



OCN Review

CARCINOGENESIS PATHOPHYSIOLOGY DIAGNOSIS AND STAGING

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THINGS TO CONSIDER

- What is the socioeconomic impact of cancer
- Who are the people who have cancer
- What are the risk factors that lead to cancer
- What do we know about cancer cells
- How do we detect cancer
- What might we do to prevent cancer

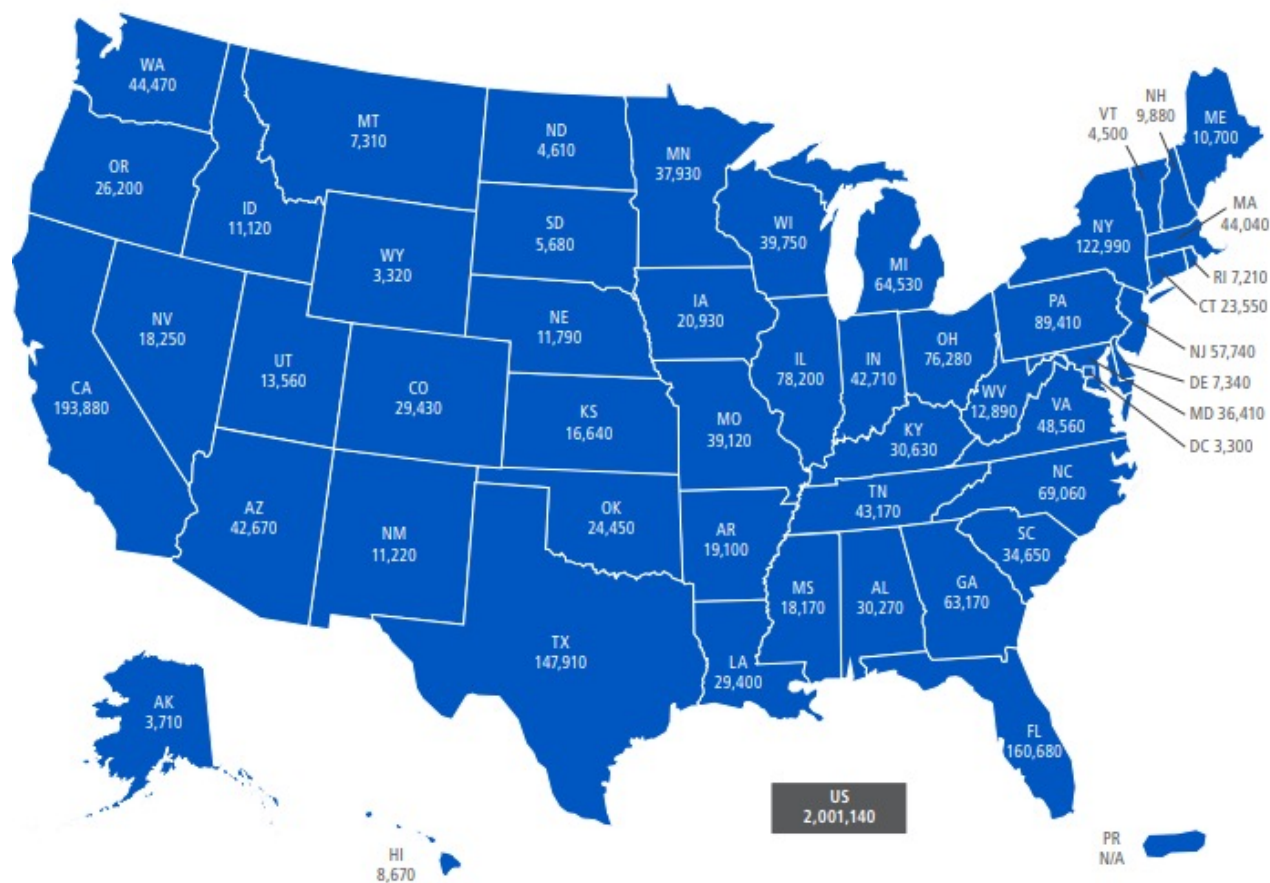
THE IMPACT OF CANCER

- Cancer is a major public health problem. One in four U.S. deaths due to cancer.
- In **2021**, there will be an **estimated 1.9 million** new **cancer** cases diagnosed in the United States
- **606,570 estimated cancer deaths** for **2021** in the United States.
- In **2019**, approximately **140,690 cancer cases** diagnosed and about **103,250 cancer deaths** among the **oldest old** in the US.
- Cancer in the **oldest old** accounts for **8% of all cases** diagnosed in the US with **17% of all cancer deaths**.

THE IMPACT OF CANCER

- Places a high economic burden on society.*
 - National Cancer Institute estimates that cancer-related cost were 183 billion in 2015 and are projected to increase to 246 billion in 2030, a 34% increase based upon population growth and aging alone
 - Economic burden on patients
 - Lost productivity
 - Loss of contribution to family and significant others

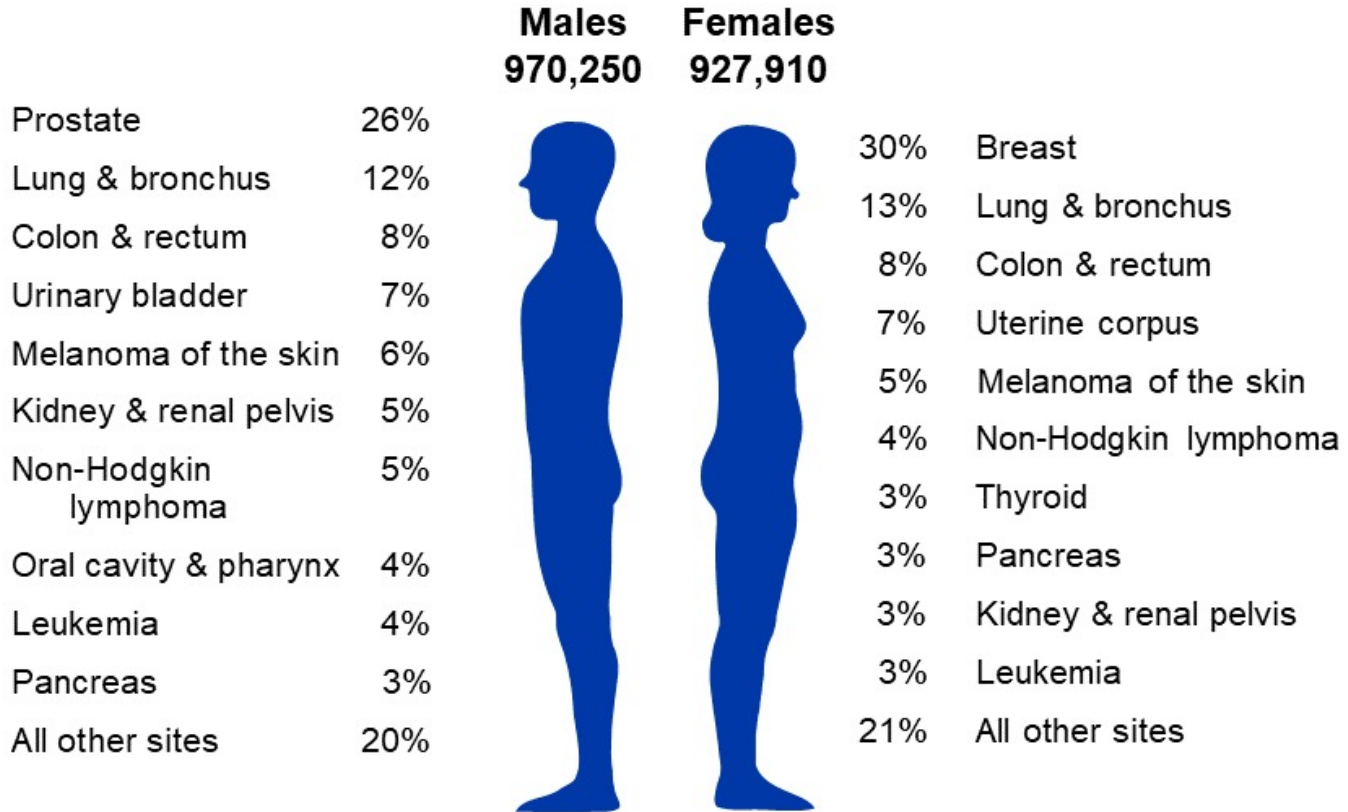
Cancer Facts & Figures 2024



Estimated number of new cancer cases for 2024, excluding basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Estimates are not available for Puerto Rico.

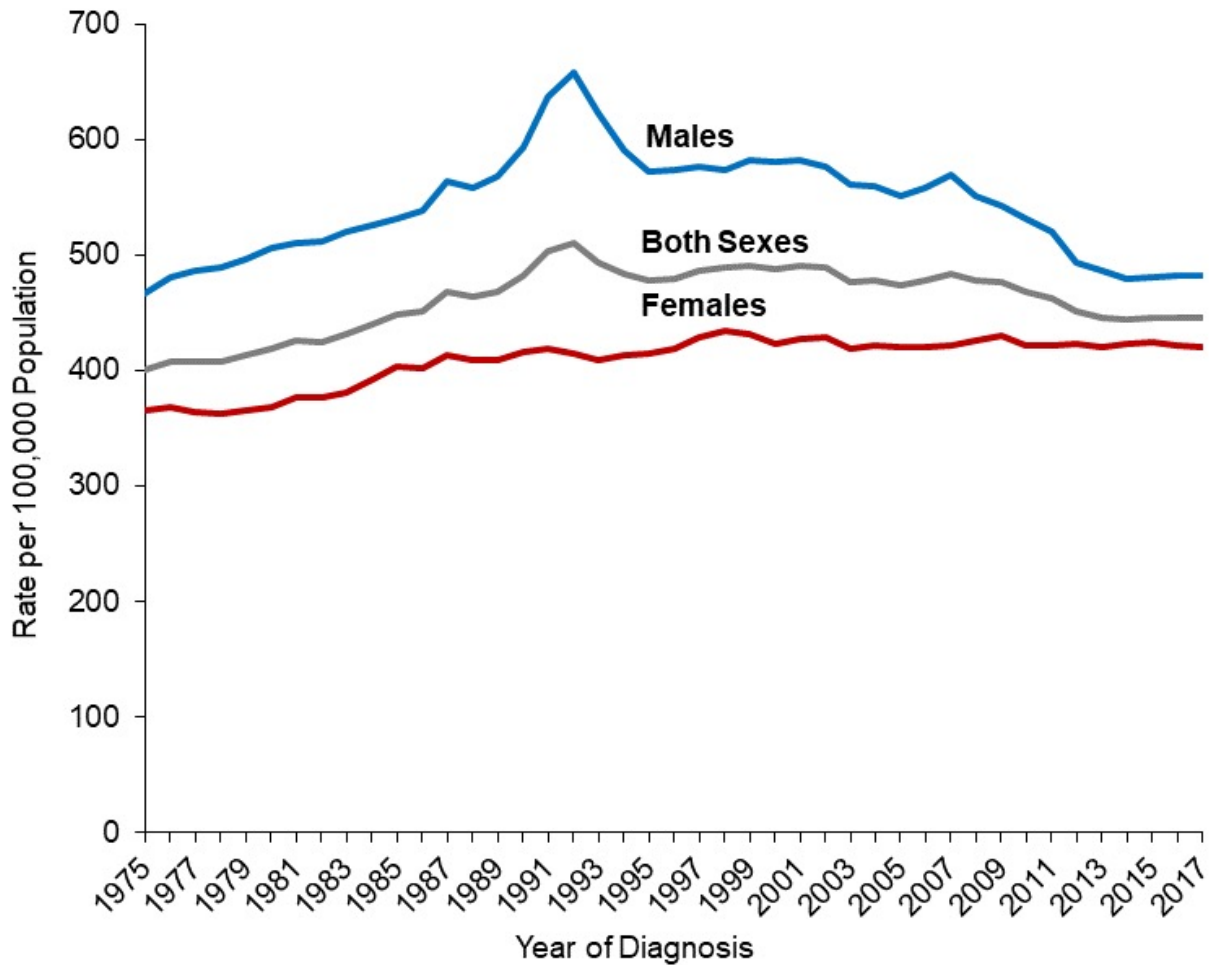
Note: Incidence counts are model-based projections and should be interpreted with caution. State estimates may not equal US total due to rounding.

Estimated New Cancer Cases* in the US in 2021



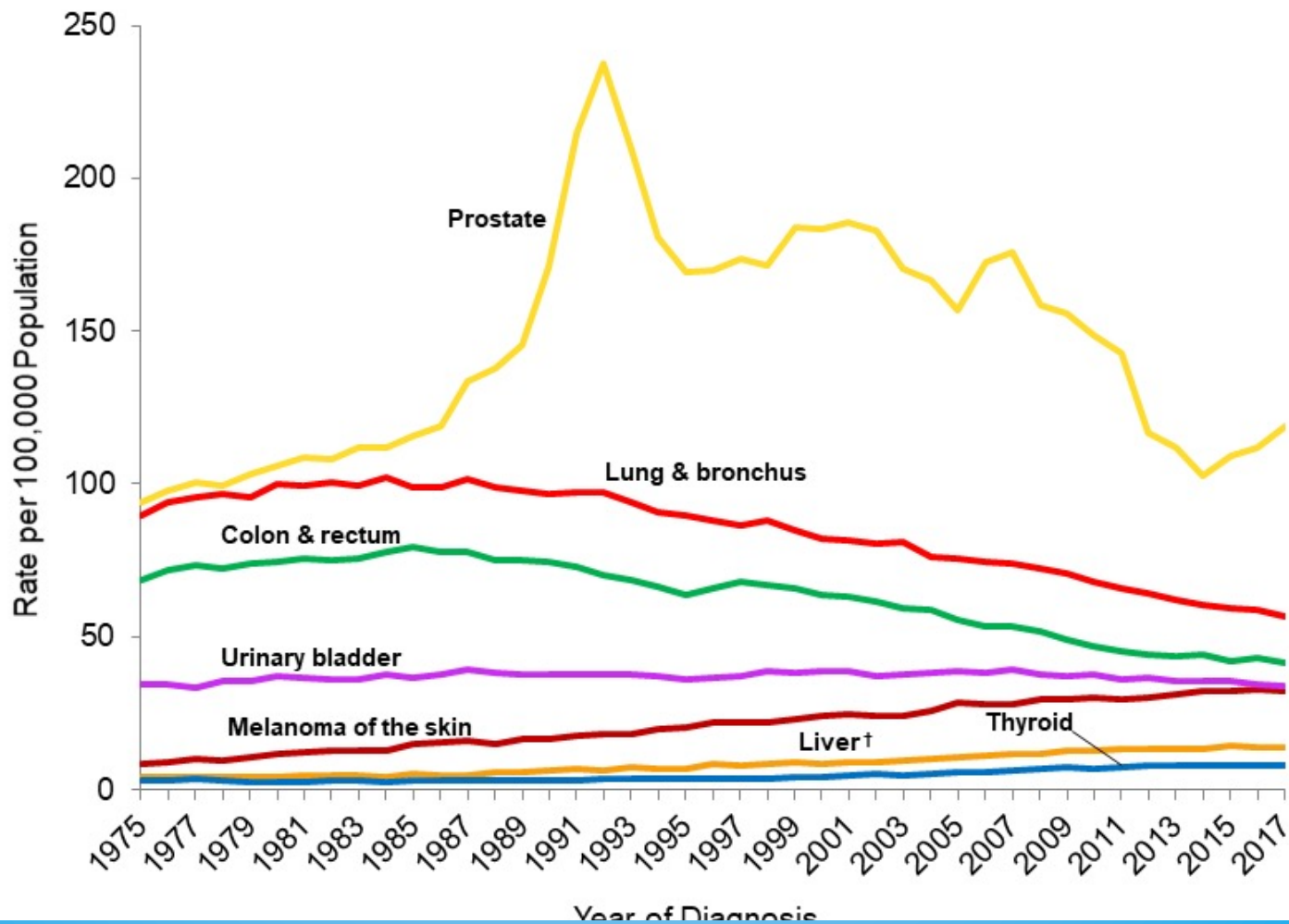
*Excludes basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder.

Trends in Cancer Incidence Rates*, US, 1975-2017

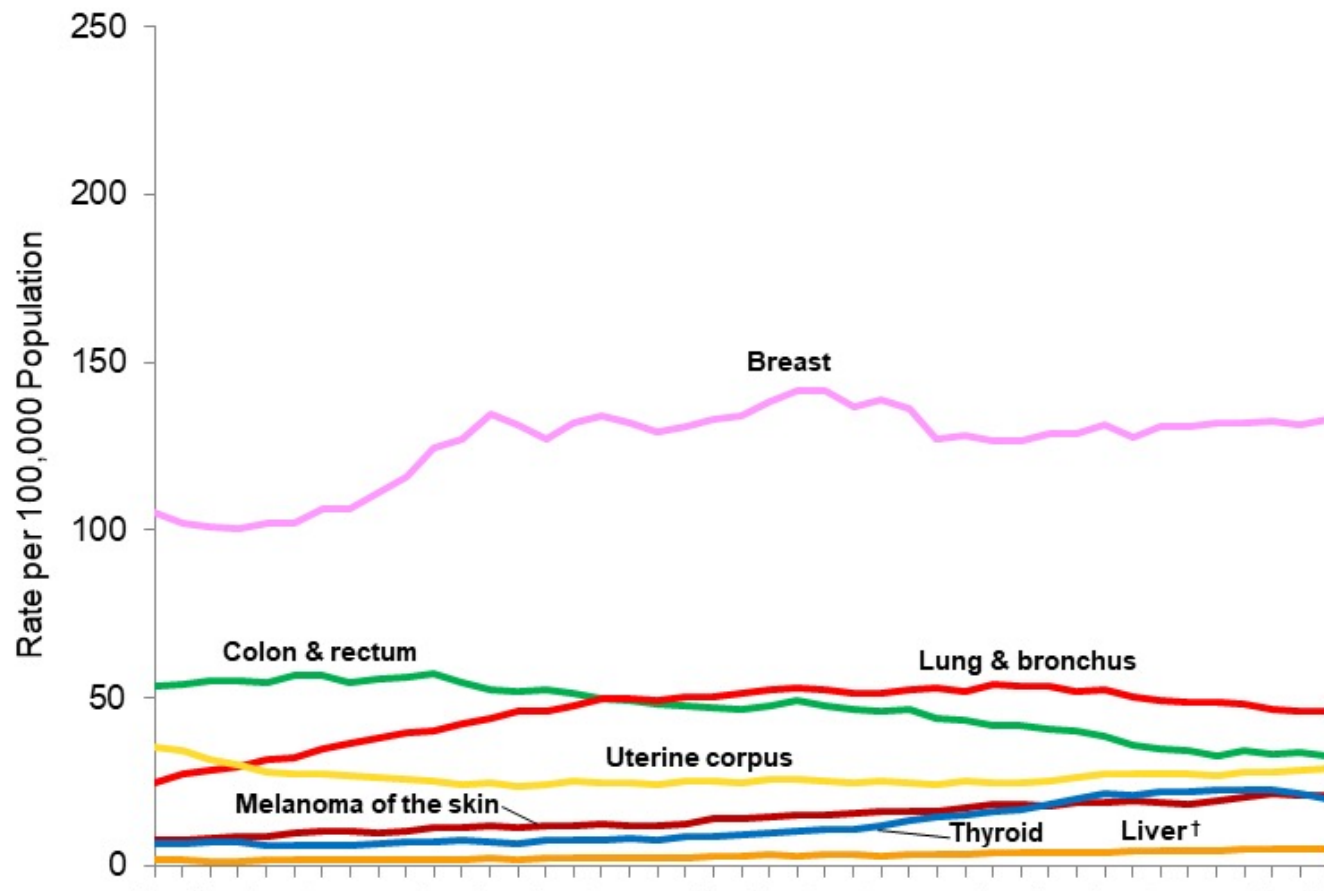


*Age-adjusted to the 2000 US standard population and adjusted for delays in reporting.
Source: Surveillance, Epidemiology, and End Results (SEER) Program, National Cancer Institute, 2020.

Trends in Cancer Incidence Rates* Among Males, US, 1975-2017



Trends in Cancer Incidence Rates* Among Females, US, 1975-2017

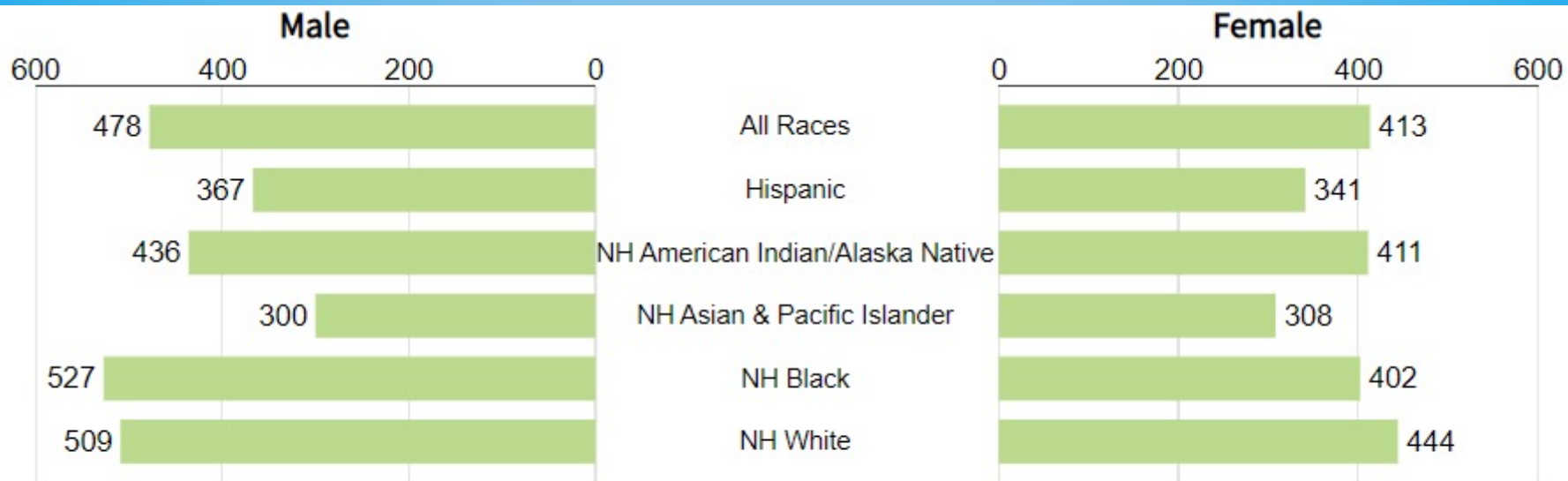


POLL QUESTION:

Which demographic group has the highest cancer incidence rate?

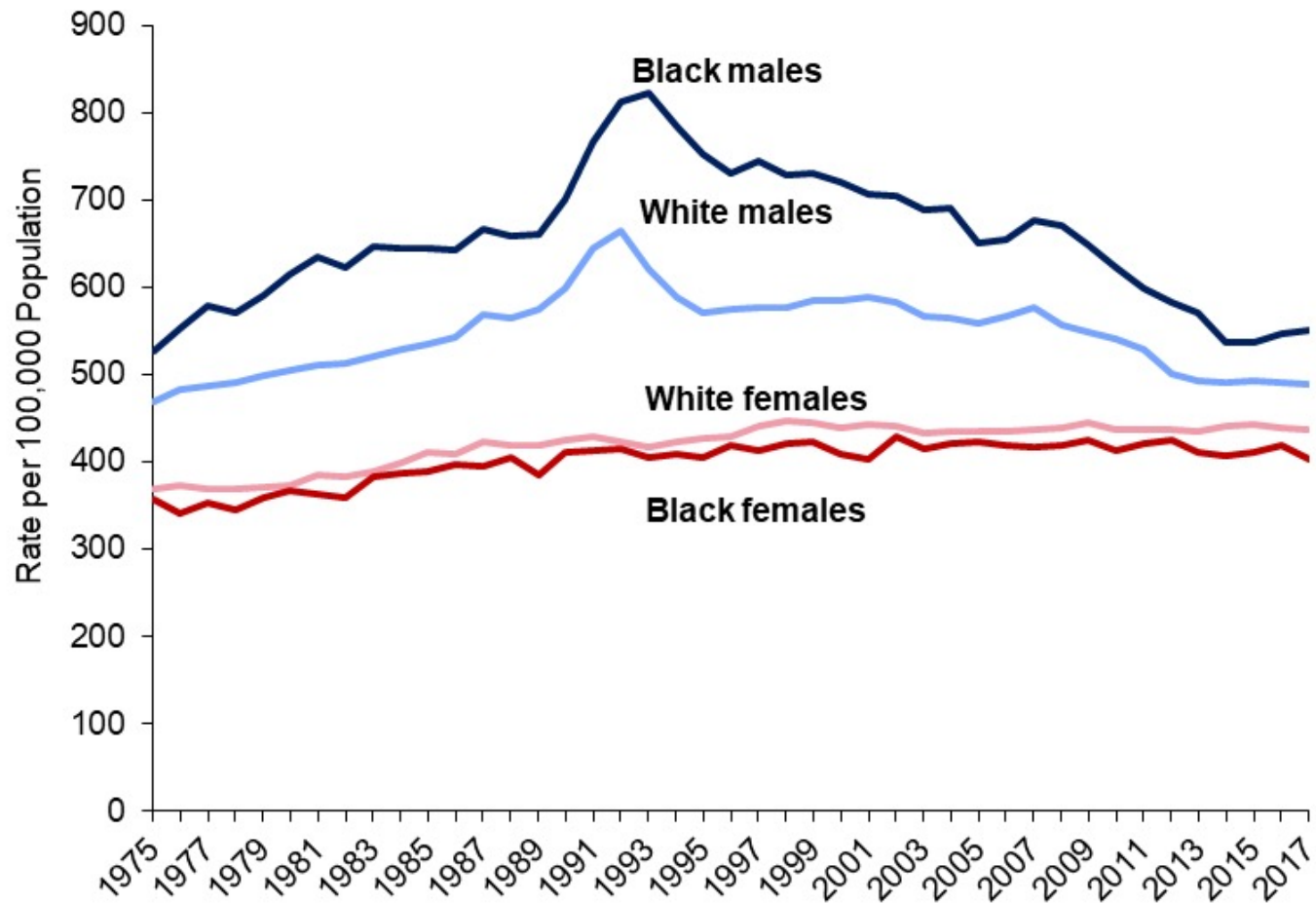
1. White males
2. White females
3. Black males
4. Black females

How Many People Are Diagnosed with Cancer by Sex and Race/Ethnicity?



SEER 22 2016–2020, Age-Adjusted Rate per 100,000

Trends in Cancer Incidence Rates* by Sex and Race, US, 1975-2017



The Lifetime Probability of Developing Cancer for Males, 2015-2017

Site	Risk
All sites*	1 in 2
Prostate	1 in 8
Lung & bronchus	1 in 15
Colon & rectum	1 in 23
Urinary bladder†	1 in 26
Melanoma of the skin‡	1 in 27
Non-Hodgkin lymphoma	1 in 42
Kidney & renal pelvis	1 in 46
Leukemia	1 in 55
Oral cavity & pharynx	1 in 60
Pancreas	1 in 60

*All sites exclude basal cell and squamous cell skin cancers and in situ cancers except urinary bladder. †Includes invasive and in situ cancer cases.

The Lifetime Probability of Developing Cancer for Females, 2015-2017

Site	Risk
All sites*	1 in 3
Breast	1 in 8
Lung & bronchus	1 in 17
Colon & rectum	1 in 25
Uterine corpus	1 in 32
Melanoma of the skin†	1 in 40
Non-Hodgkin lymphoma	1 in 52
Thyroid	1 in 53
Pancreas	1 in 62
Leukemia	1 in 78
Ovary	1 in 82

Trends in Five-year Relative Survival Rates (%), 1975-2016

Site	1975-1977	1987-1989	2010-2016
All sites	49	55	67
Breast (female)	75	84	90
Colorectum	50	60	65
Leukemia	34	43	64
Lung & bronchus	12	13	21
Melanoma of the skin	82	88	93
Non-Hodgkin lymphoma	47	51	73
Ovary	36	38	49
Pancreas	3	4	10
Prostate	68	83	98
Urinary bladder	72	79	77

Five-year Relative Survival Rates (%) by Race, 2010-2016

Site	White	Black	Absolute Difference
All Sites	68	62	6
Breast (female)	91	82	9
Colorectum	65	59	6
Esophagus	21	14	7
Non-Hodgkin lymphoma	73	68	5
Oral cavity & pharynx	68	50	18
Ovary	48	41	7
Prostate	98	96	2
Urinary bladder	77	64	13
Uterine cervix	68	56	12
Uterine corpus	84	63	21

POLL QUESTION:

Which cancer has the highest projected death rate for males in 2024?

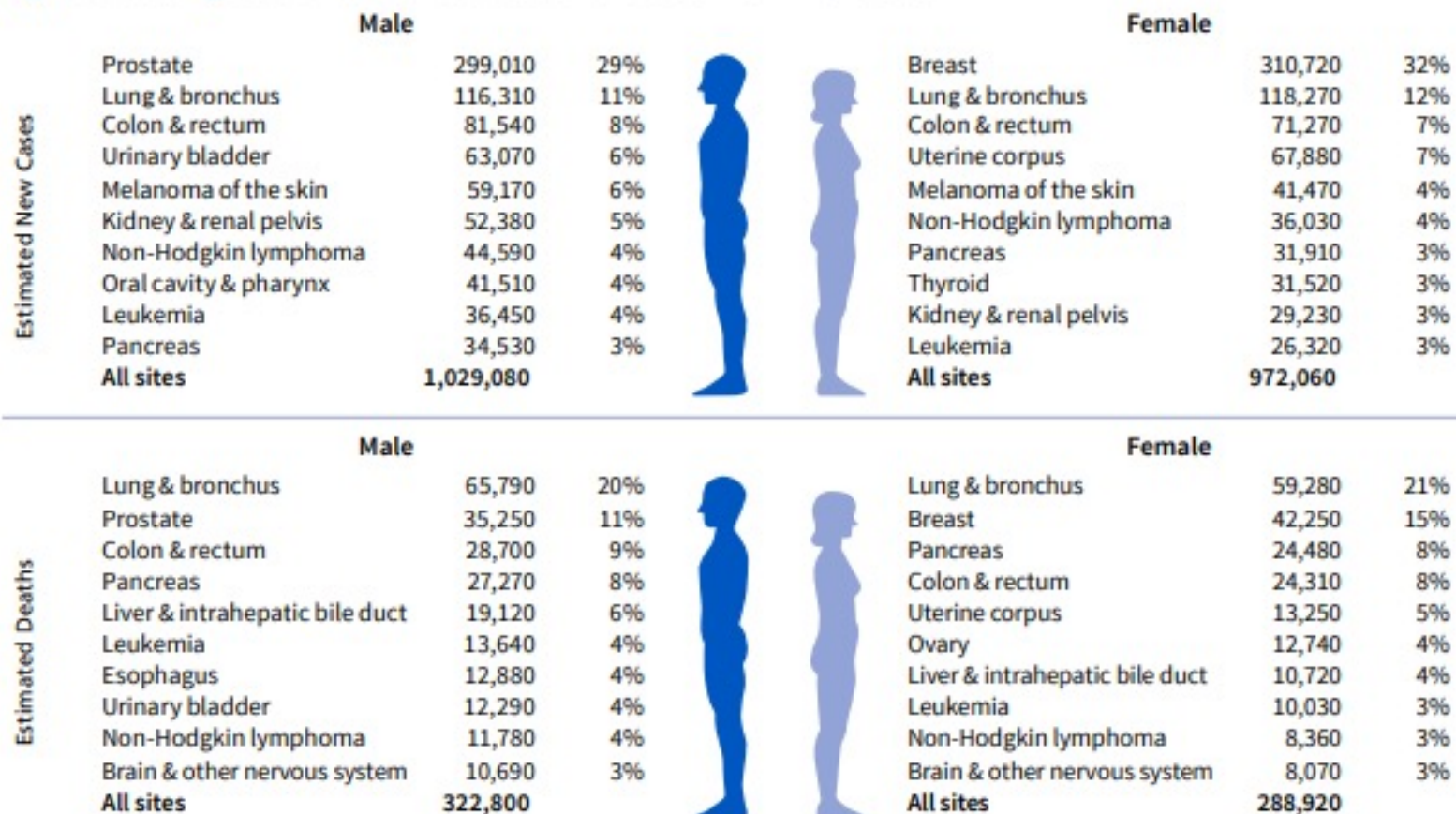
1. Prostate
2. Brain
3. Colon/rectum
4. Lung & Bronchus

POLL QUESTION:

Which cancer has the highest projected death rate for females in 2024?

1. Breast
2. Pancreas
3. Colon/rectum
4. Lung & Bronchus

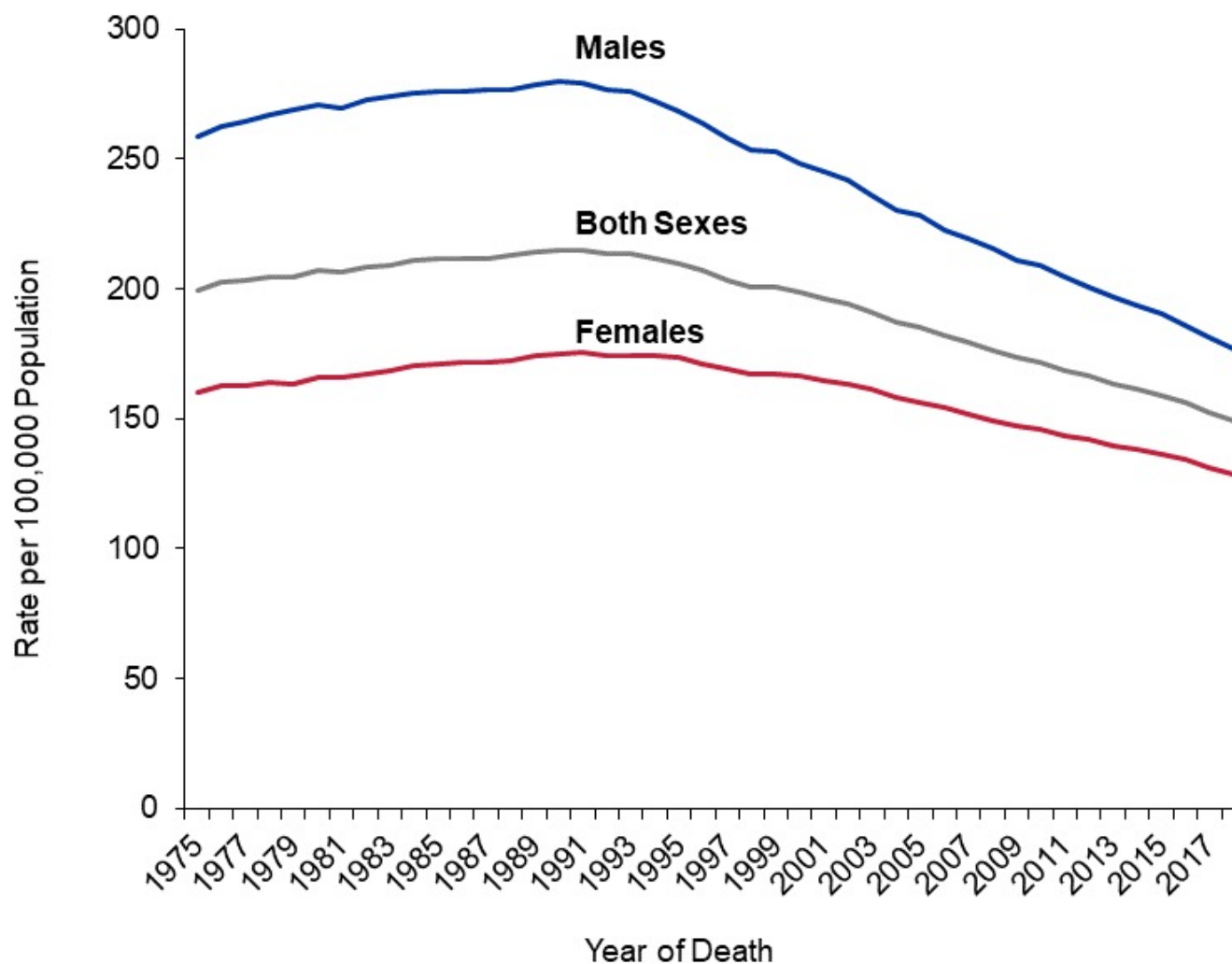
Figure 3. Leading Sites of New Cancer Cases and Deaths – 2024 Estimates



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.

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Trends in Cancer Death Rates* by Sex, US, 1975-2018



Total Number of Cancer Deaths Averted from 1991 to 2018

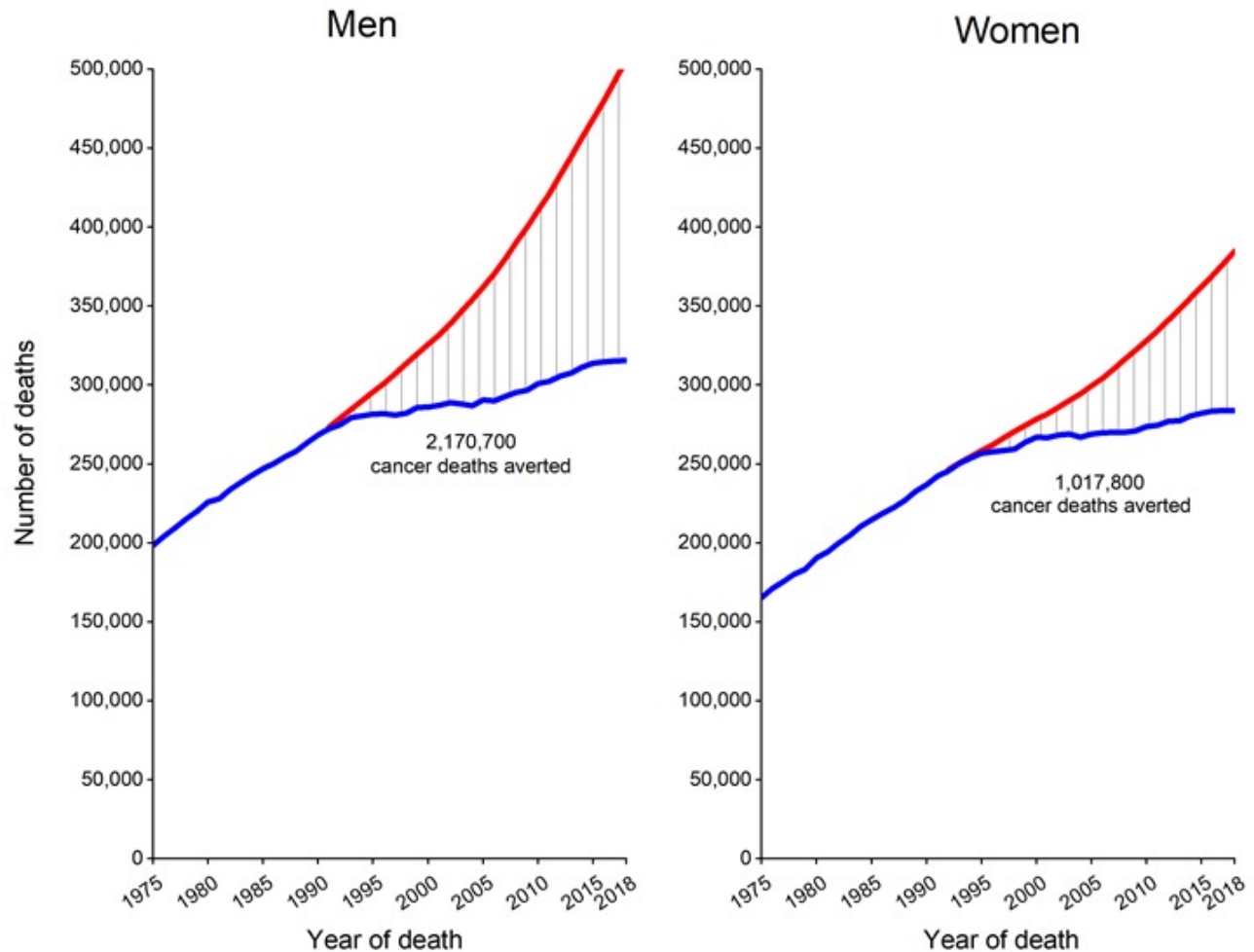
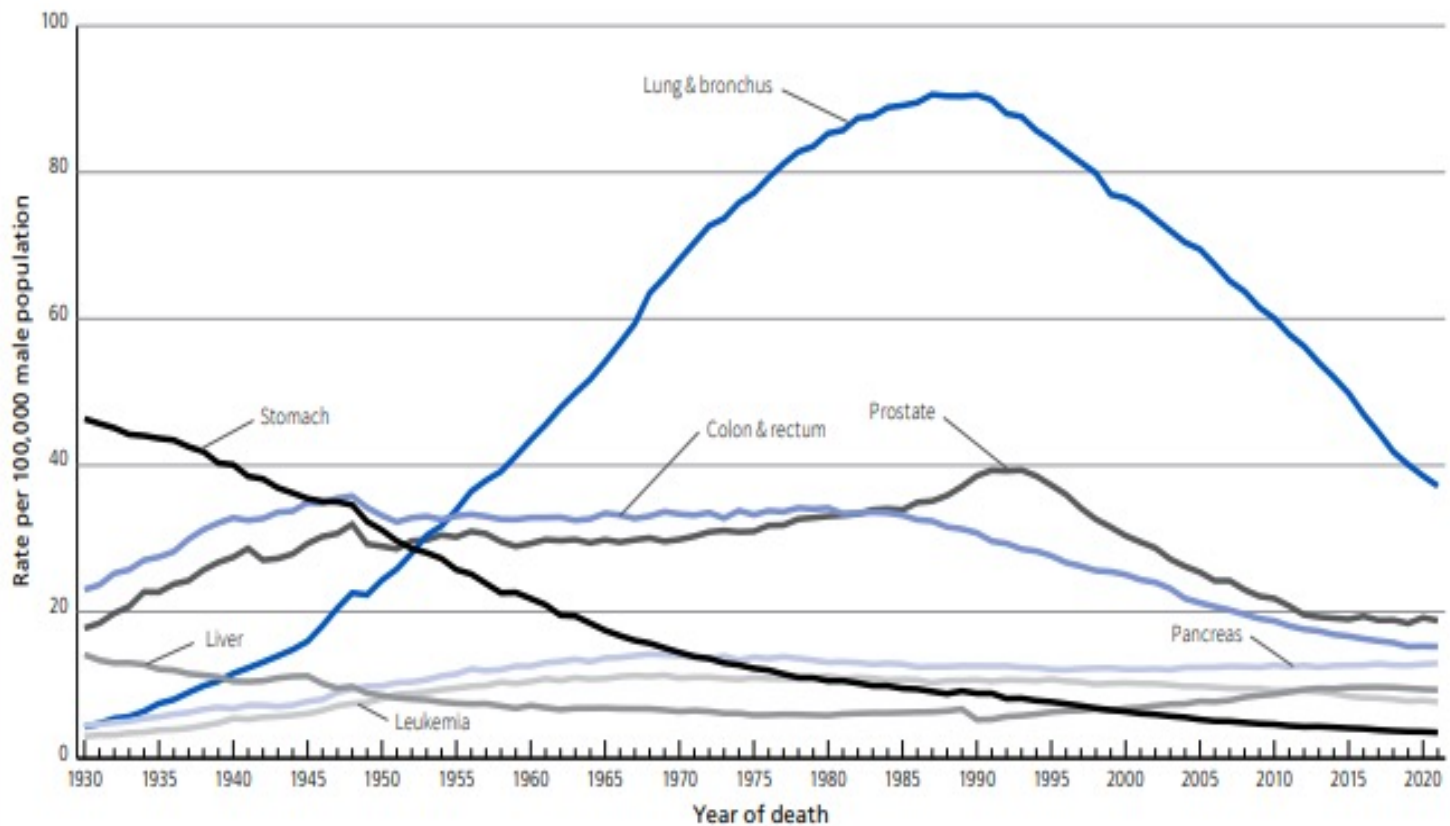


Figure 1. Trends in Age-adjusted Cancer Death Rates by Site, Males, US, 1930-2021

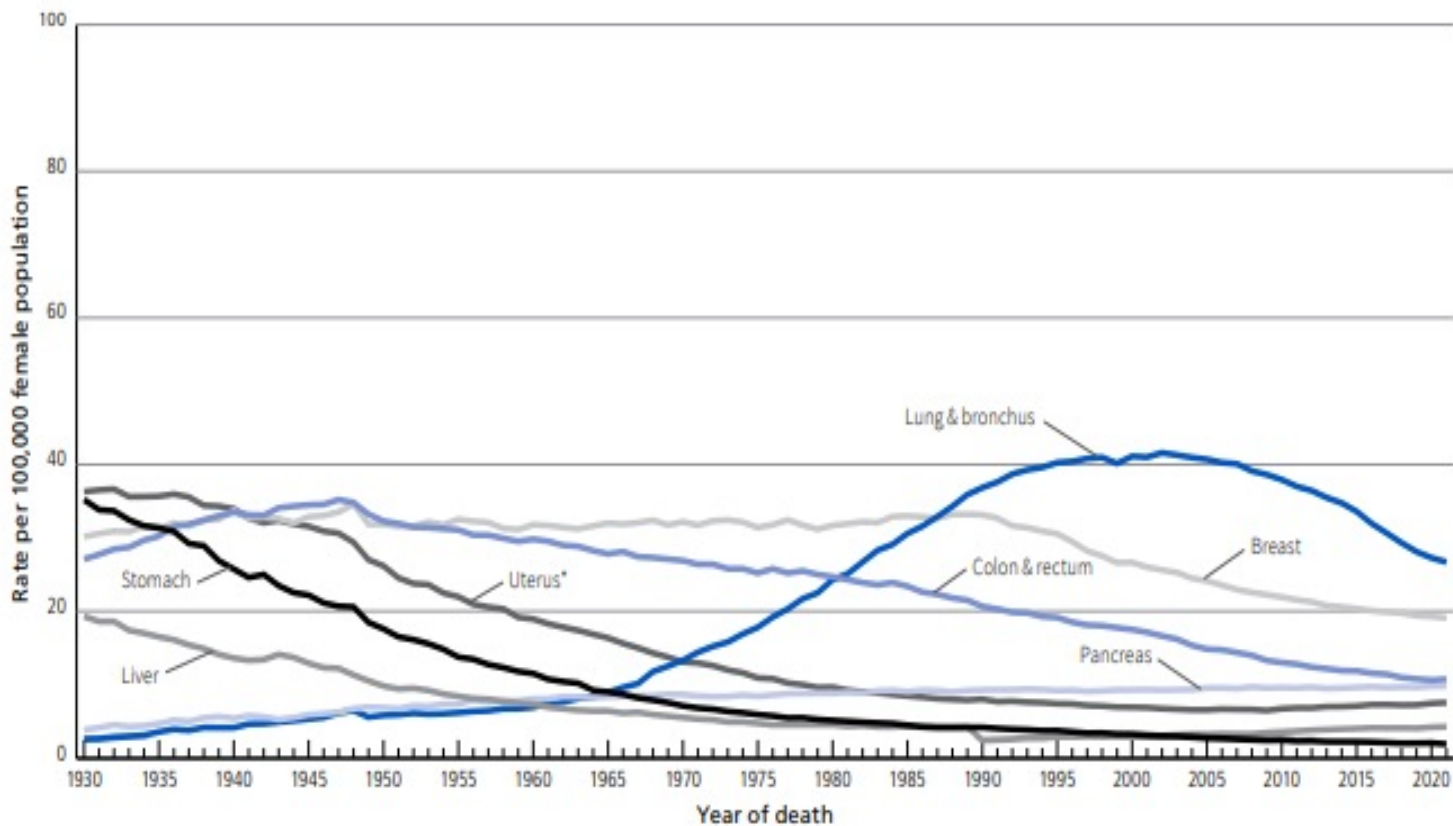


Rates are age adjusted to the 2000 US standard and exclude deaths in Puerto Rico and other US territories. Note: Due to changes in ICD coding, numerator information differs from contemporary data for cancers of the liver, lung and bronchus, and colon and rectum.

Source: US Mortality Volumes 1930 to 1959, US Mortality Data 1960 to 2021, National Center for Health Statistics, Centers for Disease Control and Prevention.

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Figure 2. Trends in Age-adjusted Cancer Death Rates by Site, Females, US, 1930-2021

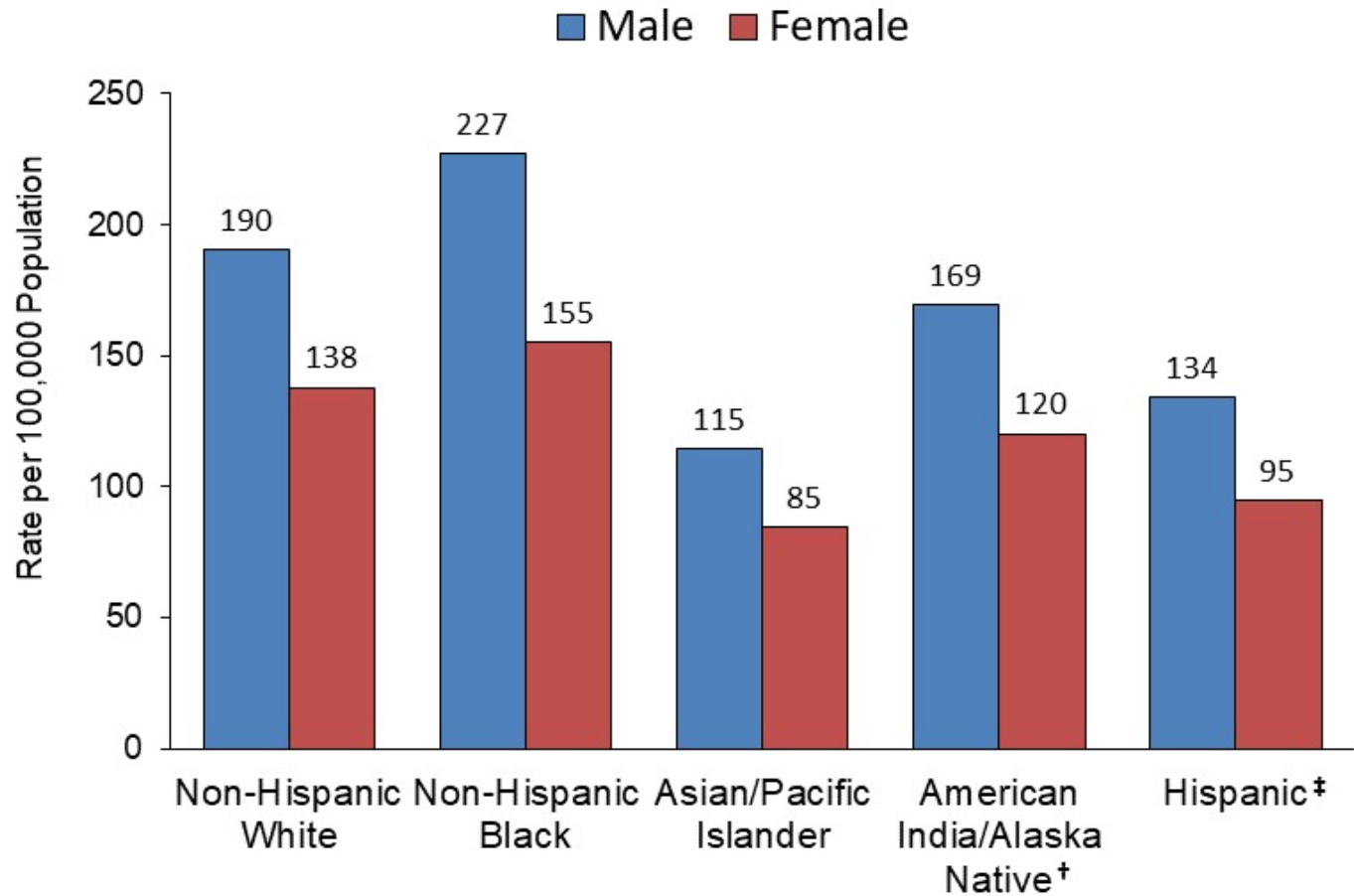


Rates are age adjusted to the 2000 US standard population and exclude deaths in Puerto Rico and other US territories. *Uterus refers to uterine cervix and uterine corpus combined. Note: Due to changes in ICD coding, numerator information differs from contemporary data for cancers of the liver, lung and bronchus, colon and rectum, and uterus.

Source: US Mortality Volumes 1930 to 1959, US Mortality Data 1960 to 2020, National Center for Health Statistics, Centers for Disease Control and Prevention.

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2018

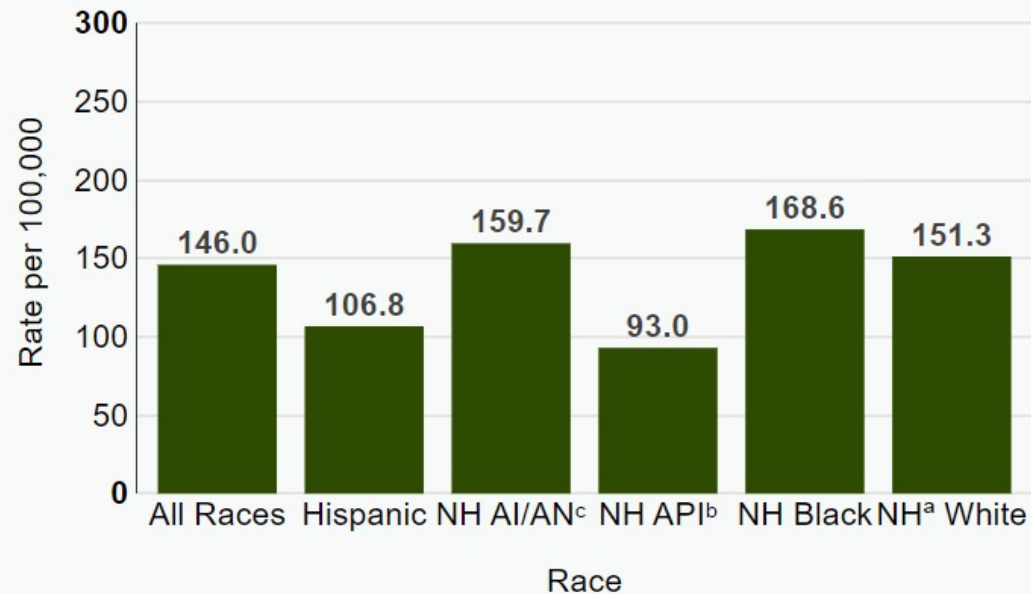


*Per 100,000, age-adjusted to the 2000 US standard population. [†]Data based on Purchased/Referred Care Delivery Area counties. [‡]Persons of Hispanic origin may be of any race.

Sources: National Center for Health Statistics, Centers for Disease Control and Prevention, 2020.

How Many People Die of Cancer by Sex and Race/Ethnicity?

Cancer Death Rates by Race/Ethnicity



U.S. Mortality 2018–2022, Age-Adjusted Rate per 100,000

^a Non-Hispanic, ^b Asian/Pacific Islander, ^c American Indian/Alaska Native

Common Cancer Types in the United States

Cancer Type	Estimated New Cases	Estimated Deaths
Bladder	81,400 *	17,980 *
Breast (Female-Male)	276,480 – 2620 *	42,170 – 520 *
Colon and Rectal (Combined)	156,540 *	66,700 *
GYN Cancers	113,520 *	33,620 *
Kidney (Renal Cell and Renal Pelvis Cancer)	73,750 *	14,830 *
Leukemia (All Types)	63, 530 *	23,100 *
Liver and Intrahepatic Bile Duct	42,810	30,160 *
Lung (Including Bronchus)	228,820 *	135,720 *
Melanoma	32,270	12,830
Non-Hodgkin Lymphoma	74,240 *	19,940 *
Pancreatic	57,600*	47,050*
Prostate	101,930 *	33,330 *
Thyroid	52,070	2,180

Estimated New Cancer Cases & Deaths, U.S. 2024

Table 1. Estimated Number* of New Cancer Cases and Deaths by Sex, US, 2024

	Estimated New Cases			Estimated Deaths		
	Both sexes	Male	Female	Both sexes	Male	Female
All sites	2,001,140	1,029,080	972,060	611,720	322,800	288,920
Oral cavity & pharynx	58,450	41,510	16,940	12,230	8,700	3,530
Tongue	19,360	13,870	5,490	3,320	2,270	1,050
Mouth	15,490	8,730	6,760	3,060	1,820	1,240
Pharynx	21,830	17,710	4,120	4,300	3,410	890
Other oral cavity	1,770	1,200	570	1,550	1,200	350
Digestive system	353,820	197,390	156,430	174,320	100,310	74,010
Esophagus	22,370	17,690	4,680	16,130	12,880	3,250
Stomach	26,890	16,160	10,730	10,880	6,490	4,390
Small intestine	12,440	6,730	5,710	2,090	1,150	940
Colon & rectum†	152,810	81,540	71,270	53,010	28,700	24,310
Colon	106,590	54,210	52,380			
Rectum	46,220	27,330	18,890			
Anus, anal canal, & anorectum	10,540	3,360	7,180	2,190	1,000	1,190
Liver & intrahepatic bile duct	41,630	28,000	13,630	29,840	19,120	10,720
Gallbladder & other biliary	12,350	5,900	6,450	4,530	1,950	2,580
Pancreas	66,440	34,530	31,910	51,750	27,270	24,480
Other digestive organs	8,350	3,480	4,870	3,900	1,750	2,150
Respiratory system	252,950	130,090	122,860	130,450	69,880	60,570
Larynx	12,650	10,030	2,620	3,880	3,120	760
Lung & bronchus	234,580	116,310	118,270	125,070	65,790	59,280
Other respiratory organs	5,720	3,750	1,970	1,500	970	530
Bones & joints	3,970	2,270	1,700	2,050	1,100	950
Soft tissue (including heart)	13,590	7,700	5,890	5,200	2,760	2,440
Skin (excluding basal & squamous)	108,270	64,220	44,050	13,120	8,700	4,420
Melanoma of the skin	100,640	59,170	41,470	8,290	5,430	2,860
Other nonepithelial skin	7,630	5,050	2,580	4,830	3,270	1,560
Breast	313,510	2,790	310,720	42,780	530	42,250
Genital system	427,800	310,870	116,930	70,100	36,250	33,850
Uterine cervix	13,820		13,820	4,360		4,360
Uterine corpus	67,880		67,880	13,250		13,250
Ovary	19,680		19,680	12,740		12,740
Vulva	6,900		6,900	1,630		1,630
Vagina & other genital, female	8,650		8,650	1,870		1,870
Prostate	299,010	299,010		35,250	35,250	
Testis	9,760	9,760		500	500	
Penis & other genital, male	2,100	2,100		500	500	
Urinary system	169,360	118,330	51,030	32,350	22,360	9,990
Urinary bladder	83,190	63,070	20,120	16,840	12,290	4,550
Kidney & renal pelvis	81,610	52,380	29,230	14,390	9,450	4,940
Ureter & other urinary organs	4,560	2,880	1,680	1,120	620	500
Eye & orbit	3,320	1,780	1,540	560	260	300
Brain & other nervous system	25,400	14,420	10,980	18,760	10,690	8,070
Endocrine system	48,010	14,480	33,530	3,300	1,580	1,720
Thyroid	44,020	12,500	31,520	2,170	990	1,180
Other endocrine	3,990	1,980	2,010	1,130	590	540
Lymphoma	89,190	49,220	39,970	21,050	12,330	8,720
Hodgkin lymphoma	8,570	4,630	3,940	910	550	360
Non-Hodgkin lymphoma	80,620	44,590	36,030	20,140	11,780	8,360
Myeloma	35,780	19,520	16,260	12,540	7,020	5,520
Leukemia	62,770	36,450	26,320	23,670	13,640	10,030
Acute lymphocytic leukemia	6,550	3,590	2,960	1,330	640	690
Chronic lymphocytic leukemia	20,700	12,690	8,010	4,440	2,790	1,650
Acute myeloid leukemia	20,800	11,600	9,200	11,220	6,290	4,930
Chronic myeloid leukemia	9,280	5,330	3,950	1,280	750	530
Other leukemia‡	5,440	3,240	2,200	5,400	3,170	2,230
Other & unspecified primary sites‡	34,950	18,040	16,910	49,240	26,690	22,550

*Rounded to the nearest 10; cases exclude basal cell and squamous cell skin cancer and in situ carcinoma except urinary bladder. About 56,500 cases of female breast ductal carcinoma in situ and 99,700 cases of melanoma in situ will be diagnosed in 2024. †Deaths for colon and rectal cancers are combined because a large number of deaths from rectal cancer are misclassified as colon. ‡More deaths than cases may reflect a lack of specificity in recording an underlying cause of death on death certificates and/or an undercount in the case estimate.

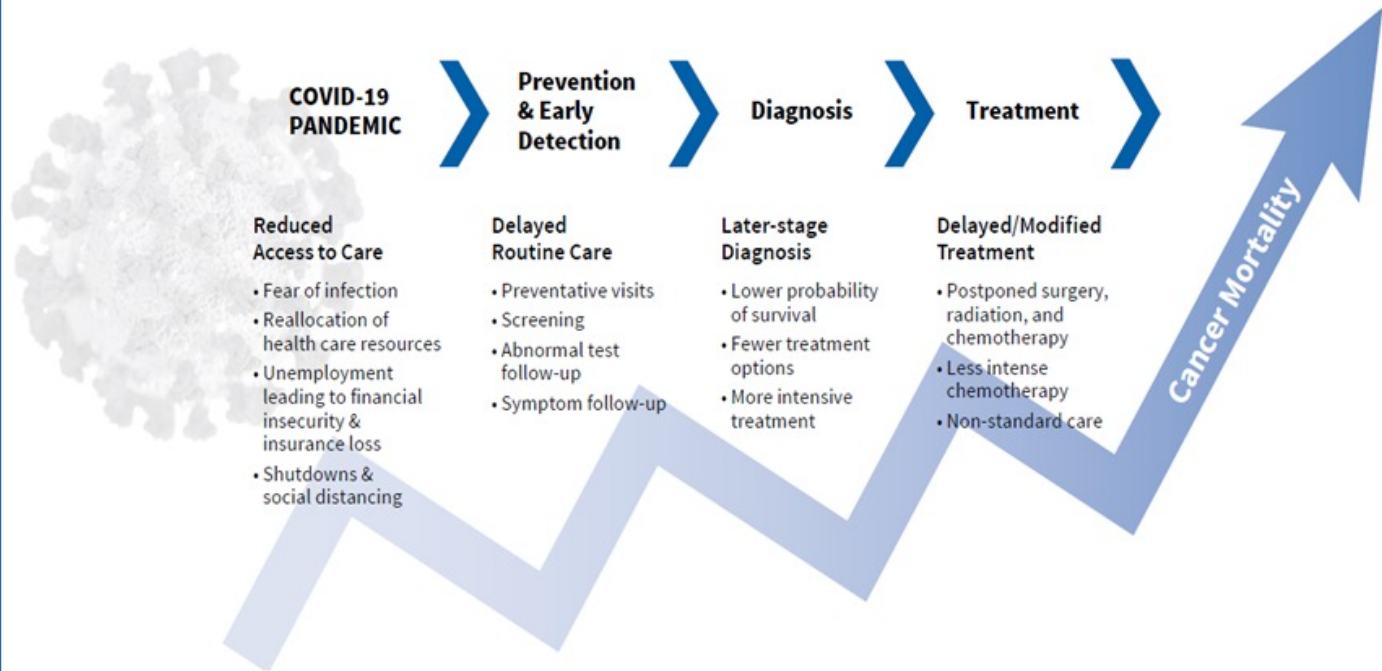
Source: Estimated new cases are based on 2006-2020 incidence data reported by the North American Association of Central Cancer Registries (NAACCR). Estimated deaths are based on 2007-2021 US mortality data, National Center for Health Statistics, Centers for Disease Control and Prevention.

Estimated Number* of New Cases for Selected Cancers by State, US, 2023

Table 2. Estimated Number* of New Cases for Selected Cancers by State, US, 2024

State	All sites	Female breast	Colon & rectum	Leukemia	Lung & bronchus	Melanoma of the skin	Non-Hodgkin lymphoma	Prostate	Urinary bladder	Uterine cervix	Uterine corpus
Alabama	30,270	4,800	2,570	780	4,230	1,400	1,000	5,180	1,190	230	840
Alaska	3,710	540	350	100	420	130	160	630	160	†	140
Arizona	42,670	6,830	3,280	1,260	4,350	3,020	1,690	4,630	2,060	290	1,380
Arkansas	19,100	2,680	1,570	580	2,840	1,040	720	2,950	750	140	500
California	193,880	32,660	16,170	5,700	16,920	10,570	8,320	26,350	7,330	1,560	7,140
Colorado	29,430	5,150	2,130	940	2,660	1,990	1,180	4,490	1,200	190	870
Connecticut	23,550	3,790	1,580	750	2,780	870	1,040	3,530	1,120	120	870
Delaware	7,340	1,140	500	210	920	420	300	1,320	350	†	250
Dist. of Columbia	3,300	630	260	80	380	70	110	390	120	†	150
Florida	160,680	23,160	11,920	6,420	18,580	9,880	7,940	24,090	7,520	1,170	4,860
Georgia	63,170	9,840	4,940	1,920	7,350	3,470	2,180	9,620	2,250	480	1,890
Hawaii	8,670	1,440	770	210	850	520	350	1,270	320	50	360
Idaho	11,120	1,730	810	420	1,070	890	460	1,660	550	70	360
Illinois	78,200	11,870	6,140	2,210	9,430	4,000	3,030	11,800	3,090	510	2,800
Indiana	42,710	6,270	3,390	1,270	5,930	2,250	1,660	6,470	1,840	310	1,470
Iowa	20,930	3,010	1,620	760	2,600	1,380	850	3,200	940	120	710
Kansas	16,640	2,620	1,420	500	2,190	920	670	2,820	710	120	470
Kentucky	30,630	4,320	2,630	890	5,120	1,490	1,110	3,510	1,240	220	950
Louisiana	29,400	4,230	2,520	890	3,740	1,200	1,050	4,330	1,100	200	690
Maine	10,700	1,490	700	340	1,600	530	410	1,560	610	†	400
Maryland	36,410	5,950	2,620	1,060	4,080	1,810	1,420	6,150	1,400	230	1,390
Massachusetts	44,040	7,150	2,790	1,300	5,620	1,530	1,790	6,420	1,950	210	1,600
Michigan	64,530	9,410	4,640	1,880	8,690	3,080	2,570	10,480	2,870	390	2,470
Minnesota	37,930	5,480	2,550	1,310	3,880	1,660	1,610	5,210	1,540	160	1,220
Mississippi	18,170	2,710	1,700	470	2,760	720	600	2,680	650	150	540
Missouri	39,120	5,980	3,020	1,220	5,820	1,760	1,520	5,510	1,570	260	1,360
Montana	7,310	1,070	550	250	740	540	280	1,070	360	†	220
Nebraska	11,790	1,770	940	380	1,190	660	470	2,270	500	70	380
Nevada	18,250	2,880	1,520	580	2,110	840	720	2,230	780	140	540
New Hampshire	9,880	1,460	650	290	1,290	570	400	1,570	510	†	390
New Jersey	57,740	8,880	4,240	1,940	5,600	2,330	2,490	9,860	2,540	370	2,230
New Mexico	11,220	1,780	960	370	950	560	470	1,370	420	100	420
New York	122,990	19,160	8,780	3,860	14,200	4,050	5,010	20,630	5,330	840	4,610
North Carolina	69,060	11,190	4,760	2,240	8,920	3,960	2,560	10,260	2,750	450	2,140
North Dakota	4,610	630	370	170	530	270	180	1,020	190	†	130
Ohio	76,280	11,500	5,890	2,050	10,390	4,290	2,880	10,670	3,380	510	2,680
Oklahoma	24,450	3,490	1,930	770	3,230	1,170	890	3,020	950	200	690
Oregon	26,200	4,440	1,860	760	3,000	1,350	1,040	3,000	1,230	140	880
Pennsylvania	89,410	13,370	6,550	2,710	11,200	3,870	3,610	13,010	4,290	510	3,460
Rhode Island	7,210	1,090	470	230	960	280	310	970	370	†	270
South Carolina	34,650	5,840	2,580	950	4,720	1,930	1,200	5,920	1,400	250	1,150
South Dakota	5,680	850	450	200	680	330	220	1,300	250	†	170
Tennessee	43,170	6,720	3,460	1,250	6,440	1,910	1,530	6,150	1,760	320	1,280
Texas	147,910	23,290	12,260	4,940	14,430	5,340	5,760	20,790	4,720	1,450	4,790
Utah	13,560	2,200	950	490	810	1,490	600	2,380	510	100	510
Vermont	4,500	670	300	140	520	310	190	690	220	†	170
Virginia	48,560	8,180	3,640	1,320	5,980	2,480	1,920	9,200	1,930	310	1,690
Washington	44,470	7,450	3,140	1,480	4,780	2,650	1,890	6,350	1,910	290	1,490
West Virginia	12,890	1,690	1,070	420	2,150	580	480	1,620	600	70	400
Wisconsin	39,750	5,710	2,610	1,400	4,610	2,040	1,630	6,870	1,690	180	1,450
Wyoming	3,320	510	270	110	330	240	120	570	170	†	100
United States	2,001,140	310,720	152,810	62,770	234,580	100,640	80,620	299,010	83,190	13,820	67,880

Potential Impact of the COVID-19 Pandemic on Future Cancer Outcomes



Coronavirus image courtesy of CDC.

CANCER THROUGHOUT THE WORLD

- 2000: 10 million new cases and 6 million deaths due to cancer
- 2020: 15 million new cases and 12 million deaths due to cancer
- Estimate 70% of cancer-related deaths will occur in developing countries due to poor resources
- 80-90% of cancer patients in developing countries will have incurable cancer at time of diagnosis, leading to long-term survival rates about half of those in the U.S.

Population-Based Studies

Regions of Highest Incidence

U.K.:
Lung
cancer

JAPAN:
Stomach
cancer

CANADA:
Leukemia

U.S.:
Colon
cancer

CHINA:
Liver
cancer

BRAZIL:
Cervical
cancer

AUSTRALIA:
Skin
cancer

EPIDEMIOLOGY

- **World Health Organization (WHO)**
- **American Cancer Society (ACS)**
- **National Cancer Institute SEER Program**
- **www.SEER.cancer.gov**
- **Surveillance, Epidemiology and End Results**
 - Incidence
 - Prevalence
 - Mortality rate
 - patient demographics
 - primary tumor site
 - tumor morphology
 - stage at diagnosis

FAST STATS

- Fast Stats is an interactive tool for quick access to key SEER and US cancer statistics for major cancer sites by age, sex, race/ethnicity and data type. Statistics are presented as graphs and tables

TERMINOLOGY

- **Incidence**
 - The number of new cases of a specific type occurring in a specific population in one year
- **Mortality**
 - The number of deaths of a specific type occurring in a specific population in one year
- **Prevalence**
 - The number of people alive on a certain date who previously had a diagnosis of cancer .
- **Survival**
 - In general, defined as people with NED at 5 years

THE GOOD NEWS . . .

- The death rate from all cancers combined has decreased by 1.5% per year for men since 1993, and by 0.8% per year for women since 1992.
- The mortality rate has continued to decrease from the three most common sites in men (lung, colorectal, and prostate), and from breast and colorectal cancers in women.

MORE GOOD NEWS . .

- Advances in molecular and cellular biology are broadening our understanding of carcinogenesis, and new treatment modalities are being developed accordingly.
- There are nearly 10 million cancer survivors today.

MORE GOOD NEWS . .

- **More targeted therapies:**

- ❖ As more is learned about the molecular biology of cancer, researchers will have more targets for their new drugs.
- ❖ Along with more monoclonal antibodies and small signaling pathway inhibitors
 - new classes of molecules –
 - antisense oligodeoxynucleotides
 - small interfering RNA (siRNA).

MORE GOOD NEWS . .

- **Immunotherapy:**

- ❖ Drugs aimed at specific immune checkpoints are being developed to help the immune system better kill cancer cells.

MORE GOOD NEWS . .

- **More on cancer genetics:**

- ❖ Researchers are looking for gene mutations that cause some patients to respond better to certain drugs.

MORE GOOD NEWS . .

- **Nanotechnology:**

- ❖ New technology for producing materials that form extremely tiny particles is leading to very promising imaging tests that can more accurately show the location of tumors.
- ❖ It also is aiding the development of new ways to deliver drugs more specifically and effectively to cancer cells.

MORE GOOD NEWS . .

- **Robotic surgery:**

- ❖ This term refers to manipulation of surgical instruments remotely by robot arms and other devices controlled by a surgeon.
- ❖ Robotic systems have been used for several types of cancer surgery;
 - radical prostatectomy is among the most common uses in surgical oncology.
- ❖ As mechanical and computer technology improve, some researchers expect future systems will be able to remove tumors more completely and with less surgical trauma.

MORE GOOD NEWS . .

- **Expression profiling and proteomics:**
 - ❖ Expression profiling lets scientists determine relative output of hundreds or even thousands of molecules (including the proteins made by RNA, DNA, or even a cell or tissue) at one time.
 - ❖ Knowing what proteins are present in cells can tell scientists a lot about how the cell is behaving.
 - ❖ In cancer, it can help distinguish more aggressive cancers from less aggressive ones and can often help predict which drugs the tumor is likely to respond to.

MORE GOOD NEWS . .

- **Expression profiling and proteomics:**
 - ❖ Proteomic methods are also being tested for cancer screening.
 - ❖ For most types of cancer, measuring the amount of one protein in the blood is not very good at finding early cancers.
 - ❖ Researchers are hopeful that comparing the relative amounts of many proteins may be more useful, and that finding large amounts of certain proteins and less of others can provide accurate, useful information about cancer treatment and its outcomes.
 - ❖ Proteins (and other types of molecules) are even found in exhaled breath, which is now being tested to find out if it can show early signs of lung cancer.
 - ❖ This is an exciting area of research and early results in [lung](#) and [colorectal cancer](#) studies have been promising.

POLL QUESTION:

African Americans are more likely to be diagnosed with cancer at advanced stages of their disease.

1. TRUE
2. FALSE

RACIAL DISPARITIES

- African Americans are more likely to be diagnosed at advanced stages of their disease.
- African American men and women have a greater chance of dying from their disease.
- 5-year relative survival is lower among African Americans than in Whites at every stage of diagnosis and nearly for every cancer site.

RISK FACTORS

- An identifiable trait or habit that is statistically associated with an increased susceptibility for disease

RISK FACTORS

- Viral
 - Hepatitis
 - HPV
 - HIV
 - EBV
 - HTLV-1
- Genetics
 - Heredity
 - Oncogenes
 - Suppressor Genes

RISK FACTORS

- Absolute Risk
 - Expressed as number of cases per 100,000
 - Average
- Relative Risk
 - Relates to one group
- Can you change the numbers???

RISK FACTORS

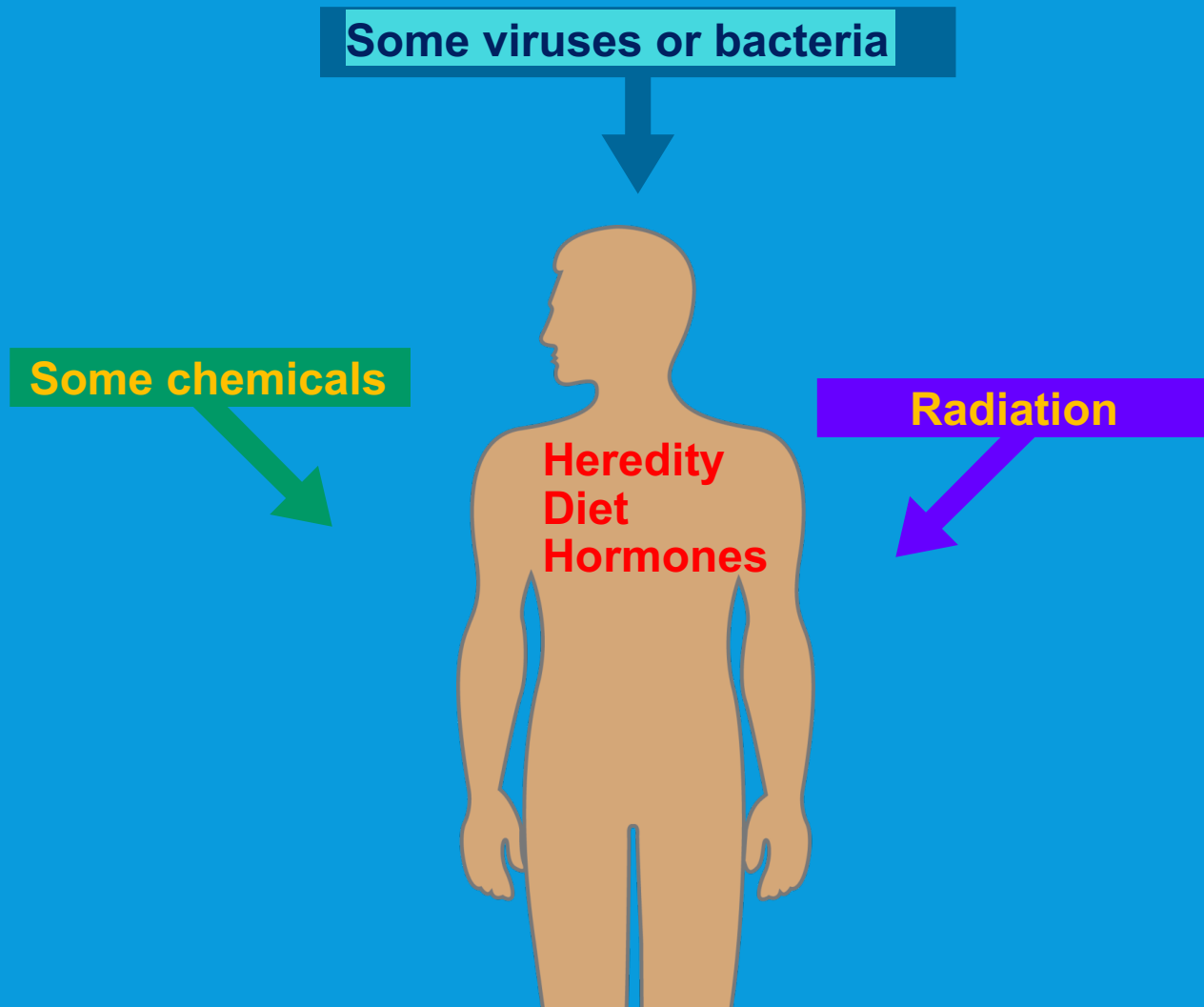
- Modifiable
- Not modifiable
- Cancer is caused by complex interactions between genes and a variety of external factors
- Recognizing risk factors identifies individuals at greater risk for cancer and provides opportunity to intervene or modify risk

POLL QUESTION:

What are the causes of cancer?

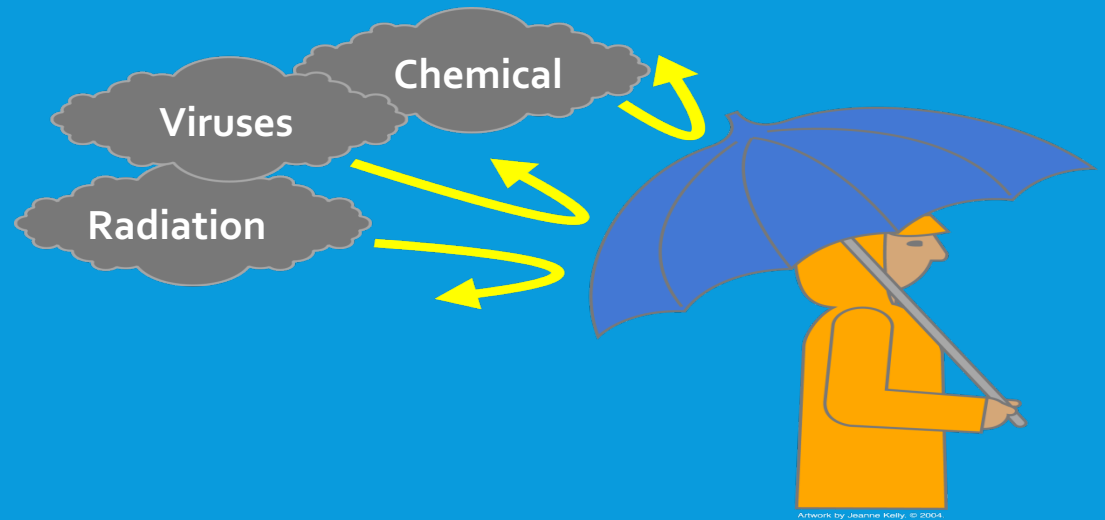
1. Viruses or bacteria
2. Chemicals
3. Radiation
4. Heredity, Diet, Hormones
5. Bad Luck
6. All of the above

What Causes Cancer?



LIFESTYLE RISK FACTORS

- Diet
- Exercise
- Substance use
- Radiation exposure
- Chemical exposure



Artwork by Jeanne Kelly. © 2004

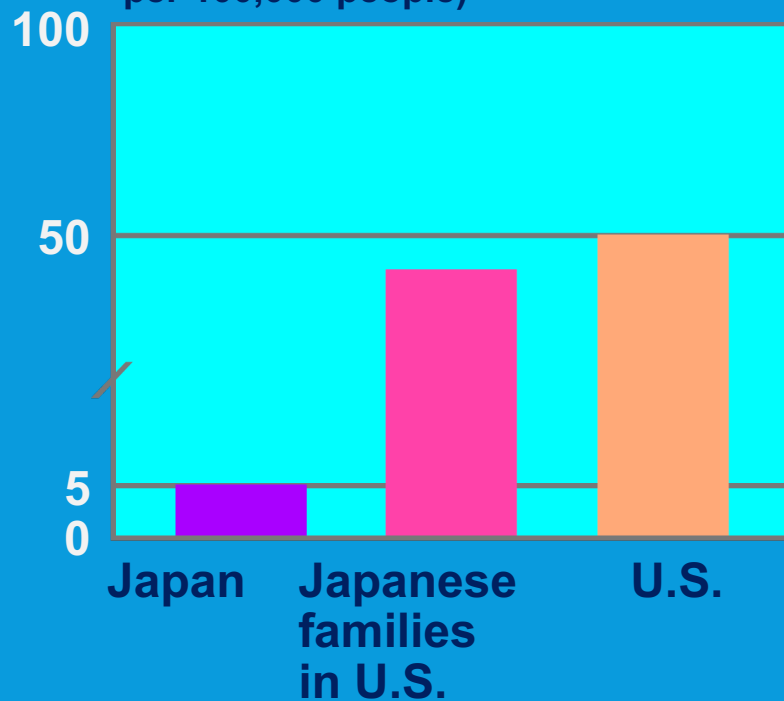


- Inherited from one or both parents
- Mutations occur in the germ cells
- These cancers represent very small number of cancers
- Examples
 - Li Fraumeni Syndrome, familial melanoma , retinoblastoma and some colon cancers

Heredity? Behaviors? Other Factors?

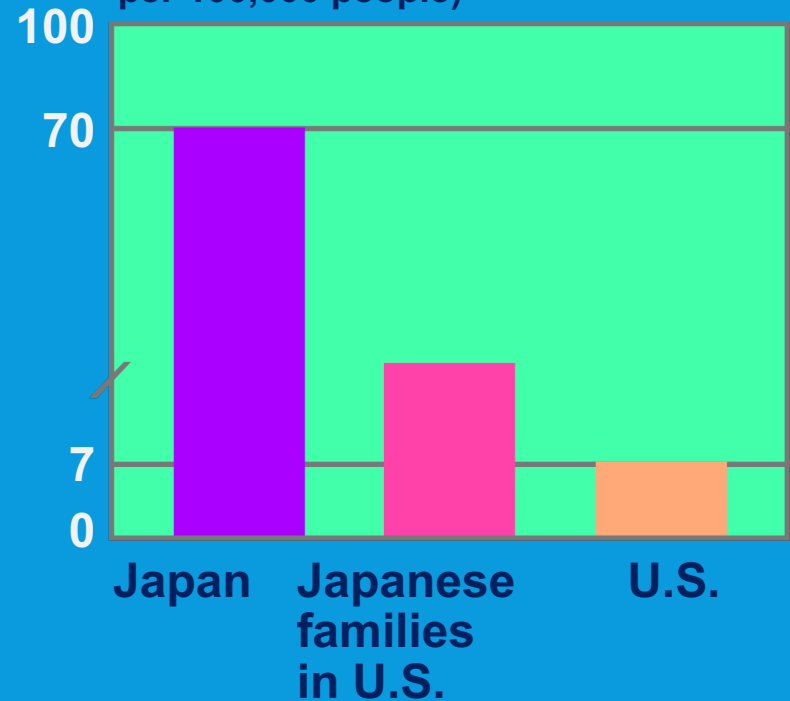
Colon Cancer

(Number of new cases per 100,000 people)



Stomach Cancer

(Number of new cases per 100,000 people)



MODIFIABLE RISK FACTORS

- Tobacco
- “Second hand “tobacco exposure
 - Workplace,
 - Home
 - Community
- Diet
 - Acrylamide (potato chips, French fries)
 - Red and processed meats/high fat
 - Artificial Sweeteners

MODIFIABLE RISK FACTORS



Environmental pollutants



Radiation

Ionizing

Non-ionizing

MODIFIABLE RISK FACTORS

- Hormones
- Alcohol
- Sedentary lifestyle

GENES

Individual units of hereditary information located at specific positions on a chromosome



Consist of a sequence of DNA that codes for a specific protein



They code for proteins whose normal function is to correct errors that arise when cells duplicate their DNA prior to cell division.

CYTOGENETICS



Focuses on the structure function and abnormalities of the chromosomes to diagnose both solid and hematologic cancers



Supports a personal approach to diagnose and treat cancers



GENETIC RISK FACTORS

- **Oncogenes may give rise to cancers when they are altered**
 - **Suppressor genes :**
 - BRCA1 repair
 - BRCA2 repair
 - **Proto-oncogenes**
 - RAS
 - ERB
 - ABL

CHARACTERISTICS OF CELLS

- Regular size and shape
- Function
- Predictable life span
- Genetic programming
- Responsive to bio feedback mechanisms
- Apoptosis (cell death)

NORMAL CELL FUNCTION 101



all cells come from preexisting cells



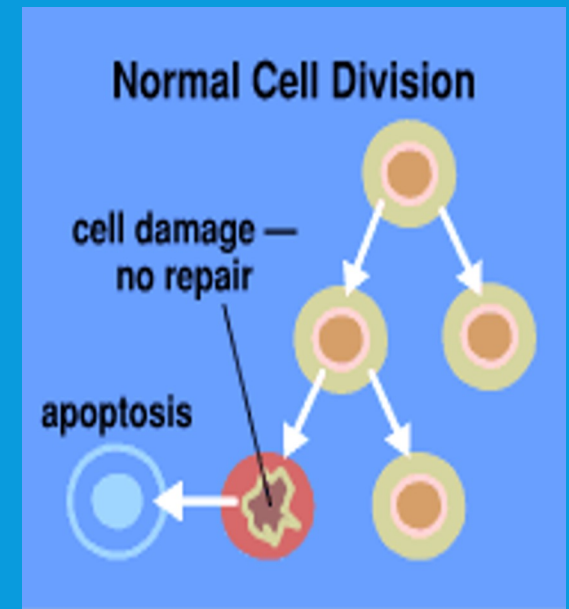
vital functions of an organism occur within cell



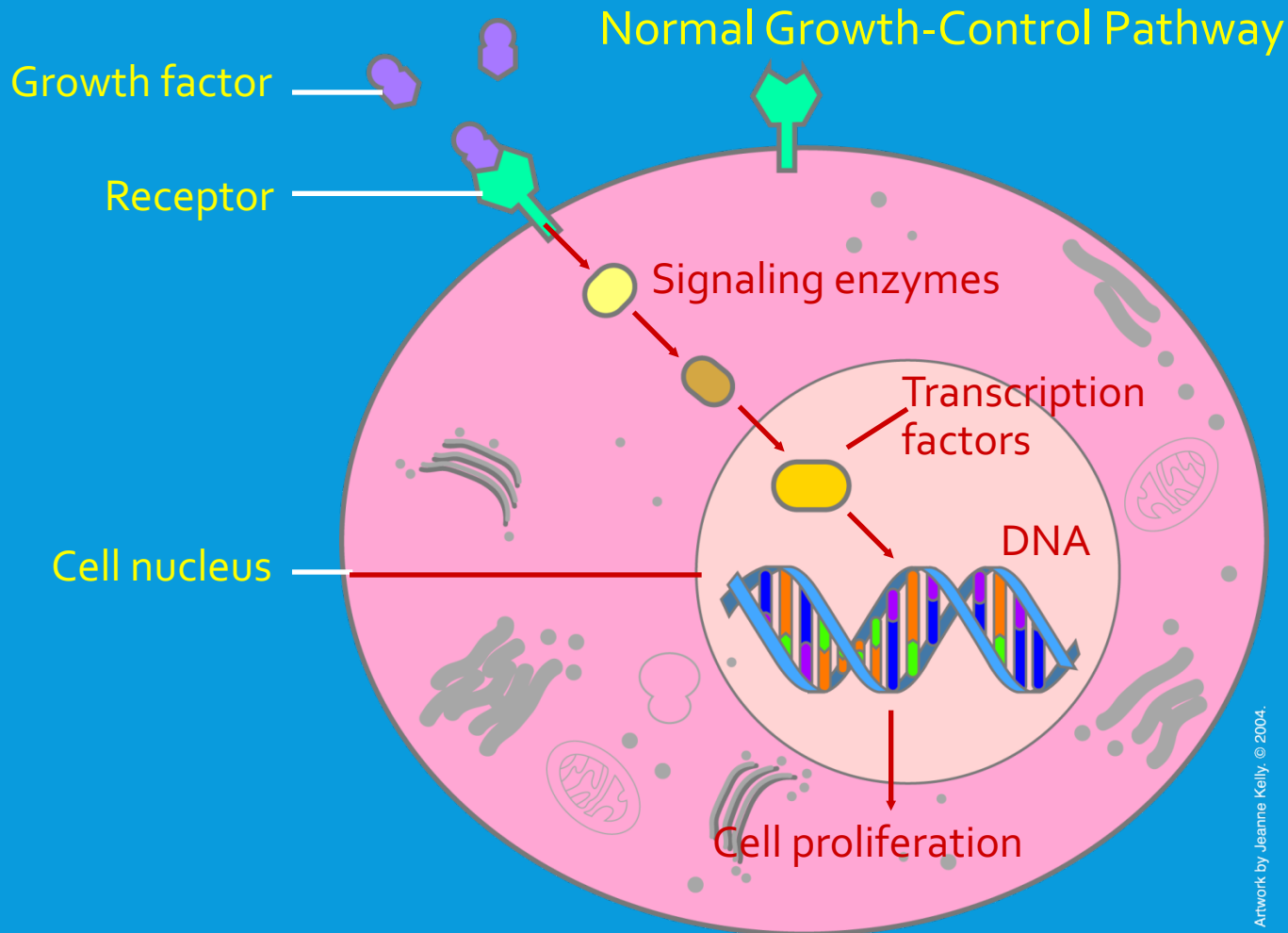
all cells contain the hereditary information necessary for regulating cell functions and for transmitting information to the next generation of cells.

CELL REPLICATION

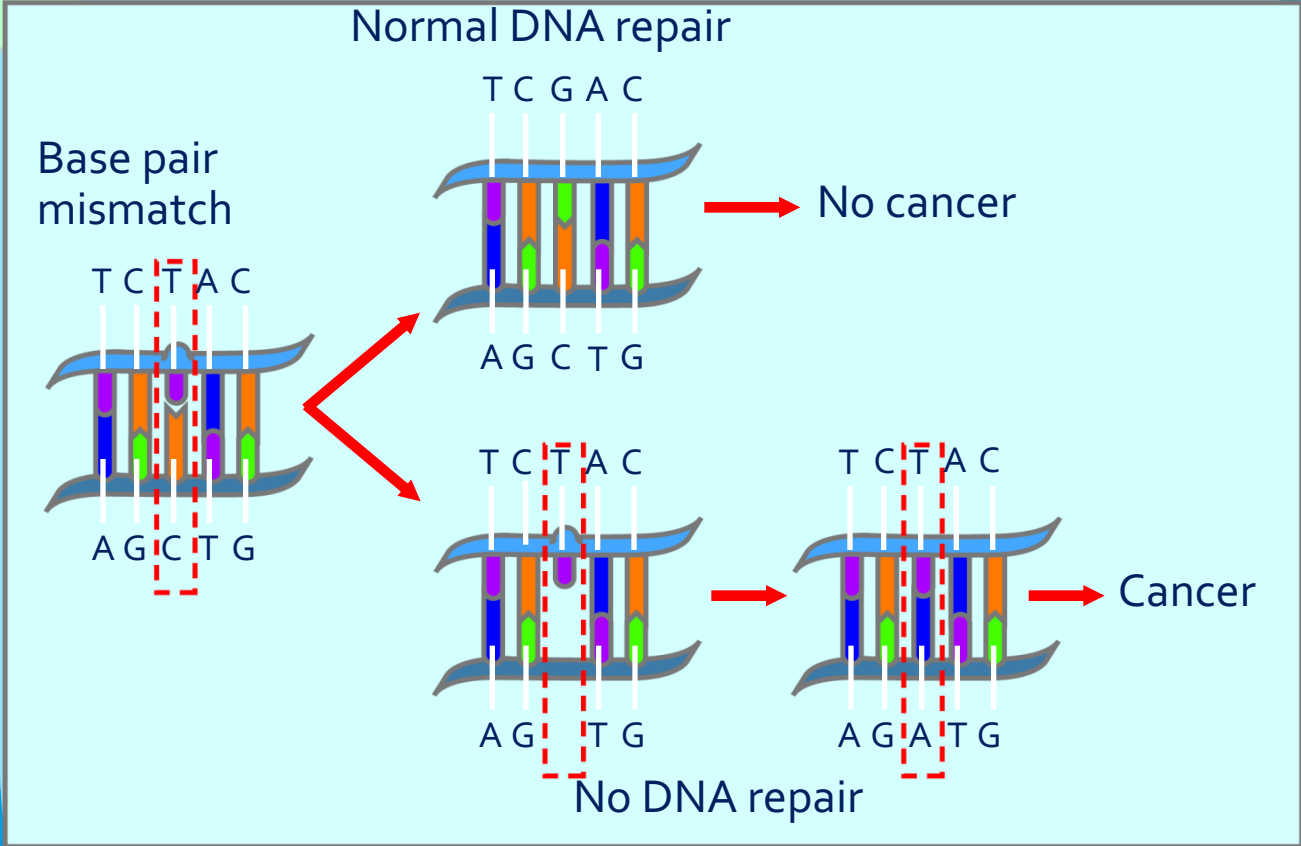
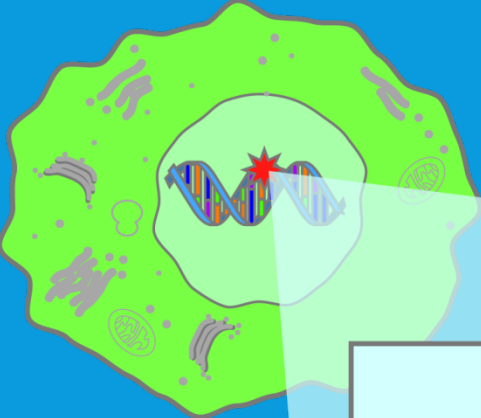
- Occurs billions of times every 24 hours to replace damaged or worn-out cells or produce proteins that support life
- Process “turned on” by growth factors
- Driven and moderated by genes
- Repair genes
 - Surveillance genes
 - Killer (suppressor) genes



NORMAL CELL REPLICATION



DNA Repair Genes



CANCER CELLS

- DNA damage/Cellular Abnormalities
- Uncontrolled replication
- Dedifferentiation
- Ability to spread
 - Invasion
 - Angiogenesis
 - Metastasis

PROPERTIES OF CANCER CELLS

- **Cytological changes**
 - Size and number
 - Nuclear/cytoplasmic ratio
- **Altered cell growth**
 - Immortality
 - Growth inhibition/cell cycle control
 - Angiogenesis
- **Cell membrane changes**
 - New antigens
 - Over expression of antigen

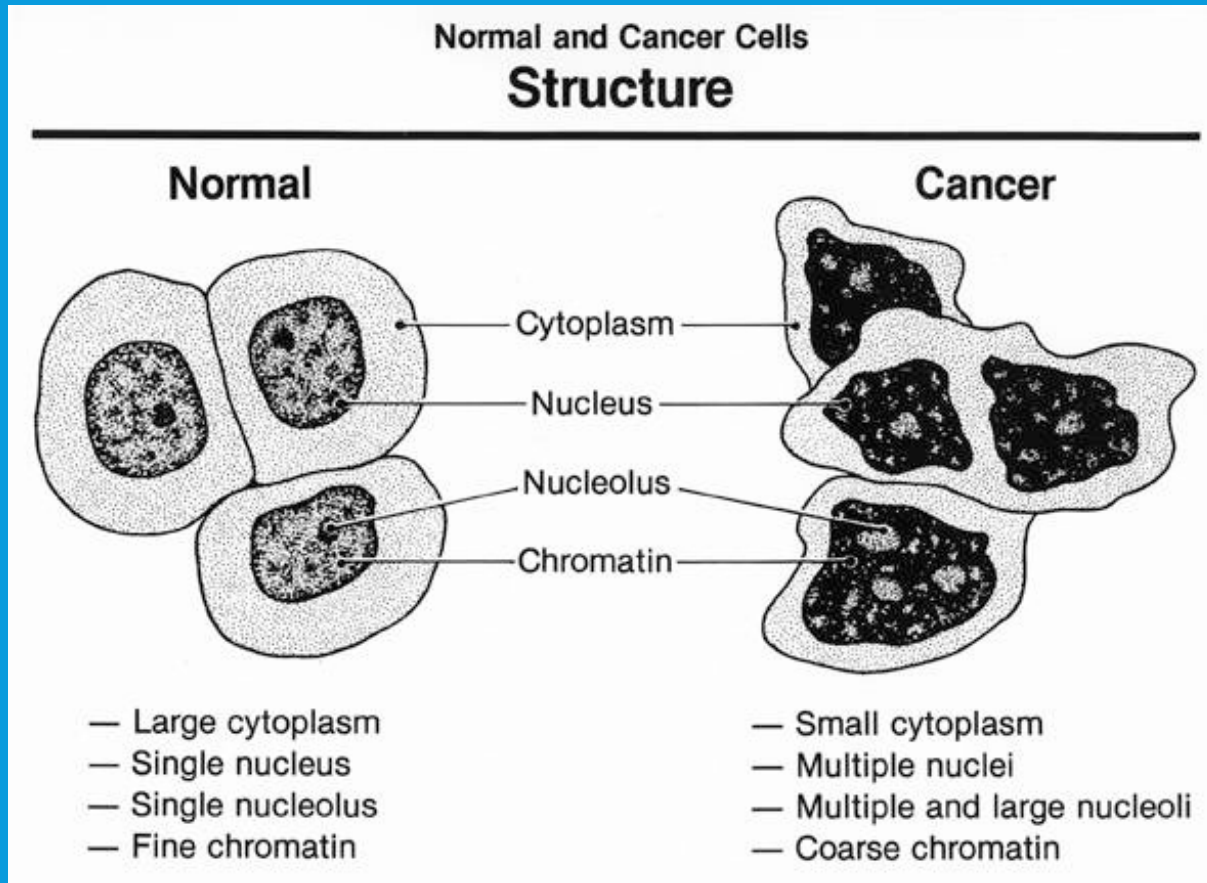
HOW CANCER CELLS DIFFER FROM NORMAL CELLS

- DNA errors
- Reproductive errors
- Dedifferentiation
- Uncontrolled proliferation

EVOLUTION OF A MALIGNANT PROCESS

- Genetic mutations or injuries
- Hormonal influences
- Environmental factors
 - Chemical exposure
 - Radiation
- Viruses
- Bad luck
- Cancer is caused by complex interactions between genes and a variety of external factors

NORMAL VERSUS MALIGNANT



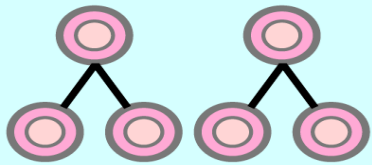
Mutations and Cancer

Genes Implicated in Cancer

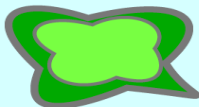
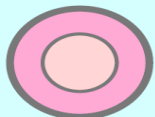
<i>The prime suspects</i>	<i>But</i>
Mutations in:	Other mutations also occur in:
■ Oncogenes	■ Cell death genes
■ Tumor suppressor genes	■ Cell signaling genes
■ DNA repair genes	■ Cell cycle checkpoint genes
	■ Cellular senescence genes
	■ Cellular differentiation genes
	■ Metastasis/invasion genes
	■ Carcinogen –activating genes –deactivating genes

Normal

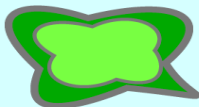
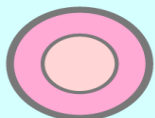
Cancer



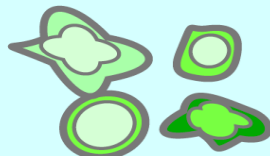
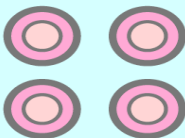
Large number of irregularly shaped dividing cells



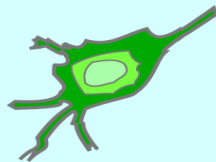
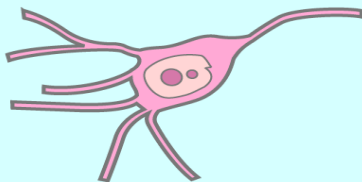
Large, variably shaped nuclei



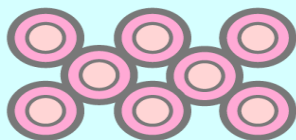
Small cytoplasmic volume relative to nuclei



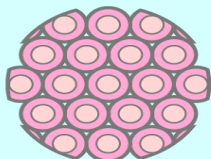
Variation in cell size and shape



Loss of normal specialized cell features



Disorganized arrangement of cells



Poorly defined tumor boundary

Stages of Malignant Transformation

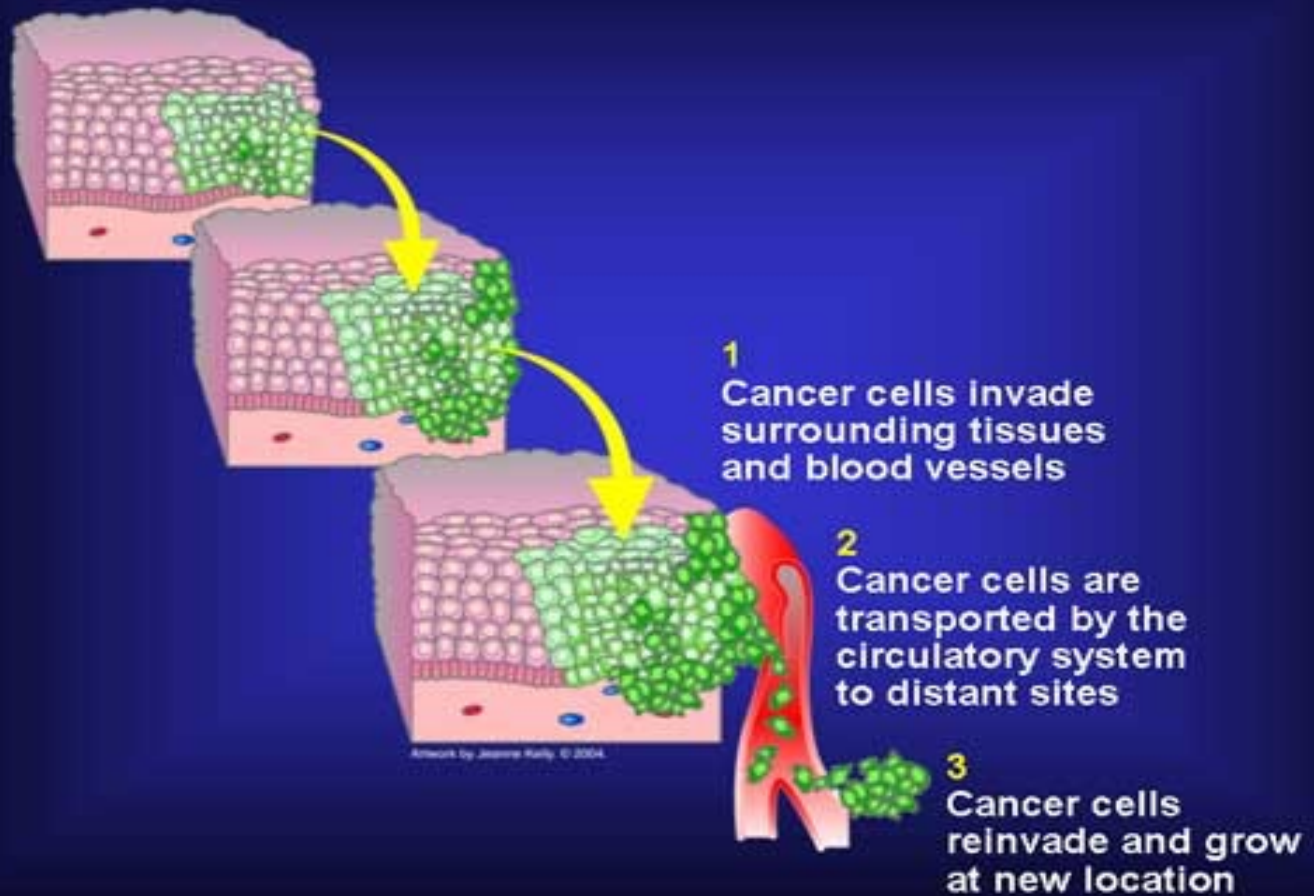
- **Initiation:** irreversible DNA damage.

- **Promotion:** cells with genetic defects start multiplication.

(Promoters are substances that enhance tumor growth by stimulating proliferation, immune suppression, etc.).

- **Progression:** neoplastic cells → malignant tumor → invasion of healthy tissue.

Invasion and Metastasis



Artwork by Joanne Kelly, © 2004

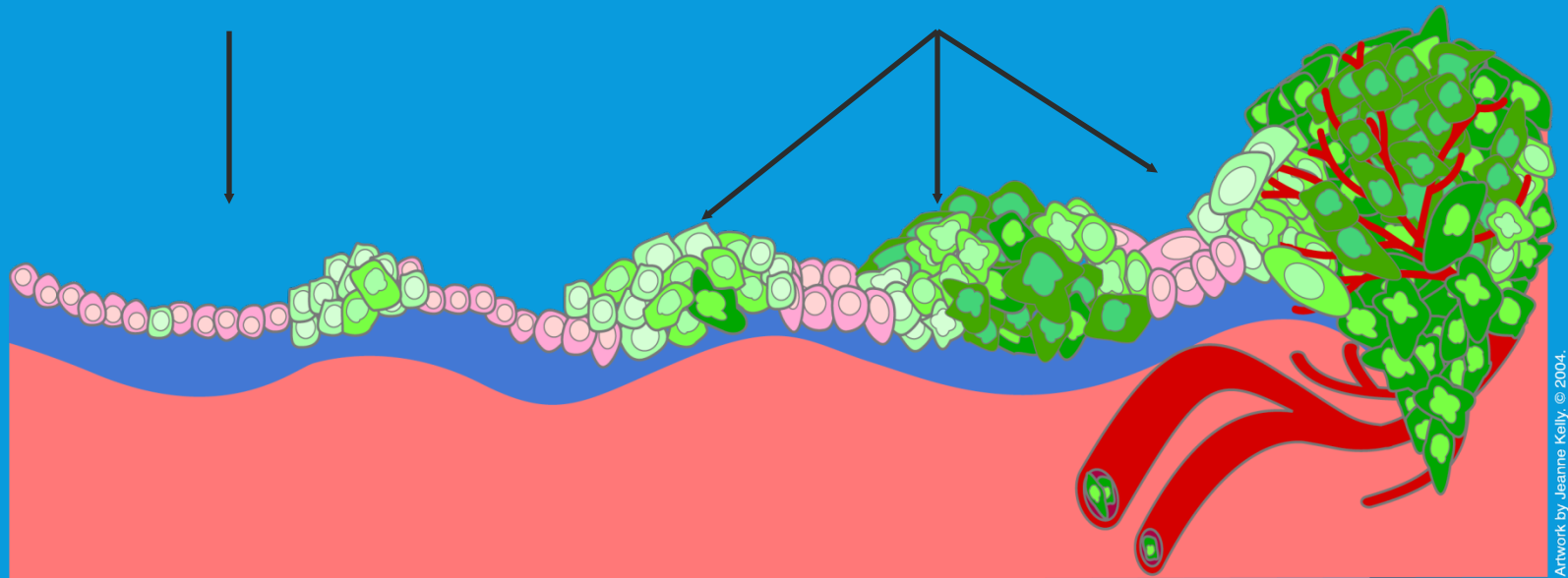
MALIGNANT TRANSFORMATION/METASTASIS

- Detachment
 - Invasion
 - Survival in transport
 - Arrest in distant organ
 - Establishment of secondary tumor
- Initiation
 - cell type specific
 - Chemical/radiation/etc.
 - Promotion
 - Proliferation free for all
 - Dysplasia, CIS
 - Progression

Cancer Tends to Involve Multiple Mutations

Benign tumor cells grow only locally and cannot spread by invasion or metastasis

Malignant cells invade neighboring tissues, enter blood vessels, and metastasize to different sites



Time

Mutation
inactivates
suppressor
gene

Cells
proliferate

Mutations
inactivate
DNA repair
genes

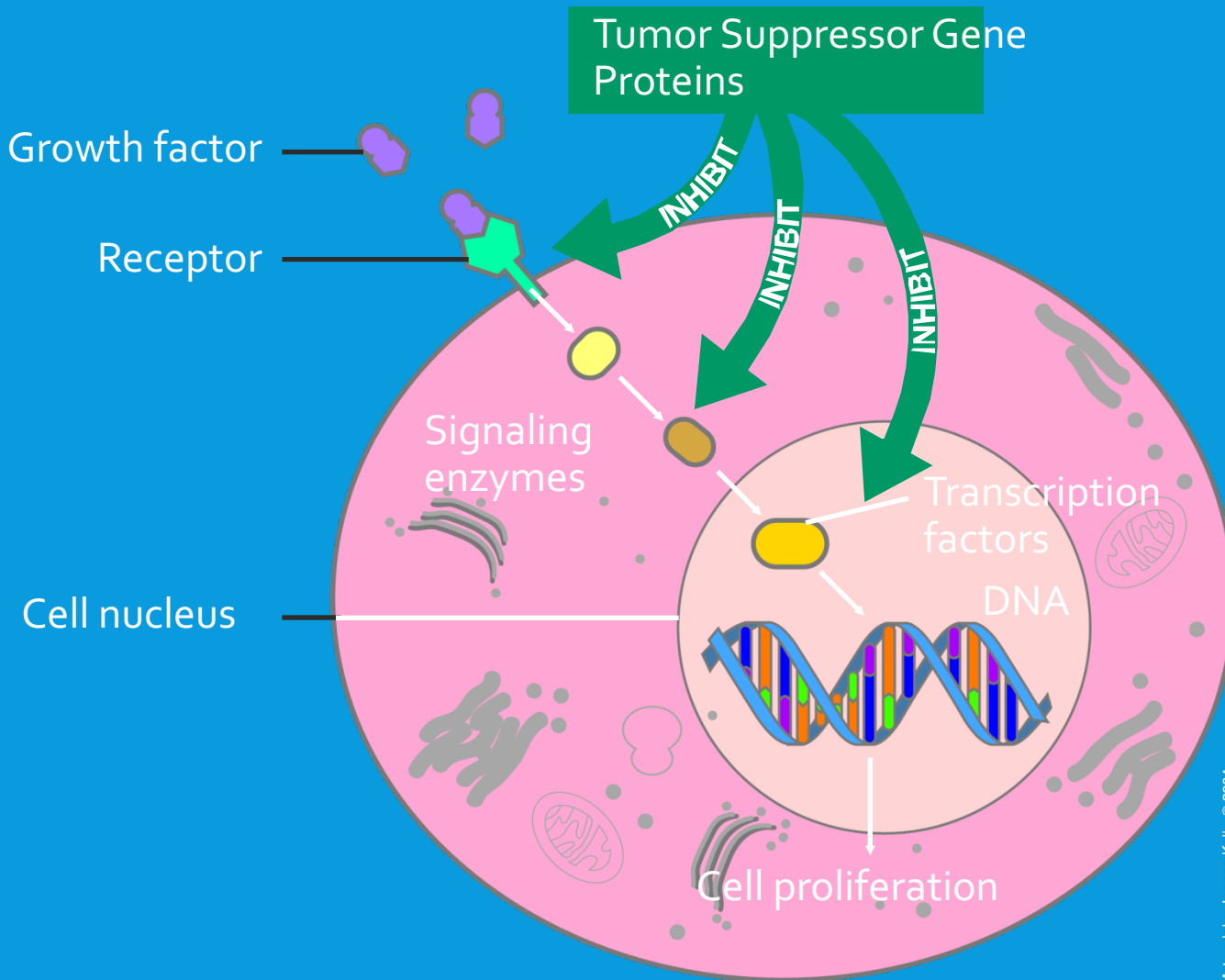
Proto-
oncogenes
mutate to
oncogenes

More
mutations &
more genetic
instability,
metastatic
disease

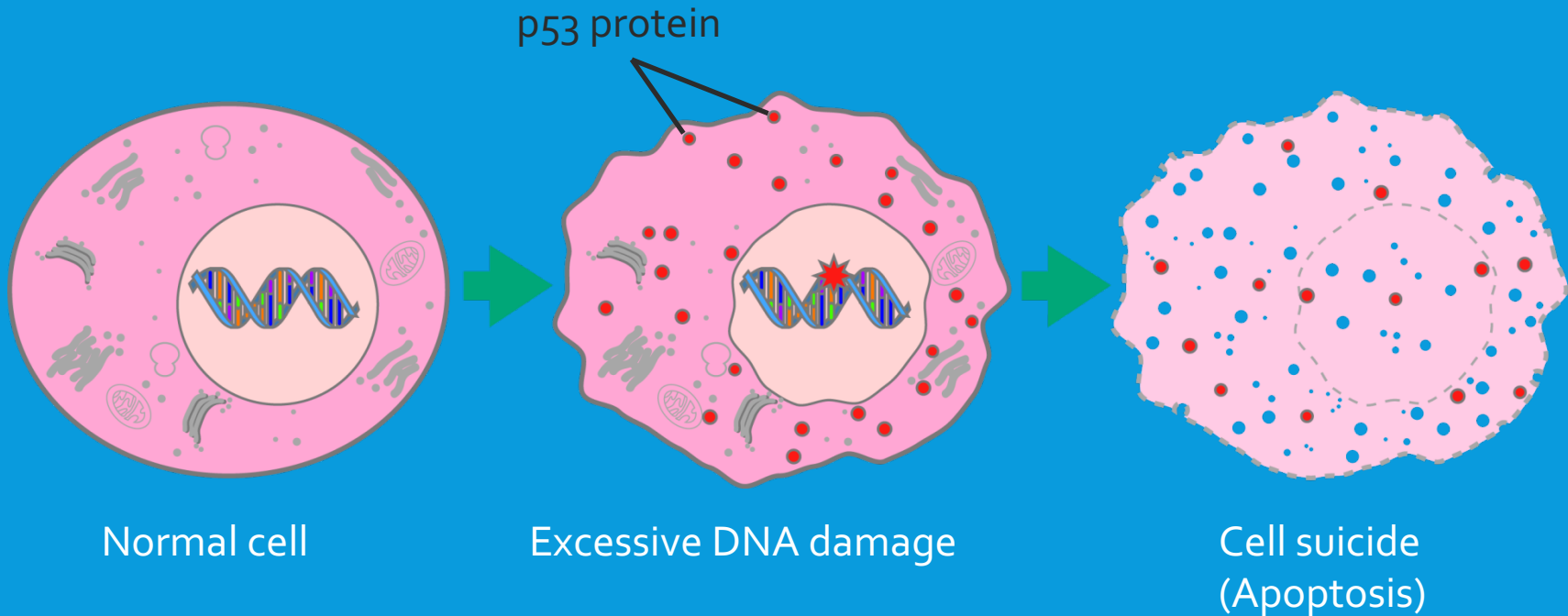
WHAT IS THE DIFFERENCE BETWEEN PROTO-ONCOGENES AND TUMOR SUPPRESSOR GENES

- ❑ Proto-oncogenes function as regulators of cell growth
- ❑ Proto-oncogenes have a role in DNA repair
- ❑ Proto-oncogenes are normal genes essential for normal cell growth
- ❑ Tumor suppressor genes function as regulators of cell growth
- ❑ Tumor suppressor genes are a type of repair gene

Tumor Suppressor Genes Act Like a Brake Pedal



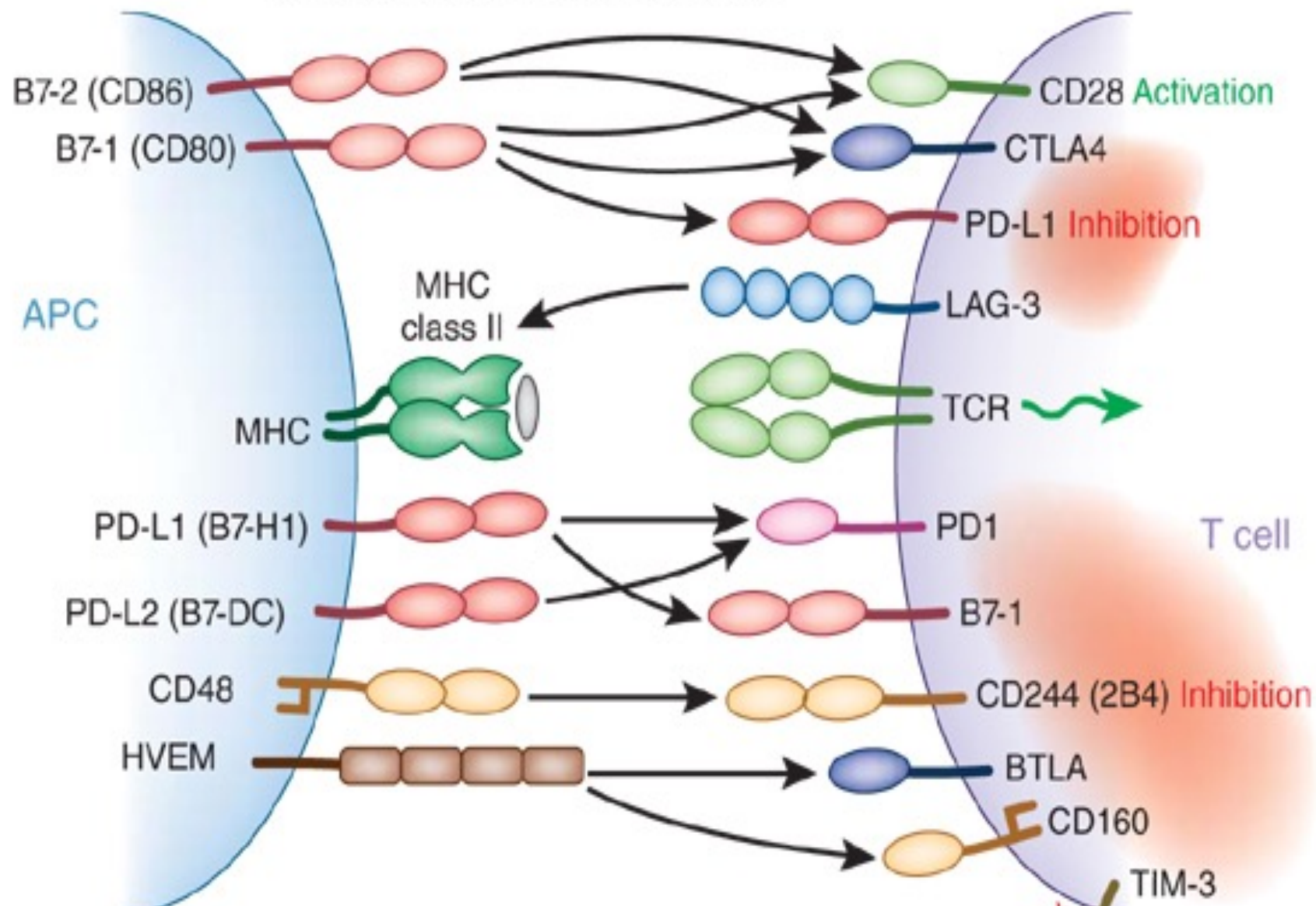
P53 Tumor Suppressor Protein Triggers Cell Suicide



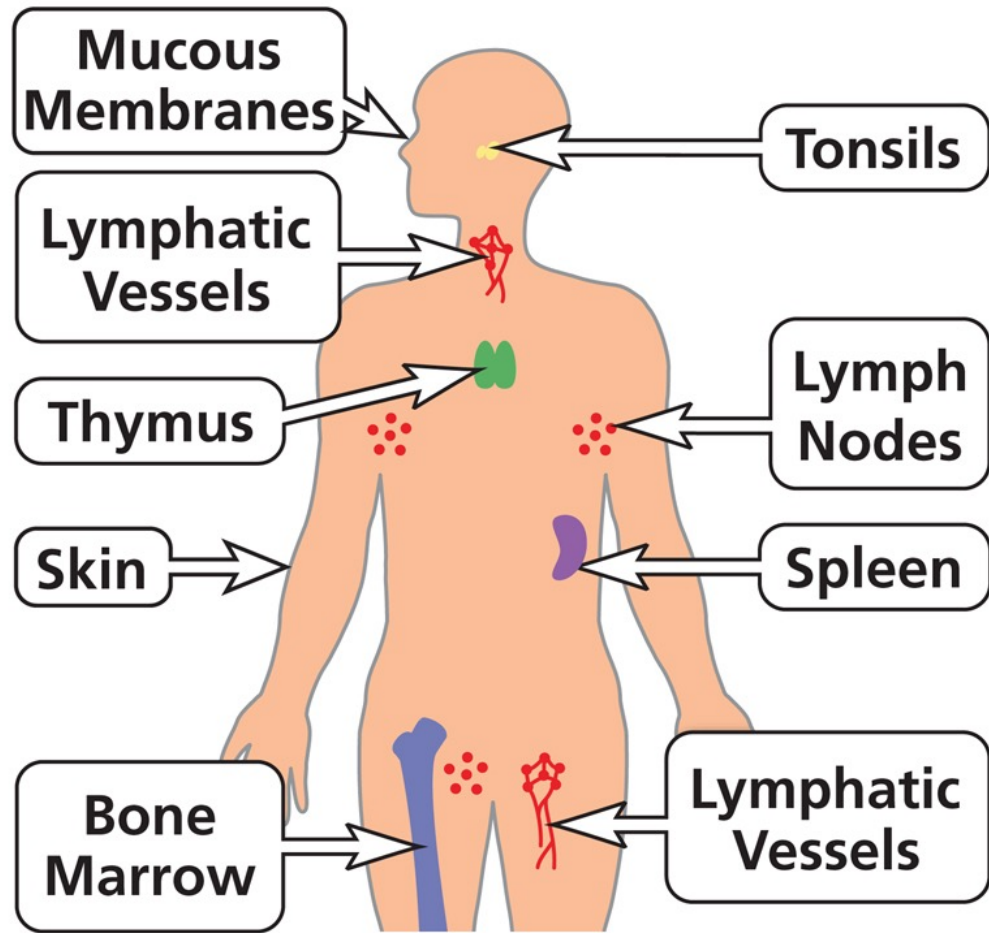
IMMUNE SURVEILLANCE

- As tumor cells differentiate, they produce proteins or antigens expressed on the cell surface
- Immune system recognizes these cells as non-self
- An immune response is mounted in defense
- Through a variety of mechanisms, the immune system destroys the foreign/non-self object (NK cells, cytotoxic T Cells, etc.)
- Tumors can develop if they evade Immune surveillance

Immuno-inhibitory pathways



Immune System



PREVENTION AND EARLY DETECTION

- The key to improving outcomes and survival
- Availability of preventative measures and resources for early detection is limited in developing countries.



DETECTION

- Screening
- Symptoms
- Happenstance

PREVENTION

- Screening
- Risky behavior modification
- Nutrition
- Chemoprevention

CANCER PREVENTION

Avoid	Avoid Tobacco
Limit	Limit Alcohol and Tobacco
Consume	Consume Fruits and Vegetables
Limit	Limit Fats and Calories
Protect	Protect Yourself From Excessive Sunlight
Avoid	Avoid Cancer Viruses
Avoid	Avoid Carcinogens at Work

SCREENING

- Identify asymptomatic persons with risk factors for a disease
- Detect occult disease
- Direct patients to genetic counseling
- Reassurance

ATTRIBUTES OF SCREENING



Sensitivity



Specificity predicative



Safe



Easy



Convenient



Cost effective

EVIDENCE BASED SCREENING

- **National Comprehensive Cancer Network (NCCN)**
- **American Cancer Society (ACS)**
- **National Cancer Institute (NCI)**
- **American College of Obstetricians and Gynecologists (AGOC)**

**SCREENING GUIDELINES-
AMERICAN CANCER SOCIETY**

- Colorectal
- Skin
- Breast
- Cervical
- Testicular
- Prostate
- Lung

SCREENING EXAMPLES

- Radiological (Mammography)
- Clinical Laboratory Testing (Pap Smears, Fecal Occult Blood Tests, PSA Test)
- Procedural (Colonoscopy, Sigmoidoscopy)
- Physical Exam (BSE/TSE, clinical breast/testicular exam, Digital Rectal Exam)

BREAST CANCER

- Women ages 40 to 44 should have the choice to start annual breast cancer screening with mammograms (x-rays of the breast) if they wish to do so.
- Women aged 45 to 54 should get mammograms every year.
- Women 55 and older should switch to mammograms every 2 years or can continue yearly screening.
- Screening should continue if a woman is in good health and is expected to live 10 more years or longer.
- All women should be familiar with the known benefits, limitations, and potential harms linked to breast cancer screening. They also should know how their breasts normally look and feel and report any breast changes to a health care provider right away.

PROSTATE CANCER

- The American Cancer Society recommends that men make an informed decision with a health care provider about whether to be tested for prostate cancer.
- Research has not yet proven that the potential benefits of testing outweigh the harms of testing and treatment.
- It is believed that men should not be tested without first learning about what is known and unknown about the risks and possible benefits of testing and treatment.
- Starting at age 50, men should talk to a health care provider about the pros and cons of testing so they can decide if testing is the right choice for them.
- If an African American male has a father or brother who had prostate cancer before age 65, they should have this talk with a health care provider starting at age 45.
- If the decision to be tested is made, the individual should get a PSA blood test with or without a rectal exam.
- How often one is tested will depend on the PSA level

LUNG CANCER

- The American Cancer Society does not recommend tests to check for lung cancer in people who are at average risk. There are screening guidelines for those who are at high risk of lung cancer due to cigarette smoking. Screening might be right if an individual have all of the following:
- 55 to 74 years of age
- In good health
- Have at least a 30 pack-year smoking history AND are either still smoking or have quit within the last 15 years (A pack-year is the number of cigarette packs smoked each day multiplied by the number of years a person has smoked. Someone who smoked a pack of cigarettes per day for 30 years has a 30 pack-year smoking history, as does someone who smoked 2 packs a day for 15 years.)
- Screening is done with an annual low-dose CT scan (LDCT) of the chest. If you fit the list above, talk to a health care provider if you want to start screening.

**WHEN TO
LOOK
CLOSER**

Change in bowel/bladder habits

Unusual bleeding/discharge

Sore that doesn't heal

Mole or wart change

Thickening or lump

Nagging cough or hoarseness

Indigestion/swallowing difficulty

**FOUND
SOMETHING,
WHAT NOW?**



LAB



IMAGING

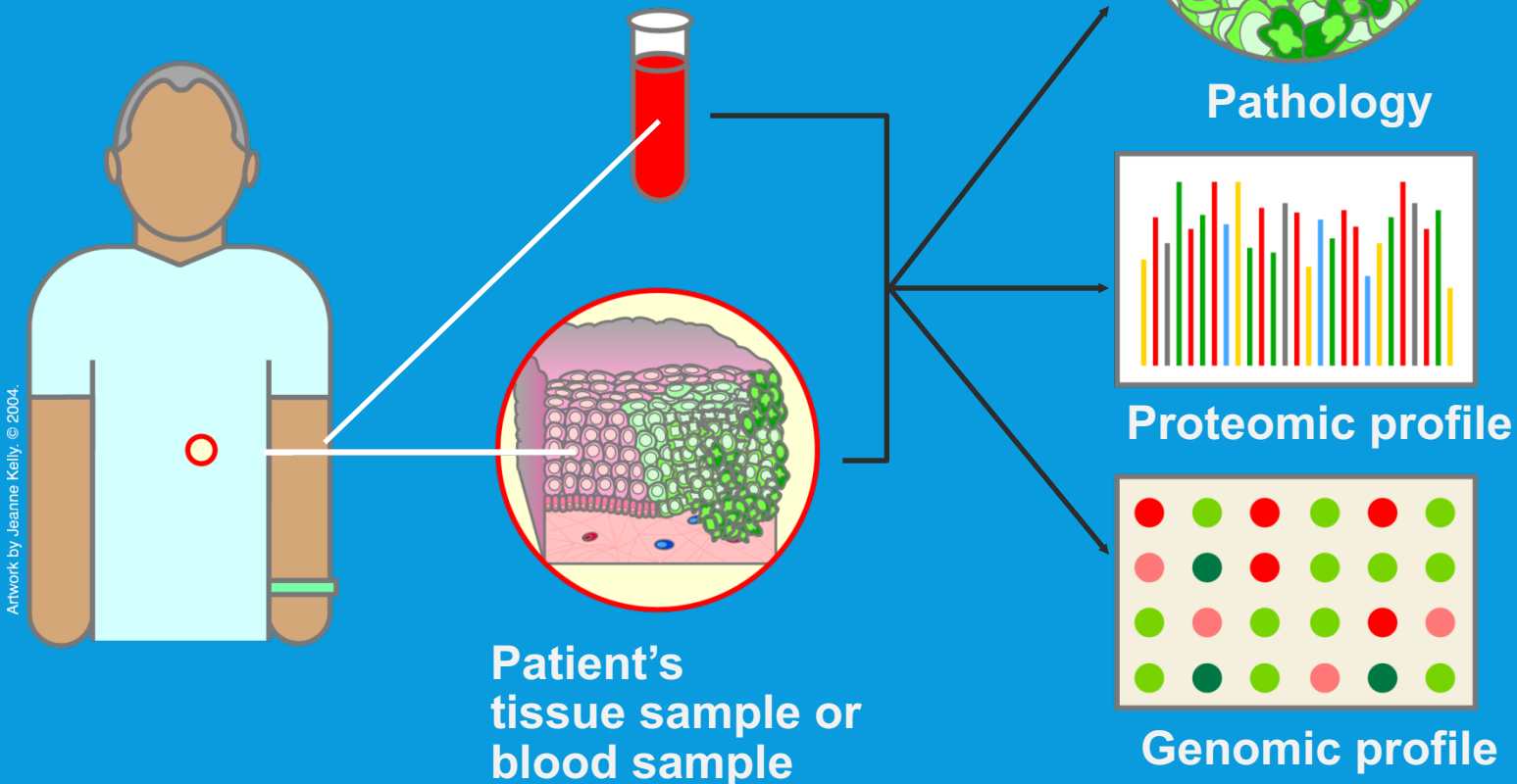


**INVASIVE
PROCEDURES**

LABORATORY INVESTIGATIONS

- Hematology studies
- Chemistry studies
- Radioimmunoassay
 - Tumor markers
 - Enzymes
 - Hormones
 - Metabolic products
 - Proteins
 - antigens
- Flow cytometry
 - DNA
 - Cell surface markers

Biopsy



PATHOLOGY

- Cytogenetics

- INDICATION FOR TEST: Gastrointestinal Tract (Colon) Adenocarcinoma, Signet-Ring Cell Type Metastatic to Hematopoietic and Lymphoid Tissue (Lymph Node)

SPECIMEN(S) TESTED: S15-35344 A2 (Massachusetts General Hospital, Boston, MA, United States)

RESULTS:

Targeted RNA next generation sequencing (NGS) using Anchored Multiplex PCR (AMP) detected no fusion transcripts in ALK, RET, and ROS1.

INTERPRETATION:

NEGATIVE for ALK, RET, and ROS1 rearrangement.

TEST INFORMATION:

We have developed Anchored Multiplex PCR (AMP) for targeted fusion transcript detection using next generation sequencing (NGS) [1]. Briefly, total nucleic acid was isolated from a formalin-fixed paraffin embedded tumor specimen after histological review for tumor enrichment. The total nucleic acid was reverse transcribed with random hexamers, followed by second strand synthesis to create double-stranded complementary DNA (cDNA). The double-stranded cDNA was end-repaired, adenylated, and ligated with a half-functional adapter. Two hemi-nested PCR reactions were applied to create a fully functional sequencing library that targets specific genes (exons) listed below. Illumina MiSeq 2 x 147 base pair paired-end sequencing results were aligned to the hg19 human genome reference using bwa-mem [2]. A laboratory-developed algorithm was used for fusion transcript detection and annotation. The integrity of the input nucleic acid and the technical performance of the assay were assessed with a qualitative reverse transcription qPCR assay and assessing the DNA/RNA content in the sequencing results. Although this assay may detect several potential fusion variants, only the most prevalent one is reported. The assay is validated for samples showing 20% or higher tumor cellularity and for clinical reporting of fusion transcripts involving ALK, RET, and ROS1.

SNAPSHOT

- TARGETED GENES (EXONS):

ADCK4 (1-2, 4-6, 9-10, 12-15), AKT3 (1-2, 13), ALK (1,3, 17, 19-22, 29), AR (1-4, 6, 7-8), ARHGAP6 (1-3), ARHGAP26 (10-13), AXL(14-15), BRAF (1-2, 8-11, 17), BRD4 (1, 10-12), CCDC6 (1-8), CD74 (1-8), CHTOP(2- 6), EGFR (7-9, 14-18, 23-28), ERBB2 (2-4), ERBB4 (17-18, 20), ESR1 (3-5),EWSR1 (1, 3-8, 12-13), FGFR1 (1, 7-13, 16-18), FGFR2 (3-4, 17), FGFR3 (3, 7-12,15-18), FGR (2-3), INSR (13-18, 21-22), INSRR (13-18, 21-22), JAK1 (1-7, 9-25),JAK2 (1, 6, 9, 11-12, 16-17, 19, 24), MAML2 (2-4), MAST1 (2, 8, 19-20, 26, 29),MAST2 (1, 5), MET (2, 11-16, 20-21), MUSK (8-9, 11-14), NFIB (1, 7-9), NOTCH1(2, 27-28, 34), NOTCH2 (1, 27, 33),NRG1 (2-4, 6), NTRK1 (1, 8-17), NTRK2 (9-11,13-20), NTRK3 (1, 11-16, 18 19), NUMBL (3-7, 9-10), NUTM1 (2-3), PDGFB (1-2, 6),PDGFRA (1, 9-11, 13-14, 20-23), PIK3CA (2-3), PKN1 (9-14), PLAG1 (2-4), PPARG(3-8), PRKACA (2-4), PRKCA (3-7), PRKCB (3-7), RAF1 (1, 9-11, 17), RET (1, 8-13,19), RHOA (1-5), ROS1 (1, 31-37, 43), TMPRSS2 (1-5).

TARGETED THERAPY

- TARGETED GENES (EXONS):

ADCK4 (1-2, 4-6, 9-10, 12-15), AKT3 (1-2, 13), ALK (1, 3, 17, 19-22, 29), AR (1-4, 6, 7-8), ARHGAP6 (1-3), ARHGAP26 (10-13), AXL(14-15), BRAF (1-2, 8-11, 17), BRD4 (1, 10-12), CCDC6 (1-8), CD74 (1-8), CHTOP (2-6), EGFR (7-9, 14-18, 23-28), ERBB2 (2-4), ERBB4 (17-18, 20), ESR1 (3-5), EWSR1 (1, 3-8, 12-13), FGFR1 (1, 7-13, 16-18), FGFR2 (3-4, 17), FGFR3 (3, 7-12, 15-18), FGR (2-3), INSR (13-18, 21-22), INSRR (13-18, 21-22), JAK1 (1-7, 9-25), JAK2 (1, 6, 9, 11-12, 16-17, 19, 24), MAML2 (2-4), MAST1 (2, 8, 19-20, 26, 29), MAST2 (1, 5), MET (2, 11-16, 20-21), MUSK (8-9, 11-14), NFIB (1, 7-9), NOTCH1(2, 27-28, 34), NOTCH2 (1, 27, 33), NRG1 (2-4, 6), NTRK1 (1, 8-17), NTRK2 (9-11, 13-20), NTRK3 (1, 11-16, 18-19), NUMBL (3-7, 9-10), NUTM1 (2-3), PDGFB (1-2, 6), PDGFRA (1, 9-11, 13-14, 20-23), PIK3CA (2-3), PKN1 (9-14), PLAG1 (2-4), PPARG(3-8), PRKACA (2-4), PRKCA (3-7), PRKCB (3-7), RAF1 (1, 9-11, 17), RET (1, 8-13, 19), RHOA (1-5), ROS1 (1, 31-37, 43), TMPRSS2 (1-5).

TUMOR MARKERS

Biological substances used to guide and monitor treatment and potential disease activity

- **CEA (carcinoembryonic antigen)**
 - Bladder, breast, colon, lung, ovarian, pancreatic, stomach, thyroid cancers
- **PSA (prostate specific antigen)**
 - Prostate
- **CA-125 (cancer antigen 125)**
 - Ovarian cancer
- **CA 27-29**
 - Breast, colon, stomach, kidney, lung, ovarian, pancreas, uterus, liver cancers
- **AFP (alfa fetoprotein)**
 - Liver cancer, non-seminomatous germ cell tumors

IMAGING

X-ray

- Lung
- Surveillance/initial detection

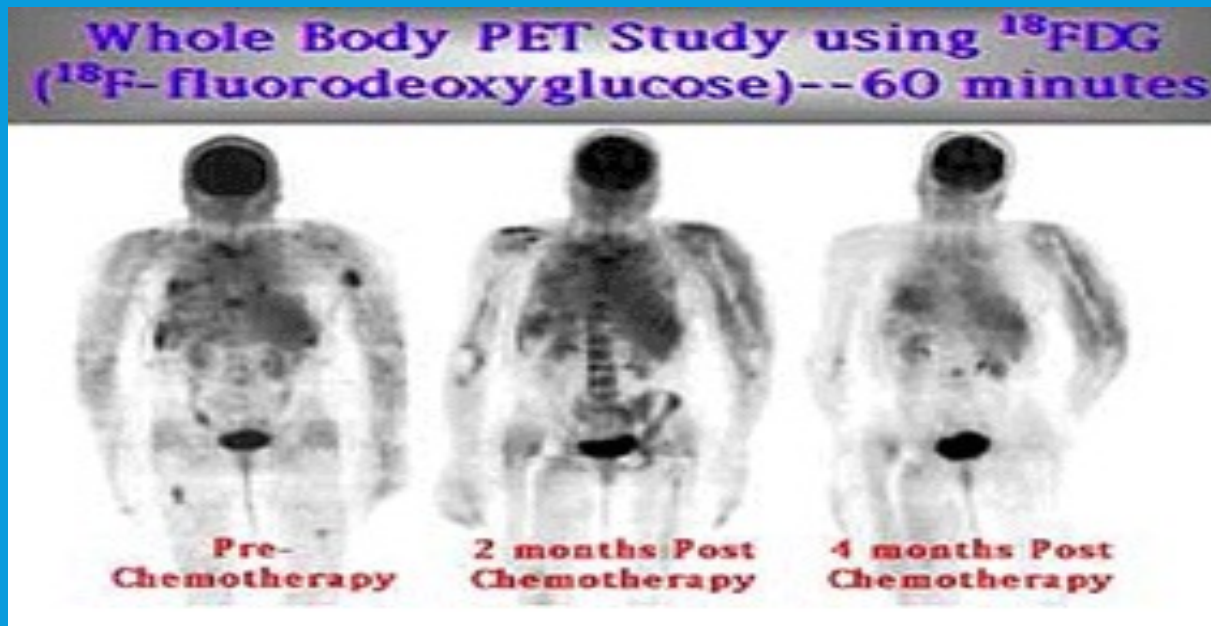
PET

- Benign/malignant
- Guidance for bx

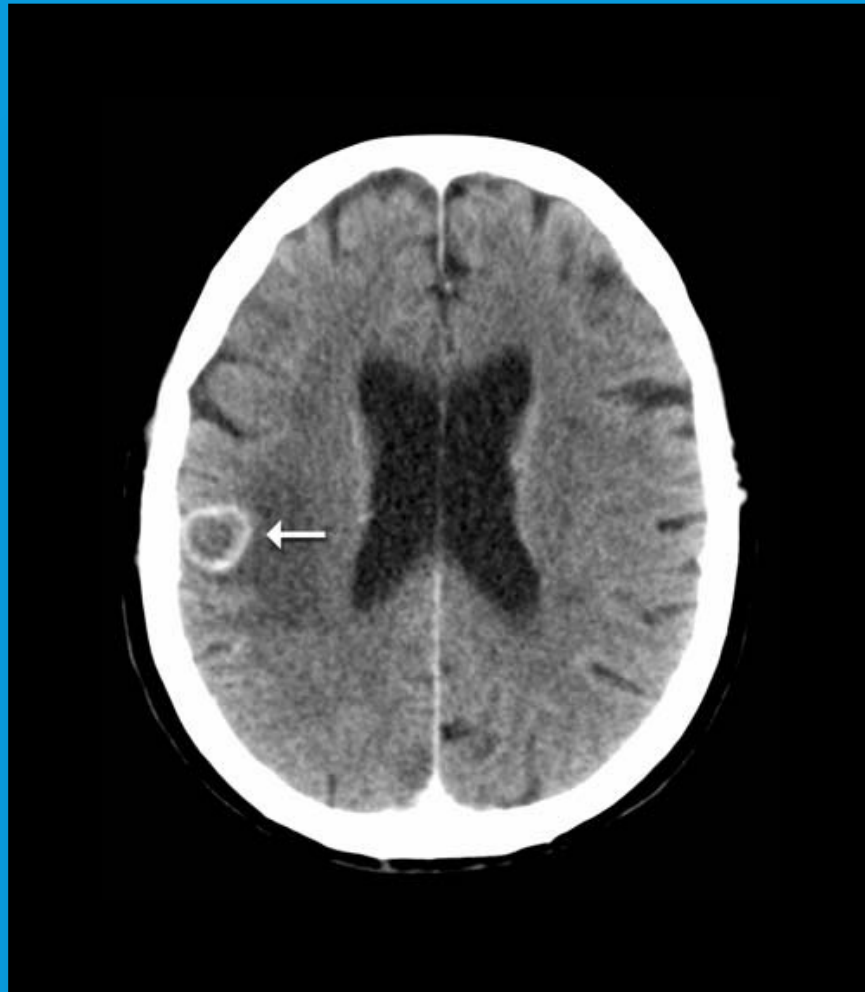
MRI

CT scans

PET CT (POSITRON EMISSION TOMOGRAPHY)



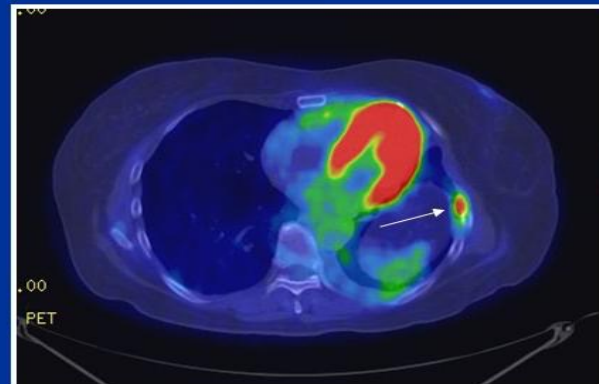
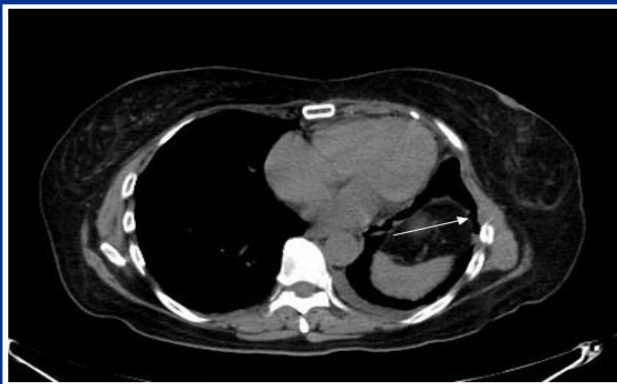
CT SCAN



MAGNETIC RESONANCE IMAGE



CT alone, and PET/CT Fusion



PET avid
pleural nodules

INVASIVE PROCEDURES

- Endoscopy
- Biopsy
 - Surgical
 - Excisional
 - incisional
 - Needle
 - FNA
 - Core
 - Vacuum

TUMOR NOMENCLATURE

- Tissue of Origin
- Benign vs. malignant
- Solid
 - Epithelial
 - Mesenchymal
 - Neural
 - mixed
- Hematologic

Nomenclature

Some common carcinomas:

Lung

Breast (women)

Colon

Bladder

Prostate (men)

Leukemias:

Bloodstream

Lymphomas:

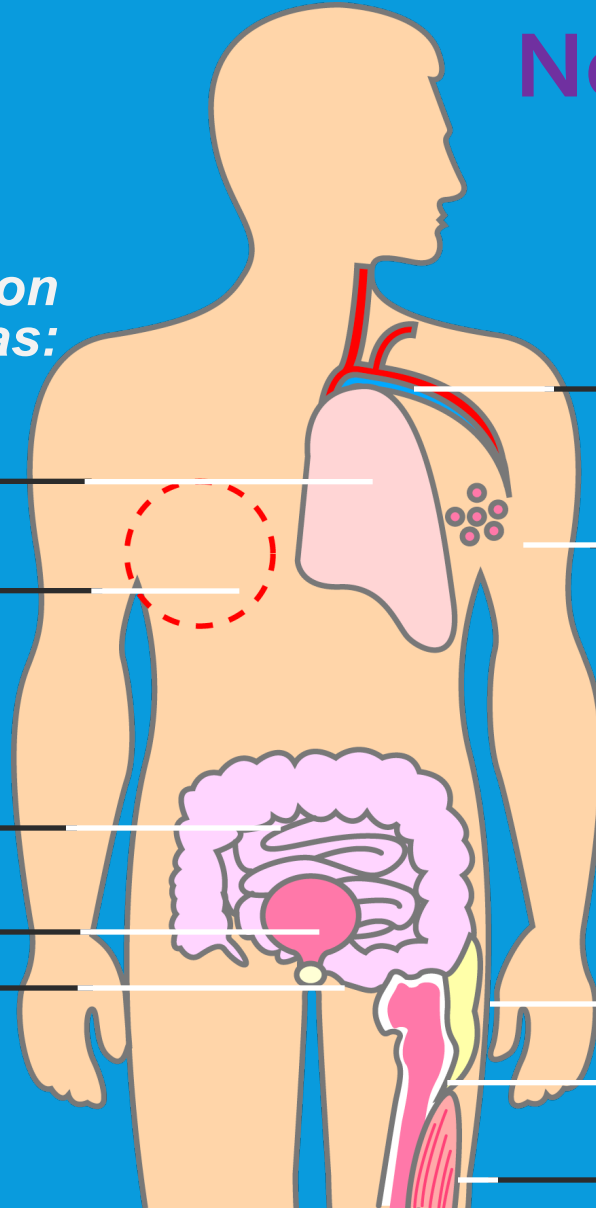
Lymph nodes

Some common sarcomas:

Fat

Bone

Muscle



Nomenclature

Cancer Prefixes Point to Location

<u>Prefix</u>	<u>Meaning</u>
---------------	----------------

adeno-	gland
--------	-------

chondro-	cartilage
----------	-----------

erythro-	red blood cell
----------	----------------

hemangio-	blood vessels
-----------	---------------

hepato-	liver
---------	-------

lipo-	fat
-------	-----

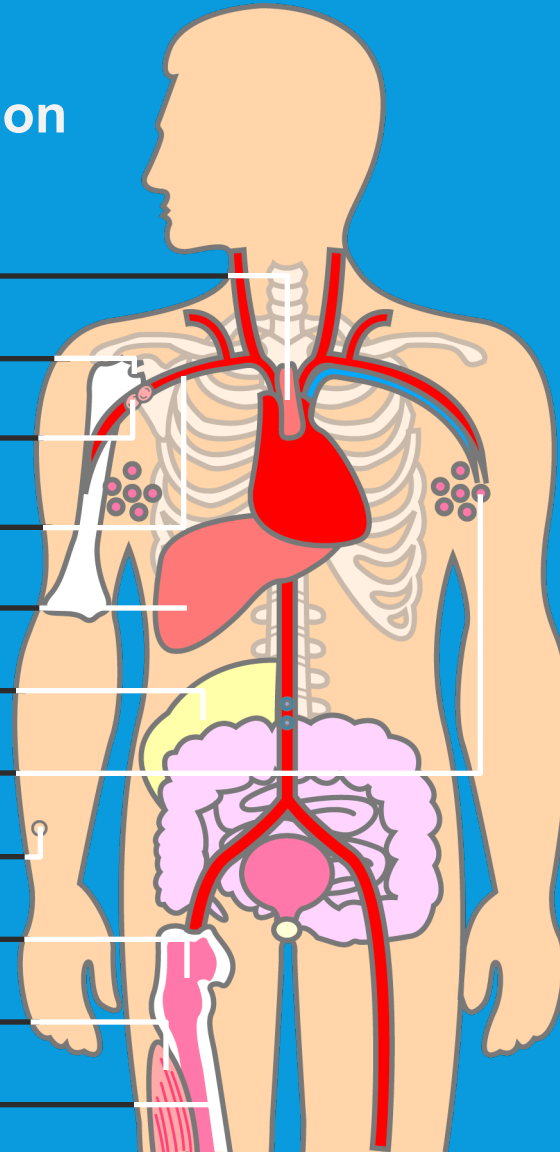
lympho-	lymphocyte
---------	------------

melano-	pigment cell
---------	--------------

myelo-	bone marrow
--------	-------------

myo-	muscle
------	--------

osteo-	bone
--------	------



GRADING AND STAGING – WAYS TO CHARACTERIZE TUMOR GROWTH AND PROGNOSIS

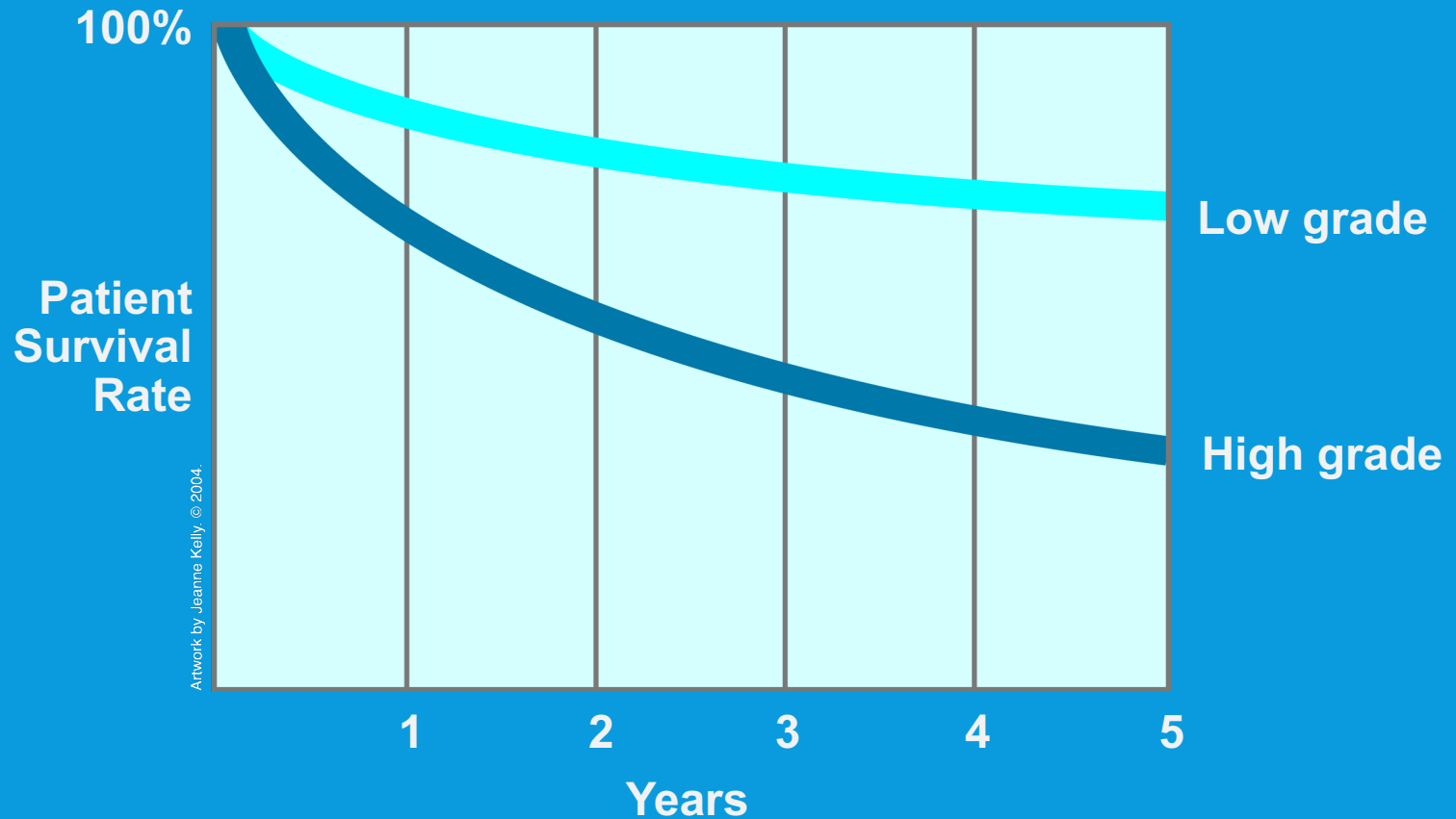
- Grading – Degree of cell dedifferentiation
- Anatomic Staging – Degree of spread
 - ❖ TNM System-The Gold Standard

TUMOR GRADING

- GX - undetermined
- G₁ – well differentiated, low grade
 - strong resemblance to parent cell
- G₂ – moderately differentiated, intermediate grade
- G₃ – poorly differentiated, high grade
- G₄ – undifferentiated, high grade
 - impossible to tell parent cell

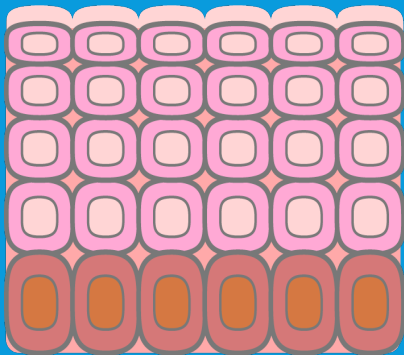
Tumor Grading

General Relationship Between Tumor Grade and Prognosis

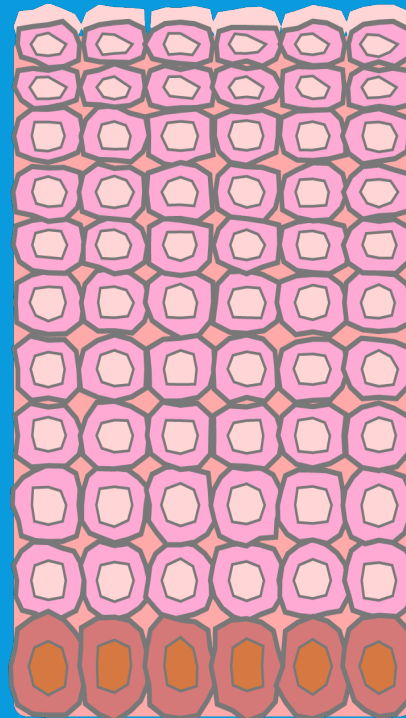


Artwork by Jeanne Kelly, © 2004.

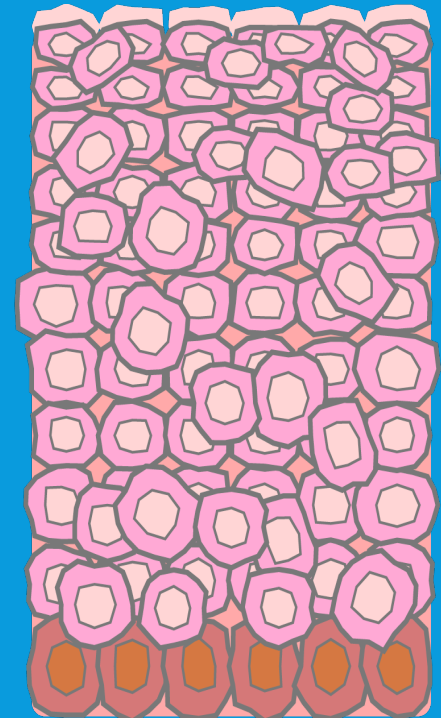
Dysplasia



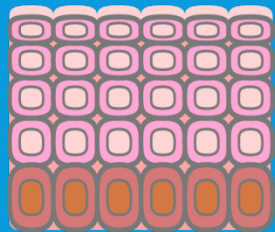
Normal



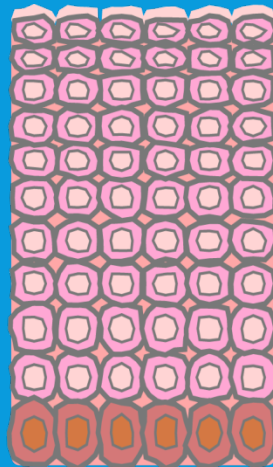
Hyperplasia



Mild dysplasia



Normal



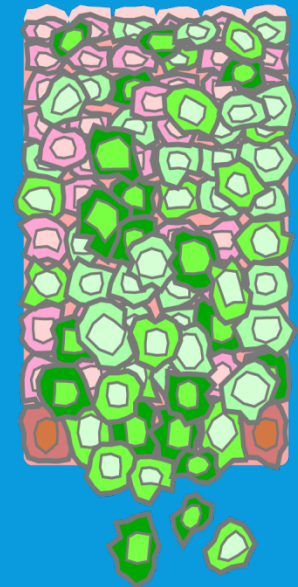
Hyperplasia



**Mild
dysplasia**



**Carcinoma in
situ (severe
dysplasia)**



**Cancer
(invasive)**

POLL QUESTION:

Which of the following represents a high grade, poorly differentiated tumor?

1. Grade I
2. Grade II
3. Grade III
4. Grade IV

STAGING

- Solid Tumors
- Hematologic Malignancies

TNM STAGING SYSTEM

- Determination of how extensive the malignancy is -
 - **T** = tumor size (also depth of invasion)
 - **N** = nodal status (number and location of positive Lymph Node)
 - **M** = metastatic disease

STAGING

- **Solid**
 - 0 – 4
 - Clark/Breslow – Melanoma
 - Dukes - Colon
- **Hematologic**
 - Ann Arbor – NHL
 - TNM doesn't fit

TNM STAGING

Stage 0	Tis	N0	M0
Stage 1A	T1	N0	M0
Stage 1B	T1	N1	M0
	T2	N0	M0
Stage II	T1	N2	M0
	T2	N1	M0
	T3	N0	M0
Stage IIIA	T2	N2	M0
	T3	N1	M0
	T4	N0	M0
Stage IIIB	T3	N2	M0
	T4	N1	M0
Stage IV	T4	N2	M0
	Any T	Any N	M1

STAGING OF HEMATOLOGIC MALIGNANCIES

- Lymphoma
- Leukemia
- Multiple Myeloma

TUMOR PATHOLOGY

- Tissue of origin
- Biological behavior
- Cell differentiation
- Hetero- vs. Homogeneity
- Mitotic count
- Vascularization
- Lymphatic invasion



JOIN THE FIGHT AGAINST CANCER

SHOP

DONATE



How can we help you?

search cancer.org

SEARCH

800-227-2345

- Home
- Learn About Cancer
- Stay Healthy
- Find Support & Treatment
- Explore Research
- Get Involved
- Find Local ACS

Stay Healthy » Information for Health Care Professionals » American Cancer Society Guidelines » Nutrition and Physical Activity Guidelines for Cancer Prevention

PRINT SHARE

Nutrition and Physical Activity Guidelines for Cancer Prevention

Stay Healthy Topics

For the great majority of Americans who do not use tobacco, weight control, dietary choices, and levels of physical activity are the most important modifiable determinants of cancer risk. The American Cancer Society guidelines reflect the most current scientific evidence related to dietary and activity patterns and cancer risk. They focus on recommendations for individual choices but also present recommendations for community action to create a supportive social and physical environment in which individuals have genuine opportunities to choose healthy behaviors.

- Stay Away from Tobacco
- Eat Healthy and Get Active
- Be Safe in the Sun
- Other Ways to Protect Yourself
- Find Cancer Early
- ACS Programs to Help You Stay Well
- Tools and Calculators
- Information for Health Care Professionals

American Cancer Society Nutrition and Physical Activity Guidelines for Cancer Prevention (2012)

Full text of current ACS guidelines on nutrition and physical activity for cancer prevention is available here.

Quick Look: Chart of American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention

View a summary chart of current ACS recommendations for individual choices and community action.

For Your Patients: ACS Guidelines on Nutrition and Physical Activity for Cancer Prevention

Review a consumer-friendly version of the American Cancer Society's nutrition and physical activity guidelines for cancer prevention.

SINCE 1913
CAMEL
BLUE



Smoking can damage the sperm and decreases fertility

SINCE 1913
CAMEL
BLUE



Smoking kills

€ 34.50

0

3 CARTRONS

Winston

Smoking kills

Winston

Winston

Winston

3 CARTRONS

€ 73.00

Winston

Sm

Sm

2 CARTON SPECIAL

Winston

Winston

WHY ARE CANCER CLINICAL TRIALS IMPORTANT?

- Clinical trials translate results of basic scientific research into better ways to prevent, diagnose, or treat cancer
- The more people that take part, the faster we can:
 - Answer critical research questions
 - Find better treatments and ways to prevent cancer



WHY ARE CANCER CLINICAL TRIALS IMPORTANT?

- Cancer Site Compare statistics for selected cancer sites.
- Race/Sex Compare cancer statistics by both race and sex.
- Race/Ethnicity Compare cancer statistics by race or by the expanded race/ethnicity groupings.

WHY ARE CANCER CLINICAL TRIALS IMPORTANT?

- Age at Diagnosis/Death Compare statistics by age groups for a selected cancer site, race, and sex.
- Sex Compare the differences between male and female cancer statistics.
- Data Type Compare Incidence, Delay-adjusted Incidence and Mortality cancer statistics.

TYPES OF CANCER CLINICAL TRIALS

- Treatment trials
- Prevention trials
- Early-detection trials/screening trials
- Diagnostic trials
- Quality-of-life studies/supportive care studies

CLINICAL TRIAL "SPONSORS"

- Cooperative Groups
- Pharmaceutical Companies
- Investigator Initiated

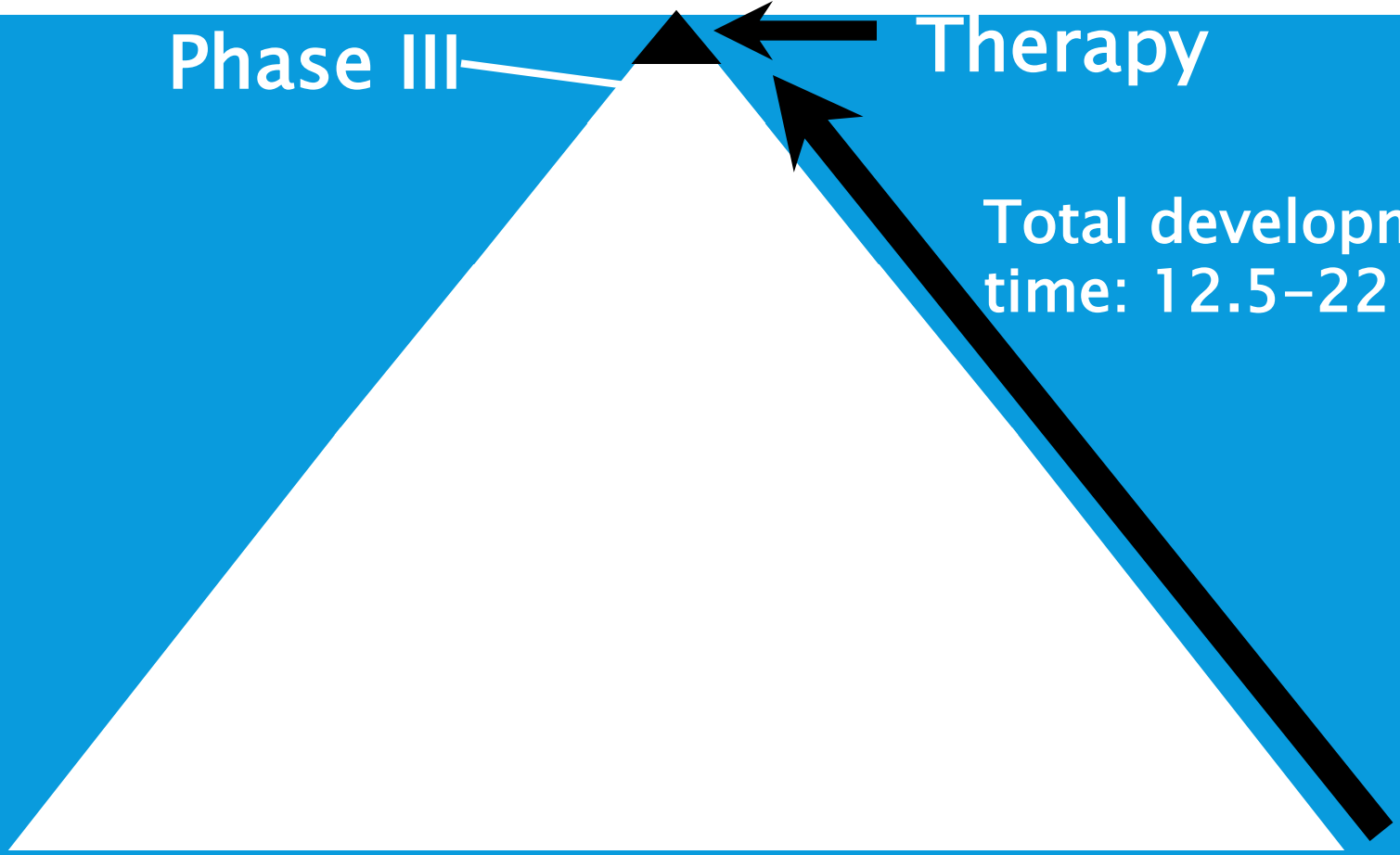


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Phase III

Therapy

Total development
time: 12.5–22 yrs.



CLINICAL TRIAL PHASES

Phase 1 trials (*helpful hint - What Dose?*)

- How does the agent(s) affect the human body?
- What dosage is safe?
- Subjects on these trials are assigned to a designated dose level of the drug(s) at the time of enrollment

Phase 1

Purpose:

To find a safe dose

To decide how the new treatment should be given (by mouth, in a vein, etc.)

To see how the new treatment affects the human body and fights cancer

Number of people taking part: from 20-80 participants

CLINICAL TRIAL PHASES

Phase 2 trials (*helpful hint – What Disease?*)

- Does the agent or intervention have an effect on the cancer?
- Patients enrolled in this phase trial share same tumor type and/or stage of disease

Phase 2

Purpose:

To determine if the new treatment has an effect on a certain cancer

To see how the new treatment affects the body and fights cancer

Number of people taking part: from 100 – 300 participants

CLINICAL TRIAL PHASES

Phase 3 trials (*helpful hint - Is it better?*)

- Is the new agent or intervention (or new use of a treatment) better than the standard?
- Rare to have a placebo alone arm in a cancer treatment trial

Phase 3

Purpose:

To compare the new treatment (or new use of a treatment) with the current standard treatment

Number of people taking part: from 300 to 3000 participants

TREATMENT DEVELOPMENT

- Phase 3 Trials
 - Randomly assigned to one of two (or more) groups



WHY IS RANDOMIZATION IMPORTANT?

So, all groups are as alike as possible

Provides the best way to prove the effectiveness of a new agent or intervention

Phase 1	Phase 2	Phase 3	Phase 4
<p>Number of Participants 20-80</p>	<p>Number of Participants 100-300</p>	<p>Number of Participants 300 - 3000* <small>* Variable based on statistical power</small></p>	<p>Number of Participants Thousands</p>
<p>Time Required Up to several months</p>	<p>Time Required Up to (2) years</p>	<p>Time Required One (1) - Four (4) years</p>	<p>Time Required One (1) year +</p>
<p>Purpose Studies the safety of medication/treatment</p>	<p>Purpose Studies the efficacy</p>	<p>Purpose Studies the safety, efficacy and dosing</p>	<p>Purpose Studies the long-term effectiveness; cost effectiveness;</p>

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ROLES OF THE CLINICAL RESEARCH NURSE

- Advocate - human subject protection
- Support the informed consent process
- Regulatory specialist, collect data
- Care coordination and continuity with the research team
- Clinician – direct care provider, study coordinator, advanced clinician

JASON CARTER
CLINICAL TRIALS PROGRAM

BE  **THE MATCH[®]**



Search...

CLINICAL TRIALS

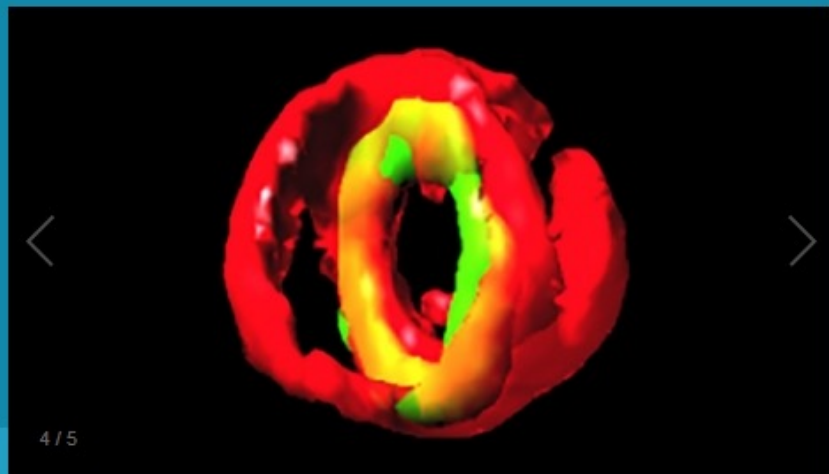
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Study reveals function of protein crucial to survival of Staph infections

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#WhyIFightFlu "It's pretty amazing how 5 seconds of my time can protect so many folks for months to come!"... <https://t.co/vGADak0YrJ>



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RT @NCICancerTrials: In this clip, Jennie Lucca of @TheChildrensInn describes the services The Inn

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For CCR Staff

EVIDENCE BASED RESOURCES

- American Cancer Society: www.cancer.org
- American Society of Clinical Oncology (ASCO):
<http://www.asco.org/portal/site/ASCO>
- International Association of Clinical Research Nurses (IACRN):
www.iacrn.org
- National Cancer Institute: www.cancer.gov
- National Comprehensive Cancer Network (NCCN):
www.nccn.org
- Oncology Nursing Society: www.ons.org
- Seer's Training: www.training.seer.cancer.gov

POLL QUESTION:

Phase 1 clinical trials primary objective is curative.

1. True
2. False

POLL QUESTION:

Phase 2 clinical trials primary objective is efficacy of the medication or treatment.

1. True
2. False

POLL QUESTION:

Phase 3 clinical trials randomize patient to test the new medication or treatment compared to the standard of treatment.

1. True
2. False

