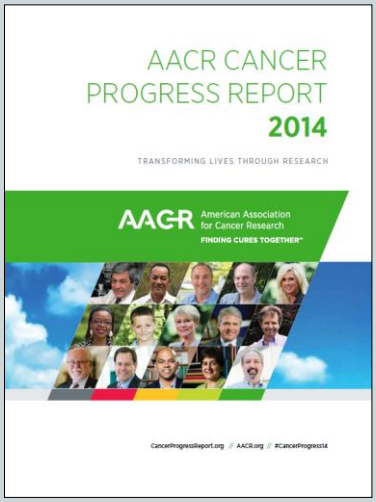

American Association for Cancer Research. AACR Cancer Progress Report 2014. ClinCancer Res 2014;20(Supplement 1):SI-S112

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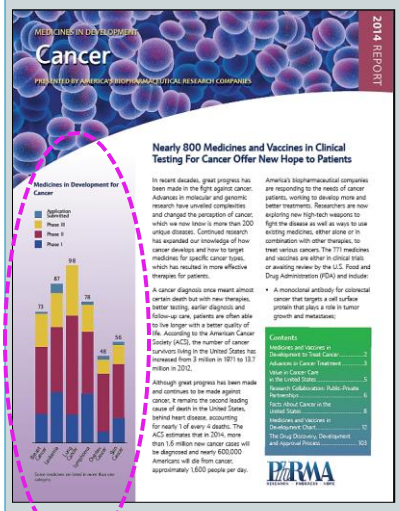

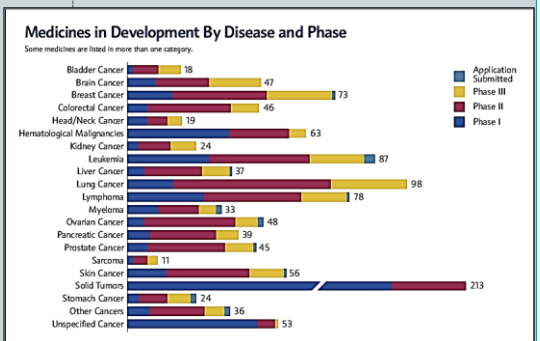

Cancer: 2014 Report PhRMA – "Medicines in Development"

Noteworthy Reports & Publications

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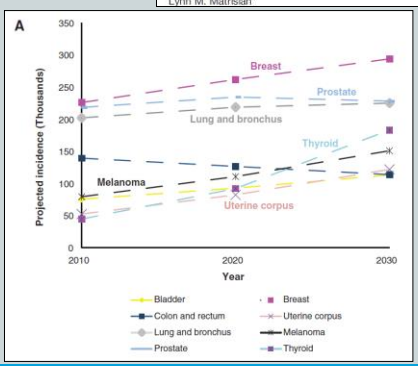
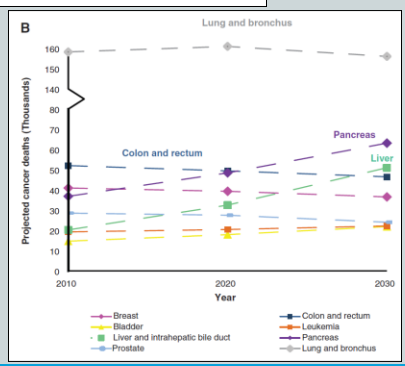
Perspective

Cancer Research

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

Lola Rahib[1], Benjamin D. Smith[2], Rhonda Aizenberg[1], Allison B. Rosenzweig[1], Julie M. Fleshman[1], and Lynn M. Matrisian[1]





Source: *Cancer Res; 1–9. 2014 AACR*

Next 20 Years - Projected Incidence

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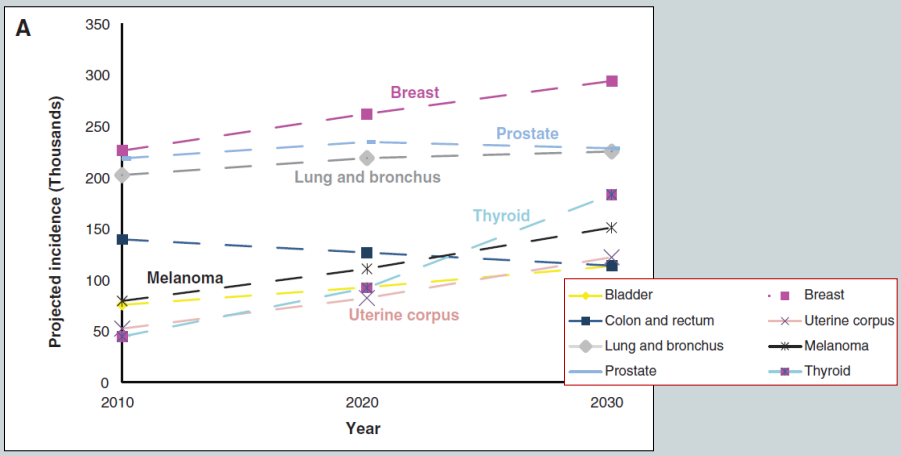

Source: *Cancer Res; 1–9. 2014 AACR*

Next 20 Years - Projected Mortality

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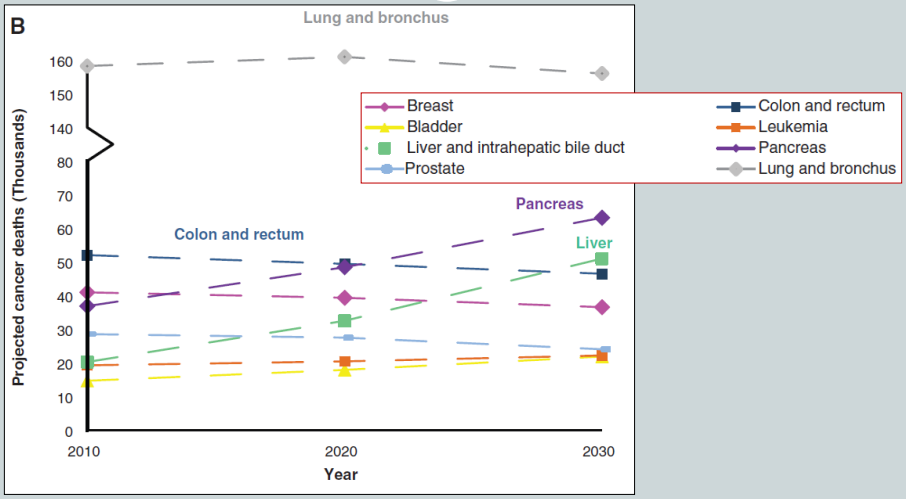

Source: *Cancer Res; 1–9. 2014 AACR*

National Toxicology Program Report on Carcinogens

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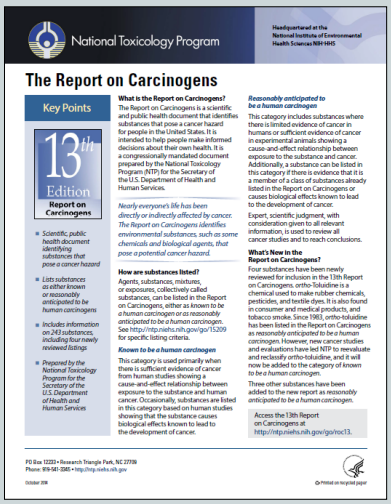


National Toxicology Program

Headquartered at the National Institute of Environmental Health Sciences NIH/HHS

The Report on Carcinogens

Key Points

13th Edition Report on Carcinogens

- Scientific, public health document identifying substances that pose a cancer hazard
- Lists substances as either known or reasonably anticipated to be human carcinogens
- Includes information on 243 substances, including four newly reviewed listings
- Prepared by the National Toxicology Program for the Secretary of the U.S. Department of Health and Human Services

What is the Report on Carcinogens?

The Report on Carcinogens is a scientific and public health document that identifies substances that pose a cancer hazard for people in the United States. It is intended to help people make informed decisions about their own health. It is a congressionally mandated document prepared by the National Toxicology Program (NTP) for the Secretary of the U.S. Department of Health and Human Services.

Nearly everyone's life has been directly or indirectly affected by cancer. The Report on Carcinogens identifies environmental substances, such as some chemicals and biological agents, that pose a potential cancer hazard.

How are substances listed?

Agents, substances, mixtures, or exposures, collectively called substances, can be listed in the Report on Carcinogens, either as *known to be a human carcinogen* or as *reasonably anticipated to be a human carcinogen*. See http://ntp.niehs.nih.gov/go/15209 for specific listing criteria.

Known to be a human carcinogen

This category is used primarily when there is sufficient evidence of cancer from human studies showing a cause-and-effect relationship between exposure to the substance and human cancer. Occasionally, substances are listed in this category based on human studies showing that the substance causes biological effects known to lead to the development of cancer.

Reasonably anticipated to be a human carcinogen

This category includes substances where there is limited evidence of cancer in humans or sufficient evidence of cancer in experimental animals showing a cause-and-effect relationship between exposure to the substance and cancer. Additionally, a substance can be listed in this category if there is evidence that it is a member of a class of substances already listed in the Report on Carcinogens or causes biological effects known to lead to the development of cancer.

Expert, scientific judgment, with consideration given to all relevant information, is used to review all cancer studies and to reach conclusions.

What's New in the Report on Carcinogens?

Four substances have been newly reviewed for inclusion in the 13th Report on Carcinogens. ortho-Toluidine is a chemical used to make rubber chemicals, pesticides, and textile dyes. It is also found in consumer and medical products, and tobacco smoke. Since 1983, ortho-toluidine has been listed in the Report on Carcinogens as *reasonably anticipated to be a human carcinogen*. However, new cancer studies and evaluations have led NTP to reevaluate and reclassify ortho-toluidine, and it will now be added to the category of *known to be a human carcinogen*.

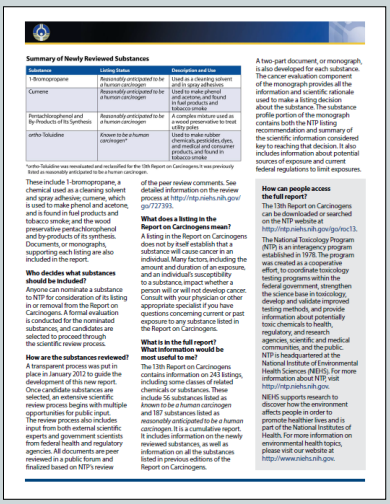
Three other substances have been added to the new report as *reasonably anticipated to be a human carcinogen*.

Access the 13th Report on Carcinogens at http://ntp.niehs.nih.gov/go/roc13.

PO Box 12233 • Research Triangle Park, NC 27709
Phone: 919-541-3345 • http://ntp.niehs.nih.gov

October 2014

Printed on recycled paper



Summary of Newly Reviewed Substances

Substance	Listing Status	Description and Use
1-Bromopropane	*Reasonably anticipated to be a human carcinogen*	Used as a cleaning solvent and in spray adhesives
Cumene	*Reasonably anticipated to be a human carcinogen*	Used to make phenol and acetone, and found in fuel products and tobacco smoke
Pentachlorophenol and By-Products of Its Synthesis	*Reasonably anticipated to be a human carcinogen*	A complex mixture used as a wood preservative to treat utility poles
ortho-Toluidine	*Known to be a human carcinogen**	Used to make rubber chemicals, pesticides, dyes, and medical and consumer products, and found in tobacco smoke

*ortho-Toluidine was reevaluated and reclassified for the 13th Report on Carcinogens. It was previously listed as reasonably anticipated to be a human carcinogen.

These include 1-bromopropane, a chemical used as a cleaning solvent and spray adhesive; cumene, which is used to make phenol and acetone, and is found in fuel products and tobacco smoke; and the wood preservative pentachlorophenol and by-products of its synthesis. Documents, or monographs, supporting each listing are also included in the report.

Who decides what substances should be included?

Anyone can nominate a substance to NTP for consideration of its listing in or removal from the Report on Carcinogens. A formal evaluation is conducted for the nominated substances, and candidates are selected to proceed through the scientific review process.

How are the substances reviewed?

A transparent process was put in place in January 2012 to guide the development of this new report. Once-candidate substances are selected, an extensive scientific review process begins with multiple opportunities for public input. The review process also includes input from both external scientific experts and government scientists from federal health and regulatory agencies. All documents are peer reviewed in a public forum and finalized based on NTP's review of the peer review comments. See detailed information on the review process at http://ntp.niehs.nih.gov/go/72393.

What does a listing in the Report on Carcinogens mean?

A listing in the Report on Carcinogens does not by itself establish that a substance will cause cancer in an individual. Many factors, including the amount and duration of an exposure, and an individual's susceptibility to a substance, impact whether a person will or will not develop cancer. Consult with your physician or other appropriate specialist if you have questions concerning current or past exposure to any substance listed in the Report on Carcinogens.

What is in the full report? What information would be most useful to me?

The 13th Report on Carcinogens contains information on 243 listings, including some classes of related chemicals or substances. These include 56 substances listed as *known to be a human carcinogen* and 187 substances listed as *reasonably anticipated to be a human carcinogen*. It is a cumulative report. It includes information on the newly reviewed substances, as well as information on all the substances listed in previous editions of the Report on Carcinogens.

A two-part document, or monograph, is also developed for each substance. The cancer evaluation component of the monograph provides all the information and scientific rationale used to make a listing decision about the substance. The substance profile portion of the monograph contains both the NTP listing recommendation and summary of the scientific information considered key to reaching that decision. It also includes information about potential sources of exposure and current federal regulations to limit exposures.

How can people access the full report?

The 13th Report on Carcinogens can be downloaded or searched on the NTP website at http://ntp.niehs.nih.gov/go/roc13.

The National Toxicology Program (NTP) is an interagency program established in 1978. The program was created as a cooperative effort, to coordinate toxicology testing programs within the federal government, strengthen the science base in toxicology, develop and validate improved testing methods, and provide information about potentially toxic chemicals to health, regulatory, and research agencies, scientific and medical communities, and the public. NTP is headquartered at the National Institute of Environmental Health Sciences (NIEHS). For more information about NTP, visit http://ntp.niehs.nih.gov.

NIEHS supports research to discover how the environment affects people in order to promote healthier lives and is part of the National Institutes of Health. For more information on environmental health topics, please visit our website at http://www.niehs.nih.gov.

Source: *NTP The Report on Carcinogens, 13th edition*

Redefining "Cancer" and New Disease Classifications

23

NCI Panel: Stop Calling Low-Risk Lesions "Cancer"

VIEWPOINT

Overdiagnosis and Overtreatment in Cancer
An Opportunity for Improvement

Laura J. Esserman, MD, MBA
University of California, San Francisco.

Ian M. Thompson Jr, MD
University of Texas Health Science Center at San Antonio.

Brian Reid, MD, PhD
Fred Hutchinson Cancer Research Center, Seattle, Washington.

Over the past 30 years, awareness and screening have led to an emphasis on early diagnosis of cancer. Although the goals of these efforts were to reduce the rate of late-stage disease and decrease cancer mortality, secular trends and clinical trials suggest that these goals have not been met; national data demonstrate significant increases in early-stage disease, without a proportional decline in later-stage disease. What has emerged has been an appreciation of the complexity of the pathologic condition called cancer. The word "cancer" often invokes the specter of an inexorably lethal process; however, cancers are heterogeneous and can follow multiple paths, not all of which progress to metastases and death, and include indolent disease that causes no harm during the erally leads to overtreatment. This Viewpoint summarizes the recommendations from a working group formed to develop a strategy to improve the current approach to cancer screening and prevention.

Periodic screening programs have the potential to identify a reservoir of indolent tumors.[4] However, cancer is still perceived as a diagnosis with lethal consequences if left untreated.

An ideal screening intervention focuses on detection of disease that will ultimately cause harm, that is more likely to be cured if detected early, and for which curative treatments are more effective in early-stage disease. Going forward, the ability to design better screening programs will depend on the ability to better char-

Fatal Retraction

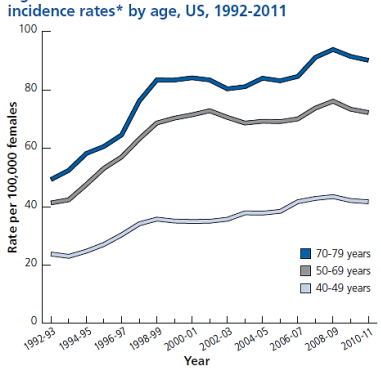
Not all cancers are lethal—despite the fear the name evokes. Although doctors often can't tell for certain which individual tumors are destined to be deadly, a growing number of studies suggest that many found at early stages may be so slow-growing they are unlikely to be fatal. Some recent estimates of this 'overdiagnosis' rate in common cancers:

Prostate	Breast	Thyroid	Skin	Lung*
60%	30%	90%	90%	18%

*Refers only to lung cancers detected by low-dose CT scans

Sources: American Cancer Society (Prostate); New England Journal of Medicine (Breast); The BMJ (Thyroid); Journal of the American Medical Association and Lancet Oncology (Skin); JAMA Internal Medicine (Lung*) The Wall Street Journal

Figure 3. Trends in ductal carcinoma in situ incidence rates* by age, US, 1992-2011



*Per 100,000 females, two-year moving averages, age adjusted to the 2000 US standard population, and adjusted for reporting delay.

Source: Surveillance, Epidemiology, and End Results (SEER) Program, 13 SEER registries, National Cancer Institute, 2014.

American Cancer Society, Inc., Surveillance Research, 2015

Sources: JAMA August 28, 2013 Volume 310, Number 8 and ACS Cancer Facts and Figures 2015

"Big Data" & New Directions in Cancer Data Mgmt.

24

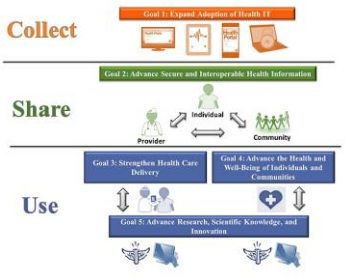
FEDERAL HEALTH IT STRATEGIC PLAN

2015 – 2020

Prepared by:

The Office of the National Coordinator for Health Information Technology (ONC)
Office of the Secretary, United States Department of Health and Human Services
http://healthit.gov

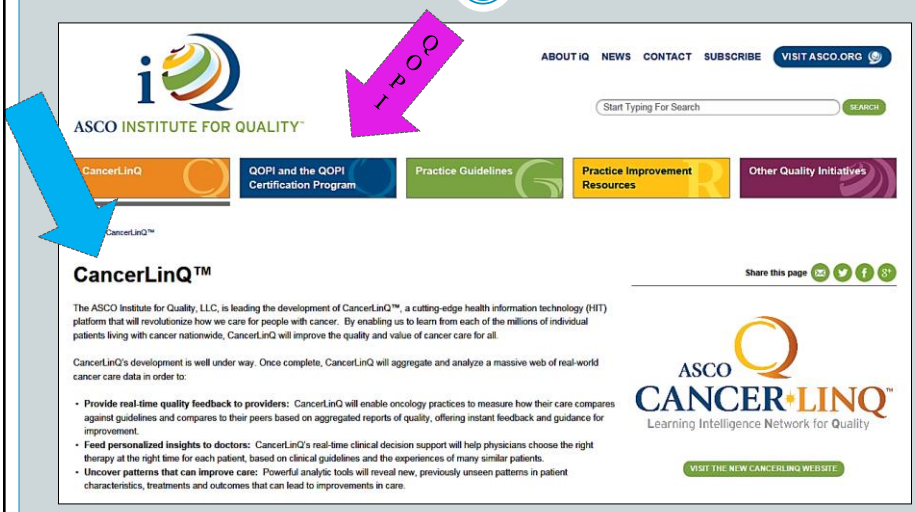
The *Federal Health IT Strategic Plan 2015-2020* describes the government's strategies to achieve five goals:



Source: Federal Health IT Strategic Plan 2015-2020 – Office of National Coordinator Health IT

ASCO QOPI and ASCO CancerLinQ

25



NCCN Celebrates 20 Years of Guidelines

26

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.

National Comprehensive Cancer Network®

PRESS RELEASES

20 Years of Improving Cancer Care Together – An NCCN Roundtable Discussion (03/13/2015)

Chemotherapy and Improved Surgical Techniques Noted as Important Advancements in Treating Ovarian Cancer over the Last Two Decades (03/09/2015)

Clinical Trials, Advanced Genetic Profiling, Improved Patient Categorization Have Led to Improved Outcomes in Acute Myeloid Leukemia since 1996 (03/09/2015)

NCCN 20th Annual Conference Will Highlight 20 Years of Cancer Treatment Improvements and Explore Value in Oncology; New and Updated NCCN Guidelines® (03/06/2015)

Looking Back on Two Decades of Breast Cancer Treatment: Targeted Therapy and Improved Surgical Procedures are Key Enhancements (2/13/2015)

NCCN Celebrates 20 Years of Improving Cancer Care (1/30/2015)

Changing the Course of Prostate Cancer Treatment: Life Expectancy Estimation, Active Surveillance, and Drug Development (11/21/2014)

Improved Outcomes in Non-Small Cell Lung Cancer Due to Advancements in Screening, Diagnosis, Radiology, and Systemic Therapies (11/19/2014)

Looking Back: 20 Years of Colorectal Cancer Treatment Breakthroughs Improve Survival, Advance Evidence-Based Choices (10/09/2014)

Oncology Experts Mark 20 Years of Evidence-Based Decision-Making in Small Cell Lung Cancer (09/04/2014)

NCCN/Flatiron Announce Outcomes Database

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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

28

Breast	Women, ages 20+	Breast self-examination (BSE)	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.
		Clinical breast examination (CBE)	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.
		Mammography	Begin annual mammography at age 40.*
Cervix†	Women, ages 21-65	Pap test & HPV DNA test	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 tests. For women ages 30-65, screening should be done every 5 years with both the HPV test and the Pap test (preferred) or every 3 years with the Pap test alone (acceptable). Women ages 65+ who have had ≥3 consecutive negative Pap tests or ≥2 consecutive negative HPV and Pap tests 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.

Source: 2015 Cancer Facts & Figures – American Cancer Society

Current Trends in Cancer Screening

29

Colorectal	Men and women, ages 50+	Fecal occult blood test (FOBT) with at least 50% test sensitivity for cancer, or fecal immunochemical test (FIT) with at least 50% test sensitivity for cancer, **or**	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 clinician's fingertip during a digital rectal examination is not recommended. Guaiac-based toilet bowl FOBT tests also are not recommended. In comparison with guaiac-based tests for the detection 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.
		Stool DNA test**, **or**	Interval uncertain, starting at age 50
		Flexible sigmoidoscopy (FSIG), **or**	Every 5 years, starting at age 50. FSIG can be performed alone, or consideration can be given to combining FSIG performed every 5 years with a highly sensitive gFOBT or FIT performed annually.
		Double contrast barium enema (DCBE), **or**	Every 5 years, starting at age 50
		Colonoscopy	Every 10 years, starting at age 50
		CT Colonography	Every 5 years, starting at age 50

Source: 2015 Cancer Facts & Figures – American Cancer Society

Current Trends in Cancer Screening

30

Lung	Current or former smokers ages 55-74 in good health with at least a 30 pack-year history	Low-dose helical CT (LDCT)	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 patients ages 55-74 who have at least a 30 pack-year smoking history, and who currently smoke or have quit within the past 15 years. A process of informed and shared decision making with a clinician related to the potential benefits, limitations, 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
Prostate	Men, ages 50+	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, after receiving information about the potential benefits, risks, and uncertainties associated with prostate cancer screening. Prostate cancer screening should not occur without an informed decision-making process.
Cancer-related checkup	Men and women, ages 20+		On the occasion of a periodic health examination, the cancer-related checkup should include examination for cancers of the thyroid, testicles, 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

Current Trends in Cancer Screening - COST

31

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

32

- 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

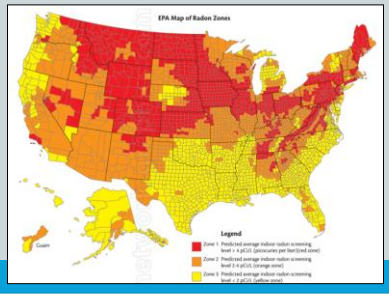
33

Targeting High Risk Populations

"Agent Orange Tied to Aggressive Prostate Cancer Risk"

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

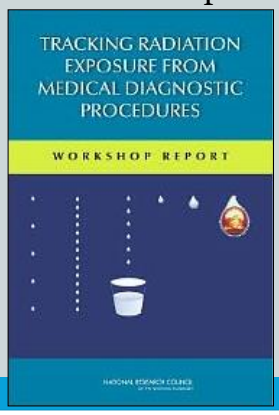
"New Report on Radon and Lung Cancer – 2nd leading cause"

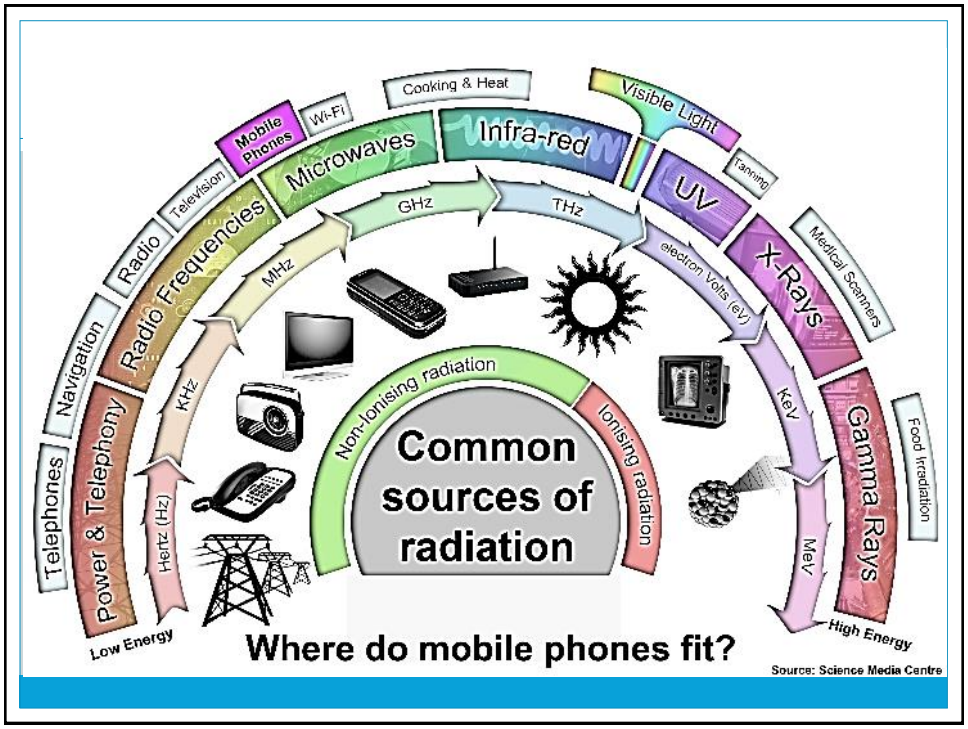


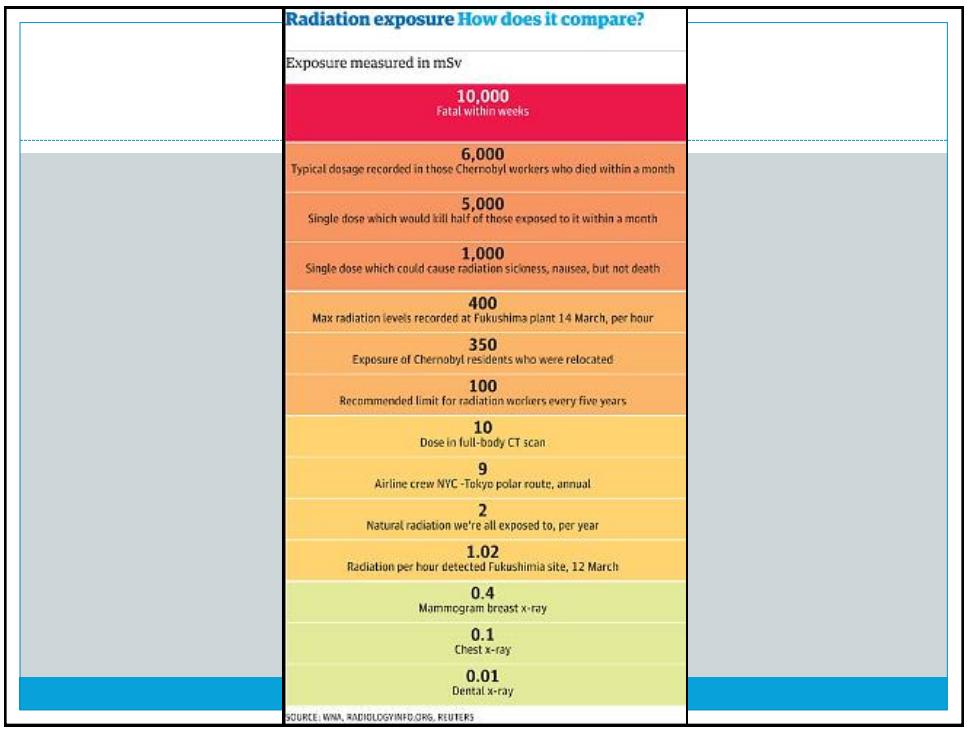
Current Trends in Cancer Screening - New Methods

34

Need to Track Radiation Exposures from Screening
Need to Track Radiation Exposure from non-screen CTs
Screening Risk from Radiation Exposure Hypothesis Testing







Radiation exposure How does it compare?

Exposure measured in mSv

10,000	Fatal within weeks
6,000	Typical dosage recorded in those Chernobyl workers who died within a month
5,000	Single dose which would kill half of those exposed to it within a month
1,000	Single dose which could cause radiation sickness, nausea, but not death
400	Max radiation levels recorded at Fukushima plant 14 March, per hour
350	Exposure of Chernobyl residents who were relocated
100	Recommended limit for radiation workers every five years
10	Dose in full-body CT scan
9	Airline crew NYC -Tokyo polar route, annual
2	Natural radiation we're all exposed to, per year
1.02	Radiation per hour detected Fukushimia site, 12 March
0.4	Mammogram breast x-ray
0.1	Chest x-ray
0.01	Dental x-ray

SOURCE: WNA, RADIOLOGYINFO.ORG, REUTERS

New Disease Classifications

37

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

Source: http://www.iarc.fr/en/publications/list/bb/

Misdiagnosis More Frequent Than Believed

38

- 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

Next Generation: Gene Expression Profiling

39

- 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.

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

Next Generation: Gene Expression Profiling

40

- 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.

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

Next Generation: Gene Expression Profiling

41

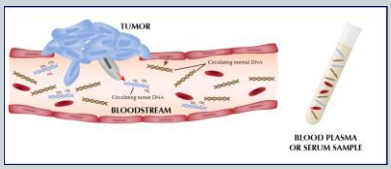
- HOWEVER – Few techniques/tests have been standardized, they are expensive but getting cheaper, and the results and interpretation of results varies widely depending upon array, specialty and experience.
  - The size and complexity of gene expression profile testing results in a wide variety of possible 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.

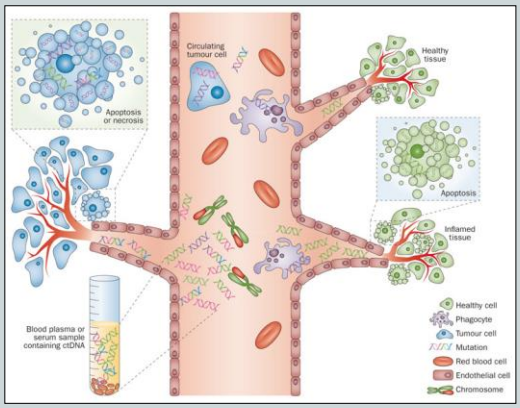
Current Oncology (2014; doi:10.3747/co.21.1524)

Fast DNA Sequencing Machines Lead to New Tests

42

"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

43

- Oncotype DX
  - Early stage hormone receptor + invasive Breast Cancer
  - Assesses risk for recurrence of DCIS/new primary
  - Assesses risk for recurrence
  - Examines 21 Genes
  - Cost - $4,000
- MammaPrint
  - Early stage hormone receptor + or – invasive Breast Cancer
  - Assesses risk for recurrence
  - Examines 70 Genes
- MammoStrat
  - Early stage hormone receptor + or – invasive Breast Cancer
  - Assesses risk for recurrence
  - Examines 5 Genes
- Prosigna Breast Cancer Prognostic Gene Signature Assay (PAM50)
  - Early stage hormone receptor + invasive Breast Cancer
  - Assesses risk for recurrence
  - Examines 58 Genes

Other Prognostic/Predictive Tests

44

- 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

45

FDA-Approved Tumor Marker Tests	
ALK Gene Rearrangements	ER/PR
AFP	Fibrin/Fibrinogen
Beta-2-microglobulin (B2M)	HE4
Beta-hCG	HER2/neu
BCR-ABL Fusion Gene	Immunoglobulins
BRAF mutation V600E	KIT
CA15-3/CA27.29	KRAS Mutation
CA19-9	LDH
CA-125	Nuclear Matrix Protein 22
Calcitonin	PSA
CEA	Thyroglobulin
CD20	Urokinase Plasminogen Activator
CgA	Plasminogen Activator Inhibitor
Chromosomes 3,7,17,9p21	5-Protein Signature (Ova1)
Cytokeratin Fragments 21-1	21-Gene Signature (OncotypeDX)
EGFR Mutation	70-Gene Signature (Mammaprint)

http://www.cancer.gov/cancertopics/diagnosis-staging/diagnosis/tumor-markers-fact-sheet

A-Z Listing and Description of >20 Tumor Markers Currently in Use and for which Cancer Types.

"although most of these can be tested in laboratories that meet standards set by CLIA, some cannot be and must be considered experimental." (No Standard Test)

http://www.cancer.gov/cancertopics/diagnosis-staging/diagnosis/tumor-markers-fact-sheet

The State of Cancer Care in America – 2015

46

- 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

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- **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 cost1, and those without a regular source of care are less likely to receive cancer screening.2 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.3 In addition, millions of Americans are expected to remain uninsured even after the ACA is implemented.

Source: American Society of Clinical Oncology – ASCO.org

The State of Cancer Care in America – 2015

48

- **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

The State of Cancer Care in America – 2015

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- **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

The State of Cancer Care in America – 2015

50

- **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

This and That: Treatment Reconsidered

51

- 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

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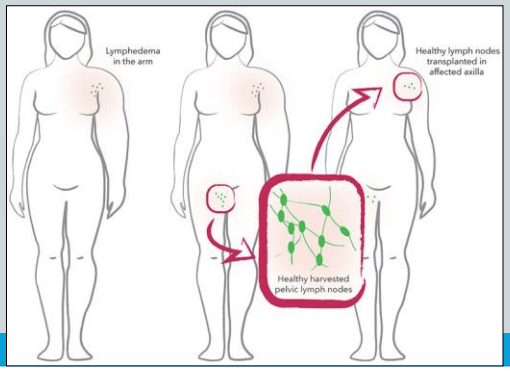
Vascularized Lymph Node Transfer (VLNTx) is a microsurgical procedure where normal lymph nodes and their associated adipose tissue are transferred to a region of the body that suffers from lymphedema.



This and That: FDA New Drugs Approved

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Generic Name	Brand Name	Approved Use	Precision or Targeted Therapy?*	Oral or Injection
Sorafenib	NEXAVAR	Differentiated thyroid carcinoma	N	Oral
Crizotinib	Xalkori	Non-small cell lung cancer, anaplastic lymphoma kinase (ALK)-positive	Y	Oral
Ibrutinib	IMBRUVICA	Mantle cell lymphoma	Y	Oral
Obinutuzumab	GAZYVA	Chronic lymphocytic leukemia	Y	Injection
Pertuzumab injection	PERJETA	HER2-positive breast cancer	Y	Injection
Paclitaxel protein-bound particles (albumin-bound)	Abraxane for injectable suspension	Adenocarcinoma of the pancreas	N	Injection
Afatinib	Gilotrif tablets	Non-small cell lung cancer, with epidermal growth factor receptor (EGFR) mutations	Y	Oral
Denosumab	Xgeva injection	Giant cell tumor of bone	N	Injection
lenalidomide capsules	REVLIMID	Mantle cell lymphoma	N	Oral
Trametinib	MEKINIST tablet	Melanoma with BRAF V600E or V600K mutation	Y	Oral
Dabrafenib	TAFINLAR capsule	Melanoma with BRAF V600E mutation	Y	Oral
Radium Ra 223 dichloride	Xofigo Injectio	Prostate cancer	N	Injection
Erlotinib	Tarceva	Non-small cell lung cancer with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations	Y	Oral
Ado-trastuzumab emtansine	KADCYLA for injection	HER2-positive, metastatic breast cancer	Y	Injection
Pomalidomide	POMALYST capsules	Multiple myeloma	N	Oral
Doxorubicin hydrochloride liposome injection	Generic version of DOXIL Injection	Ovarian cancer	N	Injection
Doxorubicin hydrochloride liposome injection	Generic version of DOXIL Injection	AIDS-related Kaposi's sarcoma	N	Injection
Bevacizumab	Avastin	Colorectal cancer	N	Injection

This and That: New Treatment Delivery Methods

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- 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

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- 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

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- "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
  - RFA – Radiofrequency-Ablation – Uses Heat – electrocautery
  - PDT – photodynamic therapy is a type of laser ablation
  - High-Intensity Ultrasound – Uses Sound Waves to create heat

This and That: Ablation or Embolization

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- "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

This and That: New Treatment Delivery Methods

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- 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

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- 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. #B9. AACR Pancreatic Cancer: Inonovations in Research and Treatment; New Orleans; May 2014.

This and That: Glioblastoma, CMV & Tetanus

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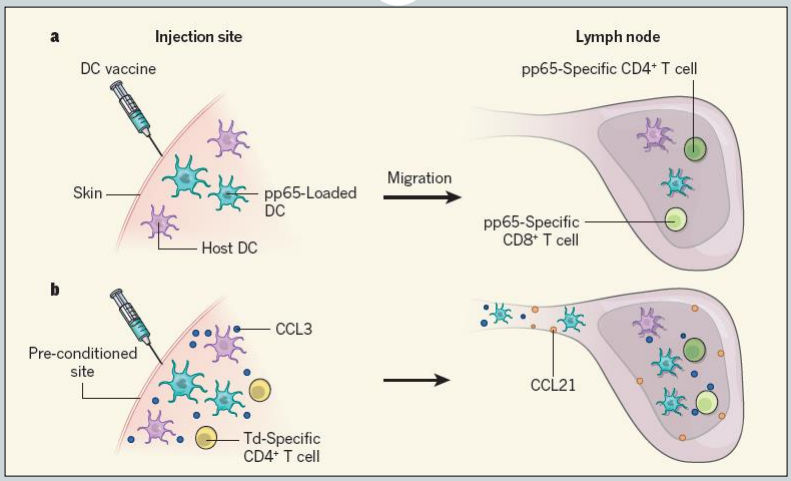

This and That: New Quality Indicators

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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)

This and That: Registry Data Limitations

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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

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OXFORD

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Commentary

COMMENTARY

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

Robert A. Hiatt, Caroline G. Tai, Douglas W. Blayney, Dennis Deapen, Michael Hogarth, Kenneth W. Kizer, Joseph Lipscomb, Jennifer Malin, Stephen K. Phillips, John Santa, Deborah Schrag

This and That: Expectations for the Registry

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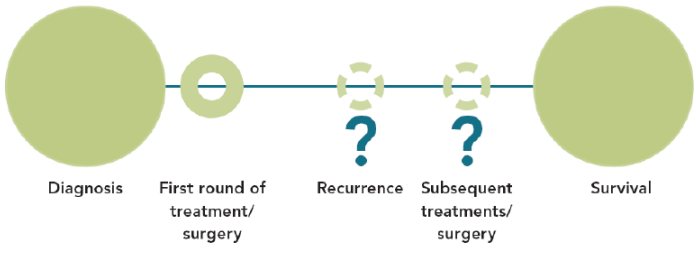
Cancer Registries: Data Strengths and Weaknesses



This and That: Expectations for the Registry

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- 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

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