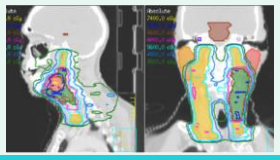
What's New in Cancer Care? Classification, Diagnosis, Imaging & Treatment

1

FCDS VIRTUAL ANNUAL CONFERENCE

8/25/2022

STEVEN PEACE, CTR



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CDC & Florida DOH Attribution

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"Funding for this conference was made possible (in part) by the Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the US Government."

FCDS would also like to acknowledge the Florida Department of Health for its support of the Florida Cancer Data System, including the development, printing and distribution of materials for the 2022 FCDS Annual Conference and the 2022-2023 FCDS Webcast Series under state contract COHAW. The findings and conclusions in this series are those of the author(s) and do not necessarily represent the official position of the Florida Department of Health.

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Presentation Outline

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- Introduction
- 2022 ACS Cancer Facts & Figures - Statistics
- 2021 Annual Report to the Nation on the Status of Cancer
- Cancer Trends Progress Report – 20th Anniversary
- AACR Cancer Progress Report 2021
- NCCN Annual Report 2021
- ASCO Report on Progress Against Cancer 2021
- FDA New Drug Therapy Approvals in 2021
- New Developments in Cancer Incidence – esophagus, endometrium, pancreas
- New Developments in Cancer Screening – pancreas, lung, melanoma, MCED Tests
- New Developments in Tumor Classification & Molecular-Biomarker Testing
- New Developments in Diagnostic Tools & Cancer Treatments – imaging, XRT, Immuno
- Update on Effects of the COVID-19 Pandemic on Cancer Diagnosis, Stage, and Treatment
- 2022 Update on Cancer Moonshot
- Questions

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Introduction

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- The burden of cancer is growing rapidly in the United States and worldwide.
- The USPSTF updated guidelines for screening of colorectal and lung cancer –
  - Begin at 45 years for colorectal cancers
  - Begin at 50 years for lung cancer
- These changes were due to increased cancer rates in these age groups
- Fast Facts on Cancer Health Disparities
  - African Americans have incidence of multiple myeloma more than twice that of non-Hispanic whites
  - American Indian/Alaskan Native individuals are more than 4 times more likely to develop stomach cancer than whites
  - During 2012-2016 incidence of early-onset colorectal cancer increased 35% for those living in rural areas
  - Cancer Mortality is 12/3% higher in US Counties where poverty is persistent compared to where poverty was no persistent
  - Women with no health insurance have double the likelihood of diagnosis of late stage breast cancer who are privately insured
- Fast Facts on New Drug Approvals
  - In 2020-2021, the US Food and Drug Administration (FDA) approved 16 new anticancer therapeutics and expanded the use of 11 previously approved anticancer therapeutics for treating new types of cancer.
  - In May 2021, the FDA approved the first molecularly targeted therapeutic against the protein KRAS, which has long been considered an undruggable target, for the treatment of certain patients with lung cancer. The agent, sotorasib (Lumakras), targets an altered form of the protein, KRAS G123C and is a new treatment option for NSCLC.
  - In March 2021, the FDA approved the first CAR T-cell therapy for treatment of patients with multiple myeloma.
  - In April 2021, the FDA approved a new immune checkpoint inhibitor, dostarlimab-gxly (Jemperli) for treatment of patietns with endometrial cancer

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2022 Incidence & Mortality Estimates

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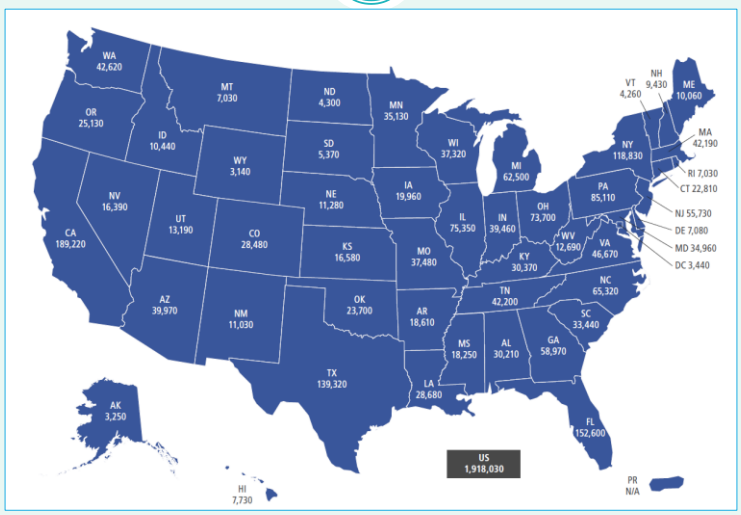

2022 Cancer Facts and Figures – American Cancer Society

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2022 Incidence & Mortality Estimates

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Figure 3. Leading Sites of New Cancer Cases and Deaths – 2022 Estimates

Estimated New Cases

Male			Female		
Prostate	268,490	27%	Breast	287,850	31%
Lung & bronchus	117,910	12%	Lung & bronchus	118,830	13%
Colon & rectum	80,690	8%	Colon & rectum	70,340	8%
Urinary bladder	61,700	6%	Uterine corpus	65,950	7%
Melanoma of the skin	57,180	6%	Melanoma of the skin	42,600	5%
Kidney & renal pelvis	50,290	5%	Non-Hodgkin lymphoma	36,350	4%
Non-Hodgkin lymphoma	44,120	4%	Thyroid	31,940	3%
Oral cavity & pharynx	38,700	4%	Pancreas	29,240	3%
Leukemia	35,810	4%	Kidney & renal pelvis	28,710	3%
Pancreas	32,970	3%	Leukemia	24,840	3%
All sites	**983,160**		**All sites**	**934,870**	

Estimated Deaths

Male			Female		
Lung & bronchus	68,820	21%	Lung & bronchus	61,360	21%
Prostate	34,500	11%	Breast	43,250	15%
Colon & rectum	28,400	9%	Colon & rectum	24,180	8%
Pancreas	25,970	8%	Pancreas	23,860	8%
Liver & intrahepatic bile duct	20,420	6%	Ovary	12,810	4%
Leukemia	14,020	4%	Uterine corpus	12,550	4%
Esophagus	13,250	4%	Liver & intrahepatic bile duct	10,100	4%
Urinary bladder	12,120	4%	Leukemia	9,980	3%
Non-Hodgkin lymphoma	11,700	4%	Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,710	3%	Brain & other nervous system	7,570	3%
All sites	**322,090**		**All sites**	**287,270**	

Estimates are rounded to the nearest 10, and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Estimates do not include Puerto Rico or other US territories. Ranking is based on modeled projections and may differ from the most recent observed data.

2022 Cancer Facts and Figures – American Cancer Society

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Trends in Death Rates – Female 1930-2019

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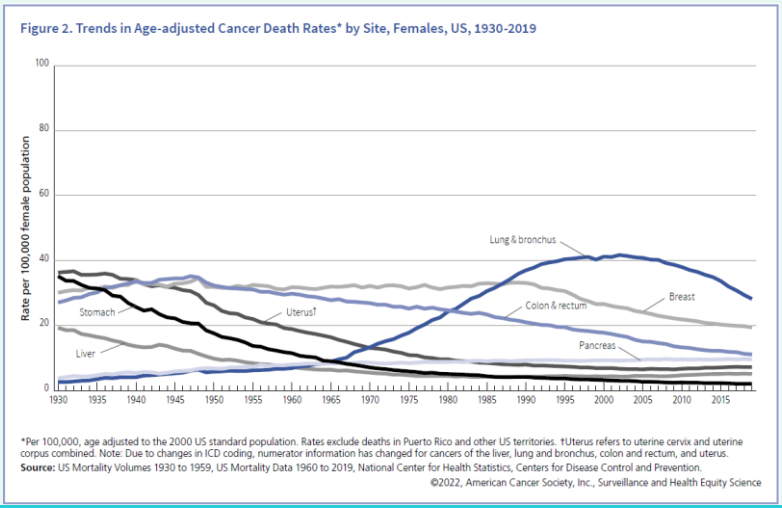

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Trends in Death Rates – Male 1930-2019

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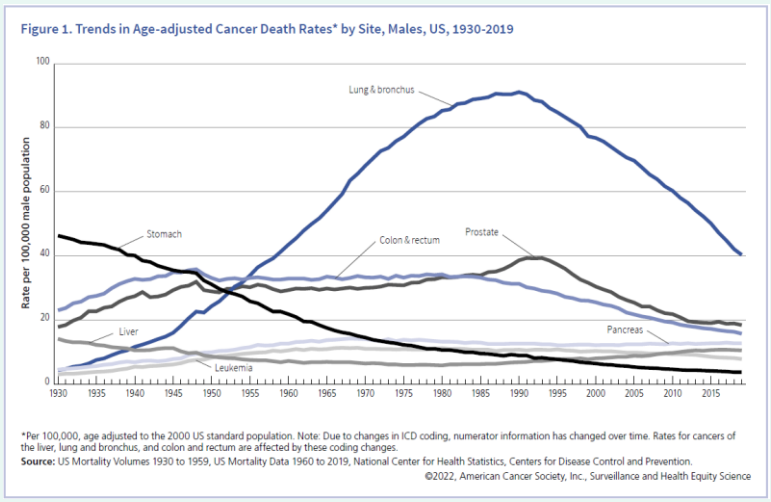

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American Indian and Alaska Native Populations

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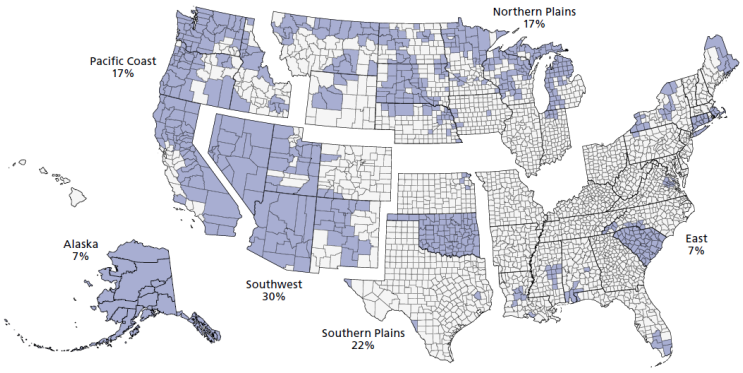
Figure S1. PRCDA Counties and the Distribution of American Indian and Alaska Native Persons by Region



PCRDA: Purchased/Referred Care Delivery Area. Percentages represent the proportion of the non-Hispanic American Indian/Alaska Native PRCDA population that lives in each region (shown in blue).
Source: US Census Bureau, 2019.

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American Indian and Alaska Native Populations

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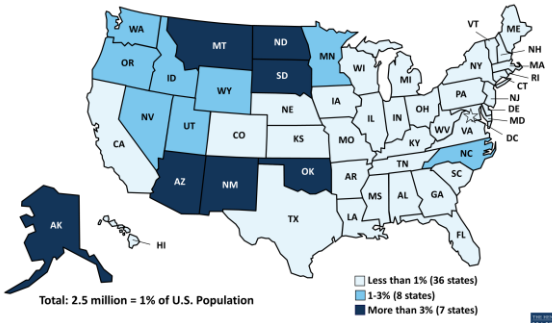
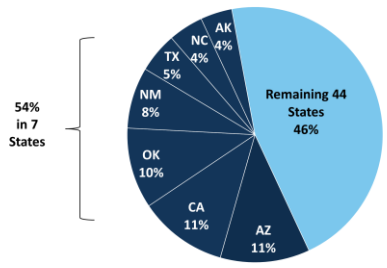
American Indians and Alaska Natives as a Share of the Total Population, by State, 2009-2011



Total: 2.5 million = 1% of U.S. Population

American Indian and Alaska Native includes people of Hispanic origin.
SOURCE: KCMU analysis of 2009 - 2011 ACS.

Distribution of American Indians and Alaska Natives Across States, 2009-2011



Total American Indians and Alaska Natives: 2.5 Million

American Indian and Alaska Native includes people of Hispanic origin. Totals do not sum due to rounding.
SOURCE: KCMU analysis of 2009-2011 ACS.

Kaiser Family Foundation

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2022 Incidence Rates Among AIAN Populations

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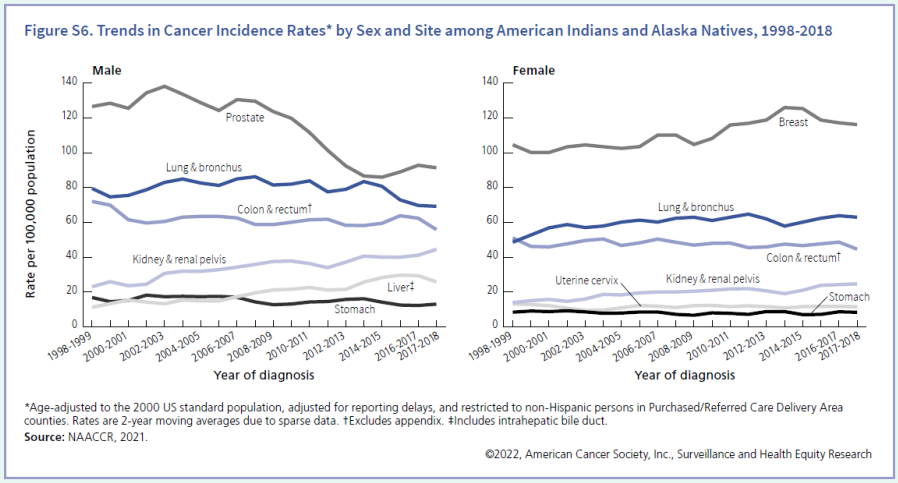

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Smoking-Related Cancers

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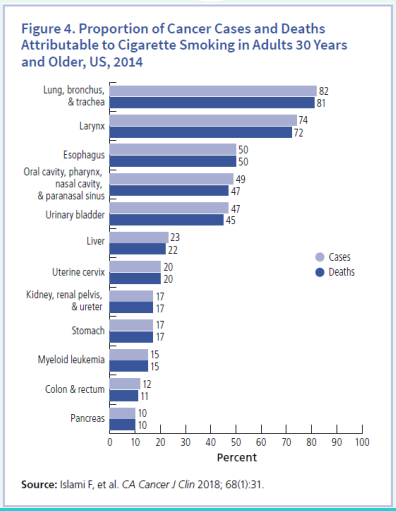

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2021 Annual Report to the Nation on the Status of Cancer

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American Cancer Society®

ANNUAL REPORT to THE NATION on THE STATUS of CANCER

www.cdc.gov/cancer/annual-report

NIH NATIONAL CANCER INSTITUTE

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

OXFORD

JNCI J Natl Cancer Inst (2021) 113(12): djab131

doi: 10.1093/jnci/djab131
First published online July 8, 2021
Article

NAACCR North American Association of Central Cancer Registries

Annual Report to the Nation on the Status of Cancer, Part 1: National Cancer Statistics

Farhad Islami, MD, PhD,[1,*] Elizabeth M. Ward, PhD,[2] Hyuna Sung, PhD,[1] Kathleen A. Cronin, PhD,[3] Florence K. L. Tangka, PhD,[4] Recinda L. Sherman, PhD,[2] Jingxuan Zhao, MPH,[1] Robert N. Anderson, PhD,[5] S. Jane Henley, MSPH,[4] K. Robin Yabroff, PhD,[1] Ahmedin Jemal, DVM, PhD,[1] Vicki B. Benard, PhD[4]

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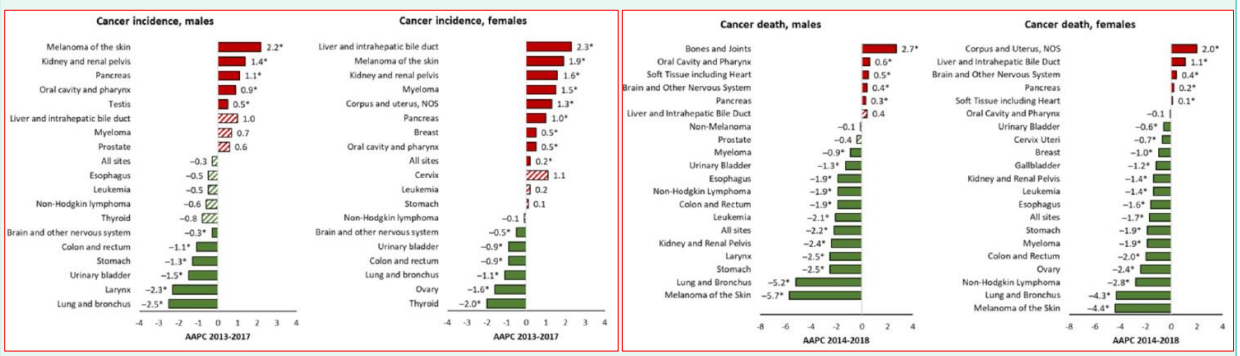
2021 Annual Report to the Nation on the Status of Cancer

14

Average annual percent change (AAPC) in age-standardized, delay-adjusted incidence rates for 2013-2017



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2021 Annual Report to the Nation on the Status of Cancer

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JNCI J Natl Cancer Inst (2021) 113(12): djab192

doi: 10.1093/jnci/djab192
First published online October 26, 2021
Article

NAACCR North American Association of Central Cancer Registries

Annual Report to the Nation on the Status of Cancer, Part 2: Patient Economic Burden Associated With Cancer Care

K. Robin Yabroff, PhD,[1,*] Angela Mariotto, PhD,[2] Florence Tangka, PhD,[3] Jingxuan Zhao, MPH,[1] Farhad Islami, MD, PhD,[1] Hyuna Sung, PhD,[1] Recinda L. Sherman, PhD,[4] S. Jane Henley, MSPH,[3] Ahmedin Jemal, DVM, PhD,[1] Elizabeth M. Ward, PhD[4]

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Cancer Trends Progress Report – 20th Anniversary

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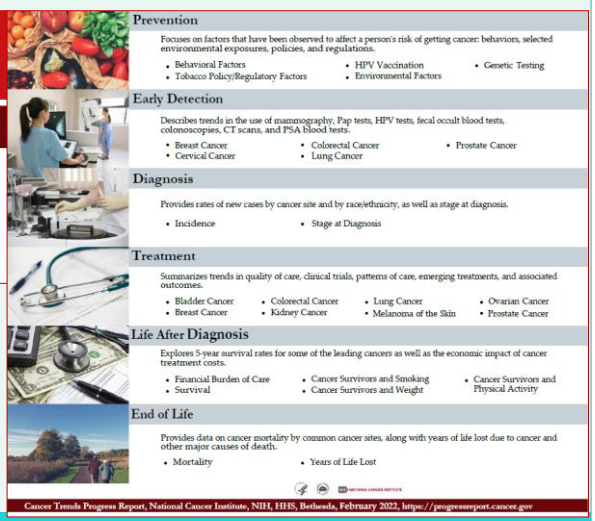
The Cancer Trends Progress Report, continually updated since its first issue in 2001, summarizes our nation's advances against cancer in relation to Healthy People targets set forth by the Department of Health and Human Services. The report, intended for policy makers, researchers, and public health professionals, includes key measures of progress along the cancer control continuum and uses national trend data to illustrate where improvements have been made and where attention is demanded. New measures this year include Sleep, Melanoma of the Skin Treatment, Outdoor Tanning, and Evidence-based Smoking Cessation Aids.



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AACR Cancer Progress Report 2021

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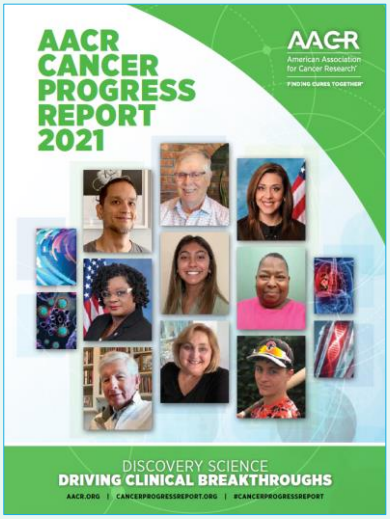

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AACR Cancer Progress Report 2021
A Few Interesting Highlights

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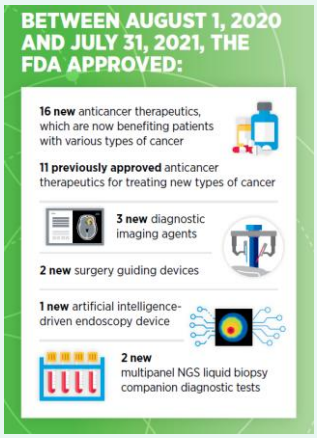
- Landmark Discoveries Fueling Advances in Lung Cancer Diagnosis and Treatment
- Detecting Early Signs of Multiple Types of Cancer from a Single Minimally Invasive Screening Test
- Advances in Treatment with Surgery
  - Non-invasive Bone Tumor Procedures
  - Using Artificial Intelligence for Precision in Surgical Oncology
- Improvements in Radiation-Based Approaches for Cancer Care
  - Imaging Prostate Cancer More Clearly
  - Detecting Neuroendocrine Tumors with High Accuracy
- Advances in Treatment with Cytotoxic Chemotherapy
  - Reducing the Risk of Blood Cancer Recurrence
  - Effectively Delivering Cytotoxic Drugs to Kill Multiple Myeloma Cells
- Advances in Treatment with Molecularly Targeted Therapy
  - New Breakthrough in Treating Lung Cancer
  - Targeting Protein Kinases for Treatment of Solid Tumors
- Advances in Cancer Immunotherapy
  - Engineering Immune Cells to Eliminate Cancer
  - Unleashing the Body's Defense System Against Cancer
- Artificial Intelligence: Shaping the Future of Cancer Science and Medicine
- Supporting a Vibrant and Diverse Cancer Research Workforce
- Addressing Cancer Health Disparities



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AACR Cancer Progress Report 2021

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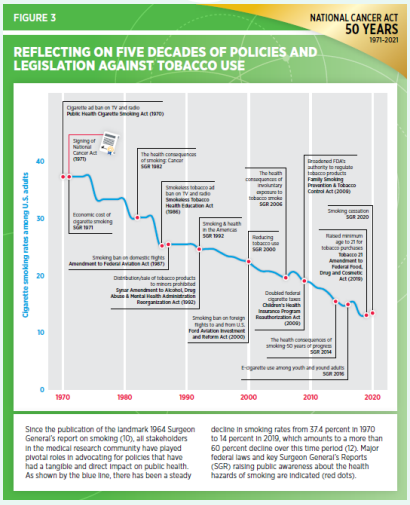

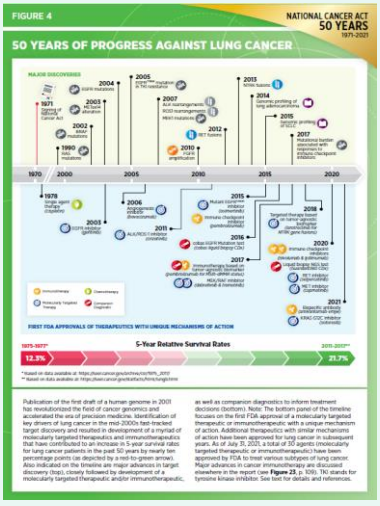

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AACR Cancer Progress Report 2021
Other Interesting Highlights

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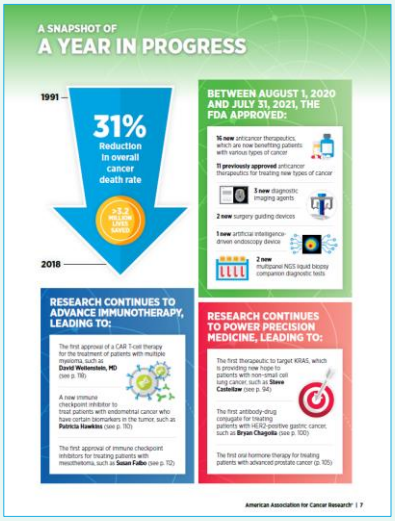

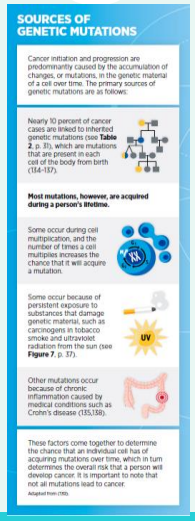

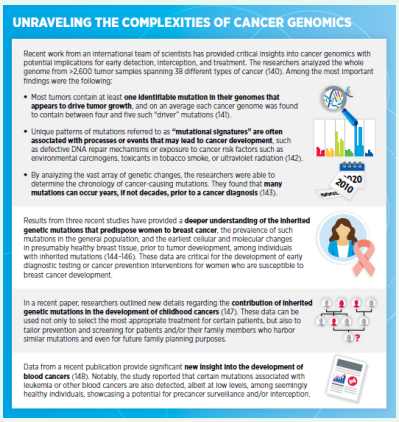

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AACR Cancer Progress Report 2021
More Interesting Highlights

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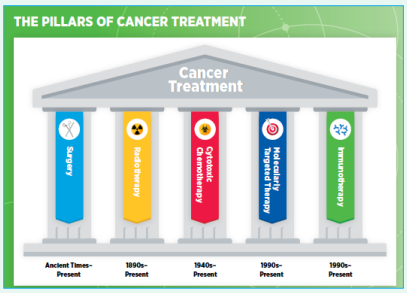
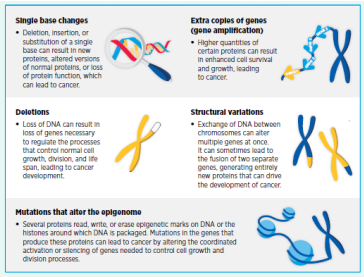
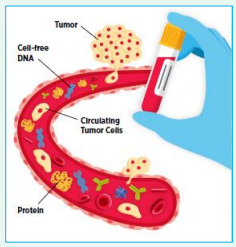
NEWLY FDA-APPROVED ANTICANCER THERAPEUTICS: AUGUST 1, 2020–JULY 31, 2021

Approved Indication	Generic Name	Trade name	Formulation
Angiogenesis Inhibitors			
Certain type of kidney cancer	tivozanib	Fotivda	
Cell-signaling Inhibitors			
Certain type of lung cancer	amivantamab-vmjw*	Rybrevant	?
Certain type of non-Hodgkin lymphoma*	crizotinib*	Xalkori	
Certain types of lung and thyroid cancers	pralsetinib*	Gavreto	
Certain type of lung cancer	tepotinib	Tepmetko	
Certain types of non-Hodgkin lymphoma	umbralisib	Ukoniq	
Certain type of lung cancer	sotorasib*	Lumakras	
Certain type of leukemia*	avapritinib	Ayvakit	
Bile duct cancer	infigratinib*	Truseltiq	
Cell Cytoskeleton-modifying Agents			
Multiple myeloma	belantamab mafodotin-blmf	Blenrep	?
DNA-damaging Agents			
Certain type of gastrointestinal cancers*	ram-trastuzumab deruxtecan-nxki	Enhertu	?
Certain type of bladder cancer*	sacituzumab govitecan-hziy	Trodelvy	?
Certain type of non-Hodgkin lymphoma	loncastuximab tesirine-lpyl	Zynlonta	?
Multiple myeloma	melphalan flufenamide	Pepaxto	?
Epigenome-modifying Agents			
Certain type of leukemia*	azacitidine	Onureg	
Hormones/Antihormones			
Certain type of prostate cancer	relugolix	Orgovyx	
Immunotherapeutics			
Certain types of skin and lung cancers*	cemiplimab-rwlc*	Libtayo	?
Certain type of non-Hodgkin lymphoma	lisocabtagene maraleucel	Breyanzi	?
Certain type of non-Hodgkin lymphoma*	axicabtagene ciloleucel	Yescarta	?
Mesothelioma*	ipilimumab and nivolumab	Yervoy and Opdivo	?
Neuroblastoma	naxitamab-gqgk	Danyelza	?
Multiple myeloma	idecabtagene vicleucel	Abecma	?
Certain type of endometrial cancer	dostarlimab-gxly*	Jemperli	?
Gastric and gastroesophageal junction cancers*	nivolumab	Opdivo	?
Certain type of breast cancer	margetuximab-cmkb	Margenza	?
Certain types of breast, gastric, and gastroesophageal junction cancers*	pembrolizumab*	Keytruda	?
Imaging Agents			
Prostate cancer	gallium 68 PSMA-11	Ga 68 PSMA-11	?
Prostate cancer	piflufolastat F-18	Pyluriy	?
Certain type of neuroendocrine tumor	copper Cu 64 dotatate	Detectnet	?
Companion Diagnostic Tests			
Certain type of lung cancer	N/A	Guardant360 CDx	
Certain types of breast, lung, ovarian, and prostate cancers	N/A	FoundationOne Liquid CDx	
Surgery Guiding Devices			
Osteoid osteoma in the extremities	N/A	Sonalleve MR-HIFU system	
Artificial intelligence–guided assessment for liver cancer	N/A	Hepatica	

*New cancer type approved 2020-2021
†Requires a companion diagnostic







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NCCN Annual Report 2021

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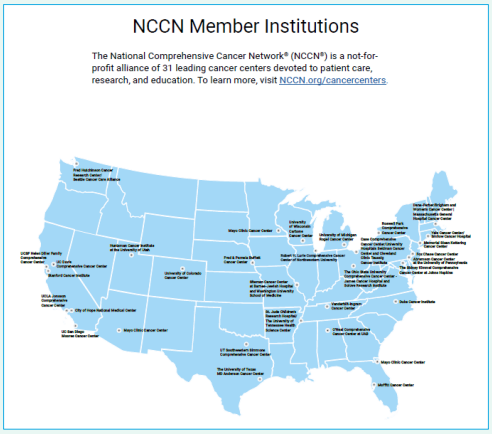

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NCCN Annual Report 2021

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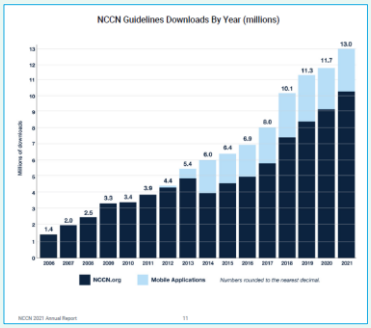
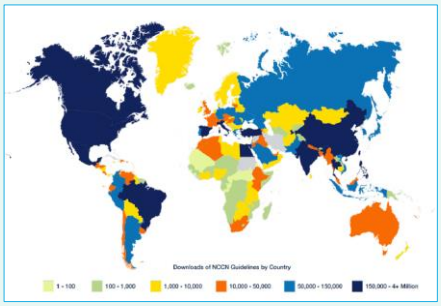
NCCN Guidelines Downloads By Year (millions)



Downloads of NCCN Guidelines by Country in 2021



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ASCO Report on Progress Against Cancer 2021

http://ascopubs.org/doi/full/10.1200/JCO.20.03420

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ASCO special articles

Clinical Cancer Advances 2021: ASCO's Report on Progress Against Cancer

Sonali M. Smith, MD[1]; Kerri Wachter, BS[2]; Howard A. Burris III, MD[3]; Richard L. Schilsky, MD[2]; Daniel J. George, MD[4]; Douglas E. Peterson, DMD, PhD[5]; Melissa L. Johnson, MD[3]; Merry Jennifer Markham, MD, FACP, FASCO[6]; Kathryn F. Mileham, MD[7]; Muhammad S. Beg, MD[8]; Johanna C. Bendell, MD[3]; Robert Dreicer, MD, MS, MACP[9]; Vicki L. Keedy, MD[10]; Randall J. Kimple, MD, PhD[11]; Miriam A. Knoll, MD[12]; Noelle LoConte, MD[11]; Helen MacKay, MD, MS, MACP[13]; Jane Lowe Meisel, MD[14]; Timothy J. Moynihan, MD[15]; Daniel A. Mulrooney, MD[16]; Therese Marie Mulvey, MD[17]; Olatoyosi Odenike, MD[1]; Nathan A. Pennell, MD, PhD[18]; Katherine Reeder-Hayes, MD, MBA, MS[19]; Cardinale Smith, MD, PhD[20]; Ryan J. Sullivan, MD[17]; and Robert Uzzo, MD, MBA[21]

Advance of the Year: Molecular Profiling Drives Progress in GI Cancers

Surgery, radiotherapy, and chemotherapy have been the mainstay of treatment for GI cancer but have limited effect and can take a heavy toll on quality of life. The development of more effective therapies for GI cancer has lagged. Molecular profiling has helped change the outlook for patients with GI cancer by identifying the molecular and genetic signatures that allow oncologists to deliver treatments that are highly specific to a tumor. For these reasons, ASCO has identified molecular profiling driving progress in GI cancer as the 2021 Advance of the Year. This selection recognizes the treatment advances made possible by molecular testing for patients with GI cancers.

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ASCO Report on Progress Against Cancer 2021

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New therapies or tests	
October 2020	
NGS-based FoundationOne CDx test	A companion diagnostic to identify fusions in neurotrophic receptor tyrosine kinase (*NTRK*) genes, *NTRK1*, *NTRK2*, and *NTRK3*, in DNA isolated from tumor tissue specimens from patients with solid tumors eligible for treatment with larotrectinib
September 2020	
Pralsetinib (GAVRETO)	For adult patients with metastatic RET fusion–positive non–small-cell lung cancer (NSCLC) as detected by an FDA-approved test
Azacitidine tablets (ONUREG)	For continued treatment of patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy
August 2020	
FoundationOne Liquid CDx test	A companion diagnostic to identify mutations in *BRCA1* and *BRCA2* genes in cell-free DNA isolated from plasma specimens from patients with metastatic castration-resistant prostate cancer (mCRPC) eligible for treatment with rucaparib (RUBRACA)
Belantamab mafodotin-blmf (BLENREP)	For adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent
July 2020	
Brexucabtagene autoleucel (TECARTUS)	A CD19-directed genetically modified autologous T cell immunotherapy, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)
June 2020	
Tazemetostat (TAZVERIK)	An EZH2 inhibitor, for adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, and for adult patients with R/R FL who have no satisfactory alternative treatment options
Lurbinectedin (ZEPZELCA)	For adult patients with metastatic small-cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy
May 2020	
Brigatinib (ALUNBRIG)	For adult patients with anaplastic lymphoma kinase (ALK)–positive metastatic non–small-cell lung cancer (NSCLC) as detected by an FDA-approved test
Ripretinib (QINLOCK)	For adult patients with advanced GI stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib
Capmatinib (TABRECTA)	For adult patients with metastatic non–small-cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
Daratumumab and hyaluronidase-fihj (DARZALEX FASPRO)	For adult patients with newly diagnosed or relapsed or refractory multiple myeloma. This new product allows for subcutaneous dosing of daratumumab
April 2020	
Sacituzumab govitecan-hziy (TRODELVY)	For adult patients with metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease
Pemigatinib (PEMAZYRE)	For the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
Selumetinib (KOSELUGO)	For pediatric patients, 2 years of age and older, with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)
Mitomycin (JELMYTO)	For adult patients with low-grade upper tract urothelial cancer (LG-UTUC)
January 2020	
Tazemetostat (TAZVERIK)	For adults and pediatric patients age 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection
Avapritinib (AYVAKIT)	For adults with unresectable or metastatic GI stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including D842V mutations
December 2019	
Fam-trastuzumab deruxtecan-nxki (ENHERTU)	For patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
Enfortumab vedotin-ejfv (PADCEV)	For adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant or adjuvant, locally advanced, or metastatic setting
November 2019	
Givosiran (GIVLAARI)	For adults with acute hepatic porphyria (AHP)
New uses	
October 2020	
Venetoclax (VENCLEXTA)	In combination with azacitidine, decitabine, or low-dose cytarabine (LDAC) for newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities precluding intensive induction chemotherapy
Nivolumab (OPDIVO) plus ipilimumab (YERVOY)	First-line treatment for adult patients with unresectable malignant pleural mesothelioma
August 2020	
Carfilzomib (KYPROLIS) and daratumumab (DARZALEX)	In combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy
July 2020	
Tafasitamab-cxix (MONJUVI)	A CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low-grade lymphoma, and who are not eligible for autologous stem cell transplant
Atezolizumab (TECENTRIQ)	In combination with cobimetinib and vemurafenib for patients with *BRAF* V600 mutation–positive unresectable or metastatic melanoma
June 2020	
Pembrolizumab (KEYTRUDA)	For the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer
Pertuzumab, trastuzumab, and hyaluronidase—zzxf (PHESGO)	A new fixed-dose combination for subcutaneous injection for treatment of patients with HER2-positive early breast cancer
Pembrolizumab (KEYTRUDA)	For patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation

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Pembrolizumab (KEYTRUDA)	For the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB H) (≥ 10 mutations/ megabase [mut/Mb]) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options
Nivolumab (OPDIVO)	For patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy
Avelumab (BAVENCIO)	For maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy
May 2020	
Ramucirumab (CYRAMZA)	In combination with erlotinib for first-line treatment of metastatic non–small-cell lung cancer (NSCLC) with epidermal growth factor receptor (*EGFR*) exon 19 deletions or exon 21 (L858R) mutations
Atezolizumab in combination with bevacizumab (TECENTRIQ and AVASTIN)	For patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy
Nivolumab (OPDIVO)in combination with ipilimumab (YERVOY) and 2 cycles of platinum-doublet chemotherapy	First-line treatment for patients with metastatic or recurrent non–small-cell lung cancer (NSCLC), with no epidermal growth factor receptor (*EGFR*) or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations
Nivolumab (OPDIVO)in combination with ipilimumab (YERVOY)	First-line treatment for patients with metastatic non–small-cell lung cancer whose tumors express PD-L1 (≥ 1%), as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations
Pomalidomide (POMALYST)	Expanded the indication to include treating adult patients with AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy and Kaposi sarcoma in adult patients who are HIV-negative.
Olaparib (LYNPARZA)	Expanded the indication to include its combination with bevacizumab for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious *BRCA* mutation, and/or genomic instability
Olaparib (LYNPARZA)	For adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC), who have progressed following prior treatment with enzalutamide or abiraterone
Atezolizumab (TECENTRIQ)	For the first-line treatment of adult patients with metastatic non–small-cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), with no *EGFR* or *ALK* genomic tumor aberrations
Rucaparib (RUBRACA)	For patients with deleterious *BRCA* mutation (germline and/or somatic)–associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
Selpercatinib (RETEVMO)	For the following indications: adult patients with metastatic *RET* fusion–positive non–small-cell lung cancer (NSCLC); adult and pediatric patients ≥ 12 years of age with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy; adult and pediatric patients ≥ 12 years of age with advanced or metastatic RET fusion–positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
April 2020	
Niraparib (ZEJULA)	For the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy
Pembrolizumab (KEYTRUDA)	New dosing regimen of 400 mg every 6 weeks for pembrolizumab (KEYTRUDA) across all currently approved adult indications in addition to the current 200 mg every 3 weeks dosing regimen
Tucatinib (TUKYSA)in combination with trastuzumab and capecitabine	For adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting
Encorafenib (BRAFTOVI) in combination with cetuximab	For the treatment of adult patients with metastatic colorectal cancer (CRC) with a *BRAF* V600E mutation, detected by an FDA-approved test, after prior therapy
March 2020	
Durvalumab (IMFINZI) in combination with etoposide and either carboplatin or cisplatin	First-line treatment of patients with extensive-stage small-cell lung cancer
Nivolumab and ipilimumab (OPDIVO and YERVOY))	For patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
Isatuximab-irfc (SARCLISA) in combination with pomalidomide and dexamethasone	For adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
February 2020	
Neratinib (NERLYNX) in combination with capecitabine	For adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
January 2020	
Pembrolizumab (KEYTRUDA)	For the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy
December 2019	
Olaparib (LYNPARZA)	For the maintenance treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCAm*) metastatic pancreatic adenocarcinoma, as detected by an FDA-approved test, whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen
Atezolizumab (TECENTRIQ) in combination with paclitaxel protein-bound and carboplatin	For the first-line treatment of adult patients with metastatic nonsquamous non–small-cell lung cancer (NSCLC) with no *EGFR* or *ALK* genomic tumor aberrations
Enzalutamide (XTANDI)	For patients with metastatic castration-sensitive prostate cancer (mCSPC)
October 2019	
Niraparib (ZEJULA)	For patients with advanced ovarian, fallopian tube, or primary peritoneal cancer treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD)–positive status. HDR is defined by either a deleterious or suspected deleterious *BRCA* mutation, or genomic instability in patients with disease progression greater than 6 months after response to the last platinum-based chemotherapy

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FDA New Drug Therapy Approvals in 2021

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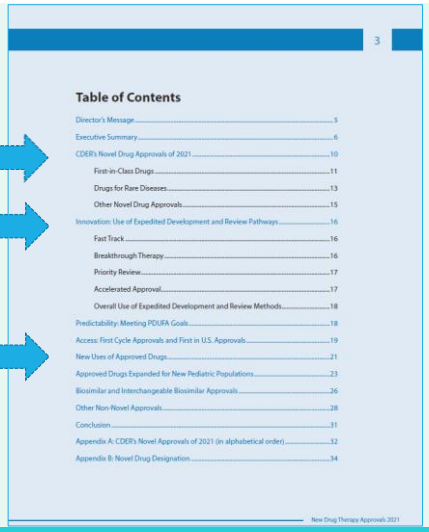

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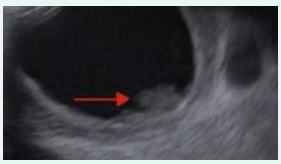
- Brain and Spinal Cord Neoplasms
- Esophageal and GE Junction Cancers
- Pediatric Liver Cancers
- Plasma Cell Myeloma



The IPMN Path Description must include at least one of the clarifying descriptive terms below;

- IPMN, with high grade dysplasia
- IPMN, non-invasive
- IPMN, in-situ
- IPMN, associated with invasive carcinoma
- IPMN, invasive

- Pancreato-Hepato-Biliary Cancers
- Clarification of Reporting for IPMN and related cancers
- Inconsistency in Reportable Cases of 'high grade dysplasia'

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New Developments in Cancer Incidence – Endometrial CA

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- **Uterine cancer incidence has been increasing and is projected to surpass colorectal cancer as the third leading cancer and fourth leading cause of cancer death among women by 2040.**
- Endometrioid carcinoma is the predominant histologic subtype, accounting for approximately 75% of all cases that are usually diagnosed at an early stage with good prognosis. These tumors are associated with obesity as well as hormonal and reproductive factors related to cumulative lifetime estrogen exposure.
- Non-endometrioid carcinomas account for approximately 15%to 20% of cases, have been described as estrogen independent and are typically diagnosed at later stages with poorer prognosis.
- **Rates of aggressive non-endometrioid subtypes significantly increased among all women and were twice as high among non-Hispanic Black women compared with other groups for reasons still unclear**
- In a large cohort study of 208,587 women showed increasing uterine cancer mortality is associated with increasing rates of aggressive non-endometrioid carcinomas, but racial and ethnic disparities cannot solely be explained by histologic subtype and stage at diagnosis.
- Among all women, uterine corpus cancer mortality rates increased significantly by 1.8% per year from 2010 to 2017, as did rates of non-endometrioid carcinomas (2.7%), **with increases occurring in Asian (3.4%), Black (3.5%), Hispanic (6.7%) and White women (1.5%).**
- In contrast, endometrioid carcinoma mortality rates remained stable
- Despite stable incidence rates, endometrioid cancer mortality rates have not decreased over the past decade at the population level, suggesting limited progress in treatment for these cancers. The substantial disparities in mortality rates among non-Hispanic Black women cannot be fully explained by subtype distribution and stage at diagnosis.

JAMA Oncol. doi:10.1001/jamaoncol.2022.0009 May 5, 2022. and Obstet Gynecol 2022;139:645–59 DOI: 10.1097/AOG.0000000000004710

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New Developments in Cancer Incidence – Brain & CNS

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- Brain or spinal cord tumors makeup less than 2% of all cancers diagnosed each year in the United States.
- There are over 130 different types of brain and spinal cord tumors – not all are malignant
- The diversity and rarity of some brain tumors pose unique challenges to developing new treatments.
- Liquid biopsy is helping distinguish between different types of brain tumors more easily in adults
- One specific liquid biopsy test was able to detect a specific genetic alteration in children with genomic changes in DNA shed from medulloblastoma that helped identify kids that had high risk of residual tumor after treatment so they got more aggressive therapy upfront and closer follow-up for relapse.
- Artificial Intelligence is also being used to analyze images to facilitate the classification and diagnosis of brain tumors during surgery and to examine brains for residual tumor following surgical resection
- PARP Inhibitors are being used to treat glioblastoma (Gr IV), astrocytoma (Gr I-III), oligodendroglioma (Gr II-III), medulloblastoma (Gr IV) plus other Gr I-IV neoplasms with IDH1 mutations looking for changes in tumor metabolism
- Other genetics of interest include tumors with BRAF and WNT for gliomas and neurofibromatosis 1
- NCI Brain Tumor Trials Collaborative (BTTC) and NCI-CONNECT Clinical Trial Network 33 centers

Society for Neuro-Oncology, Ichimura et al.: IDH1 mutations in gliomas

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New Developments in Cancer Incidence – Pediatric Liver

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- "Hepatoblastomas with carcinoma features represent a biological spectrum of aggressive neoplasms in children and young adults. A high-risk subtype of pediatric 'hepatoblastoma with hepatocellular carcinoma features' has been discovered using molecular profiling"
- Almost all pediatric liver cancers str classified as either hepatoblastoma or hepatocellular carcinoma.
- However, pediatric pathologists have noted that certain liver tumors have histological characteristics that do not readily match either of these two carcinoma models.
- They designated these tumor types collectively as HBs with HCC features (HBCs) and outlined histological and molecular characteristics for their classification.
- The newly described tumors tended to be more resistant to standard chemotherapy and have poor outcomes when not treated with more aggressive surgical approaches, including transplantation.
- Based on the findings, the Baylor College of Medicine Team proposed a diagnostic algorithm to stratify HBCs and guide specialized treatment for these kids as children with HBCs may benefit from treatment strategies that differ from the guidelines for patients with hepatoblastoma and hepatocellular carcinoma

13 May 2022, Journal of Hepatology. DOI: 10.1016/j.jhep.2022.04.035

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Types of Cancer Screening

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- **Physical Exams** uncover signs of disease, such as lumps, abnormal moles or enlarged organs.
- **Imaging procedures** (mammogram/LDCT/PET/MRI/Ultrasound) take pictures of areas inside the body.
  - A **mammogram** is a screening test for breast cancer. This test is an x-ray picture of the breast. It has been shown to decrease the risk of dying from breast cancer.
  - **Low-dose computed tomography (LDCT)** is used to screen for lung cancer. It has been shown to decrease the risk of dying from lung cancer in heavy smokers. The procedure uses low-dose radiation to make a series of very detailed pictures of areas inside the body using a type of x-ray machine.
- **Direct Observation** involve visual examination of tissue for abnormal growths. A colonoscopy is a screening test for colorectal cancer. In this test, the rectum and colon are examined using a flexible lighted tube with a lens for viewing. A colonoscopy can find abnormal colon growths (polyps) in addition to colorectal cancer. An endoscopic ultrasound or EUS combines both direct observation and ultrasound imaging to observe or aid biopsy
- **Laboratory Tests** analyze samples of tissue, blood, urine, or other substances in the body. Cytology, Tumor Marker Testing, Blood and Urine Tests with one exception cannot be used in isolation to diagnose or confirm the presence of cancer (DX Confirmation = 5). ONLY a serum/urine protein electrophoresis test can be assigned 5.
- **Multi-Cancer Early Detection (MCED) Tests** are tests that measure molecular biomarkers or tumor markers in body fluids that may be shed by cancer cells. Currently, no MCED Tests are approved by FDA just yet. Tests can assess a few or hundreds of molecular, genetic, protein, or other tumor markers all at once in a panel.

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New Developments in Cancer Screening

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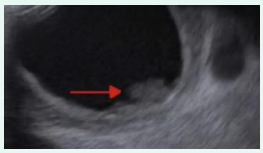
- **Targeted Screening Programs for pancreato-hepato-biliary cancers**
  - Early detection of tumor or precursor lesions with dysplasia the most effective approach to improve survival
  - Use of Endoscopic Ultrasound (EUS) or MRI Cholangiopancreatography (MRCP) -- with or without biopsy
  - Some Centers Started Identifying High-Risk Populations and Began Screening Programs in 2016
  - High-Risk Population Screening – male, black, Ashkenazi Jewish descent, obesity, smoking, diabetes
  - Hereditary Factors (BRCA2, HNPCC, BRCA1, cystic fibrosis, FAP) and Familial Pancreatic Cancer (FPC)
  - Personal History of Pancreatitis – acute, chronic, multiple episodes
  - Per SEER Instruction - Must do a biopsy that shows one or more of the following
    - PanIN3 – Pancreatic Intraepithelial Neoplasia Grade 3
    - High grade dysplasia
    - Carcinoma in-situ
    - Invasive carcinoma
  - If they don't do a biopsy – abnormality or clinical dx of malignant IPMN – the case is not reported
  - This is problematic since many of these patients may go on to have treatment even a Whipple
  - Novel techniques such as needle-based confocal laser endomicroscopy (nCLE), along with biomarkers, may be helpful to identify pancreatic lesions with more aggressive malignant potential.
  - We are also seeing this condition in other branch ducts of biliary system and hepatic duct system
  - These are mucinous and ductal carcinomas – non-invasive and early invasive



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New Developments in Cancer Screening

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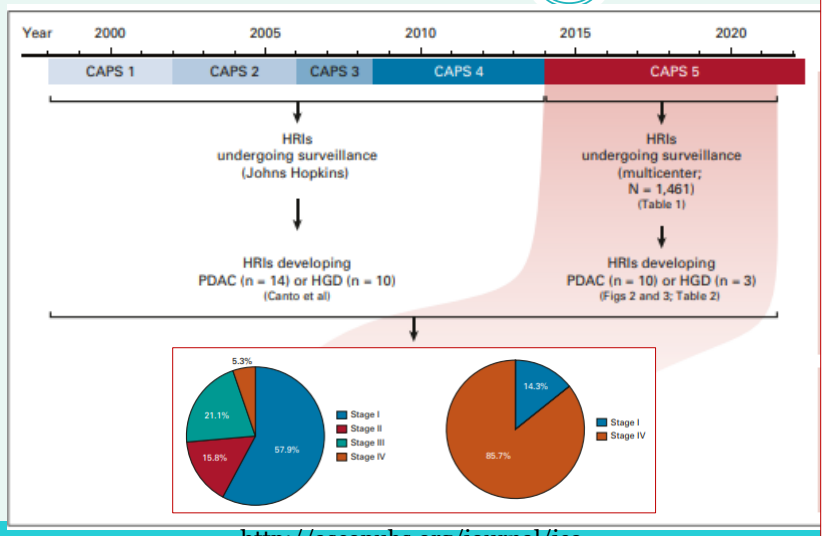

High-Risk Cohort	N = 1,461
Age, mean ± SD, years	60.3 ± 9.7
Sex (female), No. (%)	944 (64.6)
Race/ethnicity, No. (%)	
White	1,380 (94.5)
African American	51 (3.5)
Asian	19 (1.3)
Hispanic/Latino	35 (2.4)
Other/multiple	13 (0.7)
Pathogenic germline variant carriers, No. (%)	
BRCA2 + ≥ 1 FDR/SDR with PDAC	269 (18.4)
BRCA1 + ≥ 1 FDR with PDAC	68 (4.7)
CDKN2A (FAMMM syndrome)	69 (4.7)
Lynch syndrome + ≥ 1 FDR/SDR with PDAC	58 (4.0)
PALB2 + ≥ 1 FDR/SDR with PDAC	62 (4.2)
ATM + ≥ 1 FDR/SDR with PDAC	93 (6.4)
Peutz-Jeghers syndrome (*STK11*)	18 (1.2)
More than one mutation + ≥ 1 FDR/SDR with PDAC	6 (0.4)
Familial pancreatic cancer without known pathogenic germline variants, No. (%)	
≥ 2 FDR[a]	346 (23.7)
1 FDR + ≥ 1 SDR[b]	402 (27.5)
1 FDR with young onset PDAC ≤ 50 years old	5 (0.3)
Other high-risk cohort (Data Supplement), No. (%)	65 (4.5)
Personal history of cancer,[c] No. (%)	455 (31.1)
Smoking, No. (%)	
Never/former	910/1,420 (64.1)/454 (32.0)
Current	56 (3.9)
Alcohol use (current), No. (%)	733/1,414 (51.8)
Diabetes mellitus (type 1/2), No. (%)	137/1,391 (9.8)

http://ascopubs.org/journal/jco

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New Developments in Cancer Screening

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TABLE 1. Summary of population, intervention, comparator, and outcomes questions

Question	Population	Intervention	Comparator	Outcomes	Rating
1	Individuals at increased risk of pancreatic cancer because of genetic susceptibility	Screening	No screening	All-cause mortality	Critical
2	Individuals at increased risk of pancreatic cancer because of genetic susceptibility undergoing screening	Magnetic resonance imaging	EUS	Pancreatic cancer mortality	Critical
3a	Individuals with *BRCA2* pathogenic variant*	Screening	No screening	Cumulative yield of screening	Critical
3b	Individuals with *BRCA1* pathogenic variant*	Screening	No screening	Detection of resectable and borderline-resectable lesions	Important
				Psychological benefits	Important
				Harms	Critical

TABLE 2. Summary of additional management questions addressed in the guideline using non–Grading of Recommendations Assessment, Development and Evaluation methodology

Question	Population	Management question
4	Individuals at increased risk of pancreatic cancer because of genetic susceptibility	How often should screening for pancreatic cancer be performed?
5	Individuals at increased risk of pancreatic cancer because of genetic susceptibility undergoing screening a) *BRCA2* pathogenic variant b) *BRCA1* pathogenic variant c) PALB2 pathogenic variant d) Familial pancreatic cancer e) Familial atypical multiple mole melanoma syndrome f) Peutz-Jeghers syndrome g) Ataxia-telangiectasia mutated heterozygotes with first- or second-degree relative with pancreatic cancer h) Lynch syndrome with first- or second-degree relative with pancreatic cancer i) hereditary pancreatitis	At what age should screening for pancreatic cancer start?

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New Developments in Tumor Classification & Biomarker Testing

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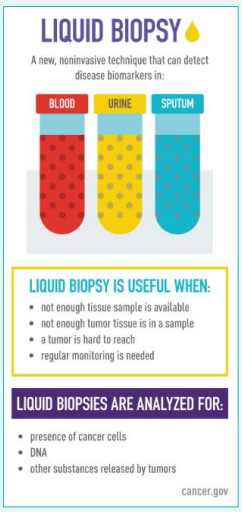
- Tumor Tissue Markers – sample of the tumor
- Circulating Tumor Markers – blood, urine, stool, body fluids
- Colorectal Cancer ctDNA Testing – tests for single DNA abnormality
- OncotypeDX – breast, colon, noninvasive breast – just a few genes in testing
- Leukemia Panel Testing for Subtype of Leukemia
- Liquid Biopsy FDA-Approved Assays – August 2020 – for solid tumors only
  - Guardant 360 CDx – 74 genes and other biomarkers
  - FoundationOne Liquid CDx – 324 genes and MSI
  - Caris Life Sciences – 592 Genes (not FDA Approved yet)
- Multi-Cancer Early Detection (MCED) Assays – a subset of liquid biopsy tests
  - Changes in DNA and/or RNA sequences,
  - Patterns of DNA methylation (a chemical change to DNA),
  - Patterns of DNA fragmentation (how the DNA is broken into smaller pieces),
  - Levels of protein biomarkers, and
  - Antibodies that a person may develop against components of growing cancer cells.



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New Developments in Tumor Classification & Biomarker Testing

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- Need to know what the molecular biomarker or tumor marker is for:
- Molecular Biomarker Testing for Risk Assessment
- Molecular Biomarker Testing for Confirmation of Disease
- Molecular Biomarker Testing for Diagnostic Workup & Extent of Disease
- Molecular Biomarker Testing for (Sub)Classification of Neoplasm
- Molecular Biomarker Testing for Treatment Choices
- Other and To Be Determined Uses

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- **Histology** – Microscopy examines the microanatomy of cells, tissues, and organs as seen through a microscope – physical characteristics. It examines the correlation between structure and function.
- **Biologic Tumor Marker** – Immunoassay can be used to identify anything present in or produced by cancer cells or other cells from blood, urine and body fluids. Tumor Markers provide information about a cancer, aggressiveness, what kind of treatment it may respond to, or whether it is responding to treatment. Tumor markers can be proteins, conjugated proteins, peptides and carbohydrates.
- **Immunohistochemistry** – a microscopy-based technique that allows selective identification and localization of antigens in cells. IHC selectively identifies antigens (proteins) in cells from tissue by exploiting the principle of antibodies binding specifically to antigens in biological tissues. IHC uses light or fluorescent microscopy to analyze results. IHC is less expensive than flow cytometry.
- **Flow Cytometry** – a laser-based technique that detects and measures the physical and chemical characteristics of a cell population. Flow cytometry can be used to count and sort cells (identify proliferation of cells and type), determine cell characteristics, identify biomarkers and to diagnose/classify certain cancers. It is more precise metric for antigens than histology or IHC testing.
- **Cluster of Differentiation (CD) Molecules** – cell surface molecules used to classify white blood cells that are especially important for diagnosis of lymphomas and leukemias. CD marker antibodies have been widely used for cell sorting, phenotyping, and blood cancer diagnosis and for treatment.
- **Immunophenotype** – uses the CD system to define markers associated with specific cells or conditions
- **Cytogenetics** - involves testing samples of tissue, blood, or bone marrow in a laboratory to look for changes in chromosomes, including broken, missing, rearranged, or extra chromosomes. Changes in certain chromosomes may be a sign of a genetic disease or condition or some types of cancer. FISH is common cytogenetics test.
- **DNA Microarray** – used to study the extent to which certain genes are turned on or off in cells and tissues. It is used to identify the changes in gene sequences that are most often associated with a particular disease.
- **Next Generation Sequencing** – a large-scale DNA and RNA sequencing technology to determine the order of nucleotides in entire genomes or targeted regions of DNA or RNA in cells and tissues.

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New Developments in Diagnostic Tools & Cancer Treatments

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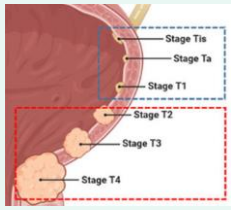
- Erdafitinib (Balversa) the first mutation-targeted bladder cancer drug is being underused
- The drug was approved by the U.S. Food and Drug Administration (FDA) in early 2019.

- About 20% of advanced urothelial carcinomas are driven by mutations that cause growth-related receptors called FGFRs (Fibroblast Growth Factor Receptors) to be overactive.
- Erdafitinib works as an inhibitor of FGFR activity. It is meant to be used in patients who have susceptible FGFR mutations and are no longer responding to standard chemotherapy.

- A large, nationwide database of cancer cases was examined by researchers at the University of Pennsylvania. Between 2019 and 2021, in a sample of nearly 800 bladder cancer patients potentially eligible for treatment, fewer than half had a record of being tested for the relevant gene mutation.



- Of those tested and found to have the mutation, fewer than half received treatment.

- 81,000 Americans are diagnosed with bladder cancer each year – 7/8 are men.
- About 17,000 people die from the disease annually.
- The five-year survival rate is about 77 percent

- Genetic testing needs to be more widely available for patients to learn about and access, and education for treating physicians is a must so they can gain knowledge on the benefits and value in use for eligible patients

JAMAOncol.2022;8(7):10701072.doi:10.1001/jamaoncol.2022.1167

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New Developments in Diagnostic Tools & Cancer Treatments

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- Flash Therapy – A REVOLUTION in Therapy
  - Rather than days or weeks of fractions of radiation given to a patient, the entire massive dose is delivered all at once very quickly in one fraction sparing normal tissue
  - Deliver radiation therapy at flash dose rates 100 times what we would normally
- Image-Guided Radiotherapy Systems
  - MRI-Guided Linear Accelerators – real-time 'dynamic' imaging during radiation
    - Two Systems Currently Available: Elekta Unity and Viewray MRIdian Systems
  - PET Radiotracer Detectors can image metastases targeting each one in real-time
    - Reflexion PET-targeting adaptive therapy technology
- Proton Therapy now considered a Mainstream Treatment Option
- PSMA (prostate-specific membrane antigen) PET imaging w/68Ga-PSAM-11
- Synthetic CT from MRI converts MRI datasets into synthetic CT image datasets for use in planning process eliminating need for a separate CT Scan
- Artificial Intelligence in Radiotherapy - Increasing Speed of Treatment Planning Systems and the Integration of Artificial Intelligence
- A new ASTRO Guide to Managing Primary Brian Tumors and Brain Metastases

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New Developments in Diagnostic Tools & Cancer Treatments

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- Disguising Cancer as an Infection Helps the Immune System Eliminate Tumors
- Although the immune system can pack a powerful punch against cancer, many tumors find ways to turn off or block immune cells.
- But NCI researchers may have found a clever way to give immune cells the upper hand—by disguising the cancer as a viral infection.
- Injected bits of viral proteins, called peptides, coat the outsides of cancer cells
- "So, you are fooling the immune system into thinking, 'I have this big virus infection, I better go attack it," Dr. Schiller said.
- The viral peptides catch immune cells' attention and unleash an attack but don't actually cause an infection – CMV Immunotherapy – still experimental but highly promising
- Researchers used peptides from Cytomegalovirus (CMV), a virus that most people's immune systems have seen before. Around 5 out of 10 people in the United States and 8 out of 10 worldwide are infected with CMV, and it usually doesn't cause any symptoms.
- Findings published June 24 in the *Proceedings of the National Academy of Sciences*

https://www.cancer.gov/news-events/cancer-currents-blog/2022/cancer-immunotherapy-cmv-peptides

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New Developments in Diagnostic Tools & Cancer Treatments

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- New image-based model may inform 'how aggressively a lung cancer should be treated'
- Lung cancer screening identifies cancers at early and presumably more treatable stages and can improve overall mortality rates for lung cancer. There is always a possibility of overdiagnosis and overtreatment in patients with screen-detected tumors.
- Overdiagnosis of pulmonary nodules can result in unnecessary diagnostic procedures that are often invasive, associated with increased costs, and associated with added stress for patients and their families. In the National Lung Screening Trial (NLST), 10 to 27% lung cancers were over-diagnosed.
- NLST created a repository of thousands of CT and Path images available from NCI for researchers to use in study.
- Using images and data from the NLST CT Repository, Moffitt Cancer Center in Tampa, Florida has developed an image-based model based on intra-tumor radiomics and volume doubling time (VDT) to help identify high-risk versus low-risk tumors that could inform how aggressively lung cancers should be treated.
- Pulmonary nodules that are of an infectious or inflammatory pathophysiology have a VDT of less than 20 days, a VDT of less than 400 days (and greater than 20 days) represents a high likelihood of malignancy, and a VDT above 500 days is likely a benign nodule.
- Furthermore, not all early stages are the same. There is a spectrum of intermediate-risk cancers as well. And some early-stage cancers can be very aggressive with poor outcomes that require aggressive treatment and adjuvant therapies. This model helps distinguish between them.
- The radiomic model used NLST data to establish 65 stable and reproducible features including; volume doubling time of lung nodules, volume doubling time cut-off points, radio-genomics, tumor genomics, biomarkers, histology, tumor location, patient characteristics, screening interval, smoking status, compactness of nodule, tumor boundary, tumor edges, roundness, and other factors were input to the model to predict tumor behavior of screen-detected lung cancers. These in turn were used to guide treatment decisions and timing of treatment based on the model.

Cancer Biomarkers, vol. 33, no. 4, pp. 489-501, 2022

Pérez-Morales, Jaileene et al. 'Volume Doubling Time and Radiomic Features Predict Tumor Behavior of Screen-detected Lung Cancers'. 1 Jan. 2022 : 489 – 501.

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Update on Effects of the COVID-19 Pandemic

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- According to a new study led by the American Cancer Society, the COVID-19 Pandemic increased the number of cancer-related deaths by 3.2% in the United States from 2019- 2020.
- The results showed the number of cancer-related deaths was 686,054 in 2020, up from 664,888 in 2019, with an annual increase of 3.2%.
- Compared to the number of projected deaths for 2020 (666,286), the number of cancer-related excess deaths was 19,768 in 2020.
- Furthermore, NCI reported that COVID-19 was third leading cause of death in the United States in both 2020 and 2021. The study appeared in JAMA Internal Medicine on 7/5/2022
- The pandemic prevented many people from getting regular cancer screening, which may result in future increases in cancer deaths with people reluctant to seek care for fear of catching COVID-19.
- During the 20-month period studied, COVID-19 accounted for 1 in 8 deaths (or 350,000 deaths) in the United States. Heart disease was the number one cause of death, followed by cancer, with these two causes of death accounting for a total of 1.29 million deaths.
- Every age group 15 years and up, COVID-19 was one of the top five causes of death during the period.

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Update on Effects of the COVID-19 Pandemic

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Cancer case trends following the onset of the COVID-19 pandemic: A community-based observational study with extended follow-up

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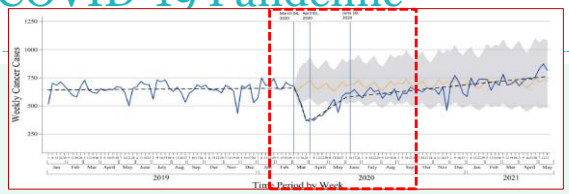

This cross-sectional study retrospectively analyzed the electronic medical records of 80,138 cancer patients diagnosed between January 1, 2019, and May 31, 2021. Outcome measures included weekly number of new cancer cases and trends in weekly cancer cases, before and after the pandemic; patient demographics; and positive COVID-19 test rates.

Beginning March 4, 2020, defined as the onset of the pandemic, weekly cancer cases declined precipitously (−110.0 cases per week) for 4 weeks, followed by a moderate recovery (+23.7 cases per week of 10 weeks duration. Thereafter, weekly cancer cases trended slowly back toward pre-COVID- 19 baseline levels.

Following the pandemic onset, there was a cumulative year-over-year decline in cancer cases overall of 7.3%, including a 20.2%, 14.3%, and 12.8% decline in nonmelanoma skin cancer, breast cancer, and prostate cancer.

The data in this study demonstrate a substantial reduction in cancer diagnoses following the onset of COVID-19, Which appear to reach expected pre-COVID norms 12 months later. The largest reduction was noted among cancers that are typically screen-detected or identified as part of a routine wellness examination.

Cancer 2022;128:1475-1482.

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Update on Cancer Moonshot

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- President Biden Reignites Cancer Moonshot to Speed Progress
- Administration Sets Goal of Reducing Cancer Death Rate by at least 50% over the next 25 Years and improve the experience of people and their families living with and surviving cancer to end cancer as we know it today.
- Call to Action on Cancer Screening and increased funding for NIH/NCI
- The new Cancer Moonshot initiative will include a White House Cancer Moonshot coordinator in the Executive Office of the President; a Cancer Cabinet which will unite all the major government agencies, not just those that specialize in health, and a major effort to get cancer screenings back on track.
- The President wants to establish an Advanced Research Projects Agency for Health (ARPA-H), which would be housed within the NIH and would be modeled on the Defense Advanced Research Projects Agency (DARPA), which produced the Internet and self-driving cars.

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References and Resources

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- American Cancer Society. Cancer Facts & Figures 2022 and Special Section: Cancer in the American Indian and Alaska Native Population. Atlanta: American Cancer Society; 2022.
- 2021 Annual Report to the Nation on the Status of Cancer. JNCI J Natl Cancer Inst (2021) 113(12): djab131 and djab192
- NIH Cancer Trends Progress Report (20th Anniversary) https://progressreport.cancer.gov
- AACR Cancer Progress Report 2021; http://cancerprogressreport.org. Philadelphia: American Association for Cancer Research; 2021
- NCCN Annual Report 2021, National Comprehensive Cancer Network, http://nccn.org/
- ASCO Report on Progress Against Cancer 2021: ascopubs.org/journal/jco. 2/2/2021: DOI https://doi.org/10.1200/JCO.20.03420
- U.S. FDA New Drug Therapy Approvals in 2021. Silver Spring, MD. www.fda.gov
- Racial and Ethnic Differences in Hysterectomy-Corrected Uterine Corpus Cancer Mortality by Stage and Histologic Subtype, JAMA Oncol. 2022; 8(6):895-903. doi:10.1001/jamaoncol.2022.0009
- Health Disparities in Uterine Cancer: Report From the Uterine Cancer Evidence Review Conference, (Obstet Gynecol 2022;139:645–59); DOI: 10.1097/AOG.0000000000004710
- Uterine cancer deaths are rising in the United States, and are highest among Black women;NCI Media, https://www.cancer.gov/news-events/press-releases/2022/uterine-cancer-deaths-black-women?cid=eb_govdel
- Advances in Brain and Spinal Cord Tumors; https://www.cancer.gov/types/brain/research?cid=eb_govdel_cancerinfo
- Medical Imaging in 2021: 7 Industry Trends and Predications; Technical Prospects, Siemens Medical Imaging, Nov 2020

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References and Resources

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- Hepatoblastomas with carcinoma features represent a biological spectrum of aggressive neoplasms in children and young adults, Journal of Hepatology. DOI: 10.1016/j.jhep.2022.04.035
- The Multicenter Cancer of Pancreas Screening Study: Impact on Stage and Survival, ascopubs.org/journal/jco on June 15, 2022: DOI: 10.1200/JCO.22.00298
- American Society for Gastrointestinal Endoscopy guideline on screening for pancreatic cancer in individuals with genetic
- susceptibility: methodology and review of evidence; www.giejournal.org Volume 95, No. 5 : 2022 GASTROINTESTINAL ENDOSCOPY 827
- Multi-Cancer Early Detection (MCED) https://prevention.cancer.gov/major-programs/mced/questions-and-answers-cancer
- NIH Biomarker Testing for Cancer Treatment
- NIH/NCI – CMV Peptides prompt Immune Attack on Tumors – Disguising Cancer as an Infection Helps the Immune System Eliminate Tumors – July 2022, https://www.cancer.gov/news-events/cancer-currents-blog/2022/cancer-immunotherapy-cmv-peptides?cid=eb_govdel
- Alarming rise found in esophageal cancer and Barrett's esophagus in middle-aged adults – American Gastroenterological Association, May 2022
- 7 Trends in Radiation Therapy at ASTRO 2021 | Imaging Technology News; https://www.itnonline.com/article/7-trends-radiation-therapy-astro-2021
- IDH1 mutations are present in the majority of common adult gliomas but rare in primary glioblastomas. Society for Neuro-Oncology, Neuro-Oncology 11, 341–347, 2009 (Posted to Neuro-Oncology [serial online], Doc. D08-00331, May 12, 2009. URL http://neuro-oncology .dukejournals.org; DOI: 10.1215/15228517-2009-025)

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References and Resources

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- Biomarker Testing, Treatment Uptake, and Survival Among Patients With Urothelial Cancer Receiving Gene-Targeted Therapy, JAMA Oncology (2022). DOI: 10.1001/jamaoncol.2022.1167
- Lung cancer: New model may prevent overdiagnosis, overtreatment; May 2022, https://content.iospress.com/articles/cancer-biomarkers/cbm210194
- Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It | The White House
- Cancer Trends Progress Report; progressreport.cancer.gov
- President Biden "Reignites" Cancer Moonshot Initiative | AAMC; https://www.aamc.org/advocacy-policy/washington-highlights/president-delivers-final-sotu-calls-moonshot-cure-cancer
- Oncology Times Volume 44, Number 5; www.oncology-times.com – President Biden Relaunches Cancer Moonshot to Speed Progress
- Cancer case trends following the onset of the COVID-19 pandemic: A community-based observational study with extended follow-up; Cancer April 1, 2022; DOI: 10.1002/cncr.34067, Received: August 25, 2021; Revised: November 15, 2021; Accepted: November 24, 2021, Published online December 17, 2021 in Wiley Online Library (wileyonlinelibrary.com)
- NCOVID-19 was third leading cause of death in the United States in 2020 and 2021, 7/2022 JAMA Internal Medicine; DOI:10.1001/jamainternmed.2022.2476.
- New report shows COVID-19 pandemic increased cancer-related deaths in the United States (2022, May 31) retrieved 1 June 2022 from https://medicalxpress.com/news/2022-05-covid-pandemiccancer- related-deaths-states.html

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Questions