Cancer Control in the 21st Century Observations on Disparities in Health

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Disclosure Information

Otis W. Brawley

I have the following financial relationships to disclose:

Membership on Advisory Committees or Review Panels, Board Membership, etc. -

Genentech/Roche, Grail, PDS Biotech, Lyell Immunopharma, Incyte Corp., and Agilent Technologies

Stocks in publicly traded companies, excluding diversified mutual funds -

Lyell Immunopharma, PDS Biotech, Agilent Technologies, Incyte Corp.

Research Support

NCI and Bloomberg Philanthropies

– and –

I will not discuss off label use and/or investigational use in my presentation.



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- Bloomberg Philanthropies
- Maryland Cigarette Restitution Fund
- National Cancer Institute
- American Cancer Society



OBJECTIVES

- Discuss trends in cancer mortality over the past 30 years
- Define disparities in health and identify how it relates to cancer prevention, screening, diagnosis and treatment
- Define health equity and describe some possible solutions







"THOSE WHO DO NOT APPRECIATE HISTORY ARE DESTINED TO REPEAT IT."

PARAPHRASING

GEORG SANTAYANA



Respect the scientific process and scientific findings.

- I was thought from an early age that one should label things:
 - What you know
 - What you do not know
 - What you believe
- Question all things, but question what you know more so than anything else.
- These are good rules in the assessment of healthcare.



Key Point!!!

The Most Important Question in Cancer Control

How can we provide adequate high-quality care (to include preventive services) to populations that so often do not receive it?

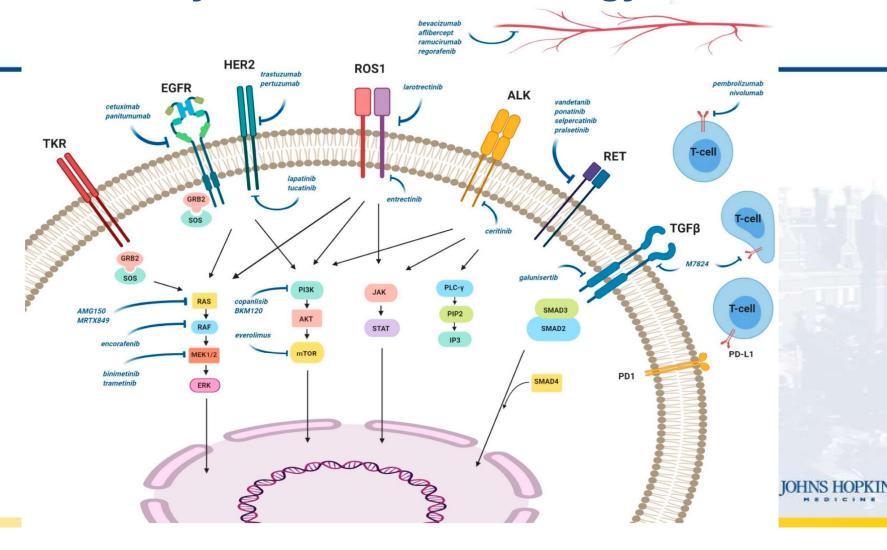
- Unnecessary care consumes limited resources and interferes with abilities to provide necessary care.
- The provision of unnecessary care is a cause of health disparities.



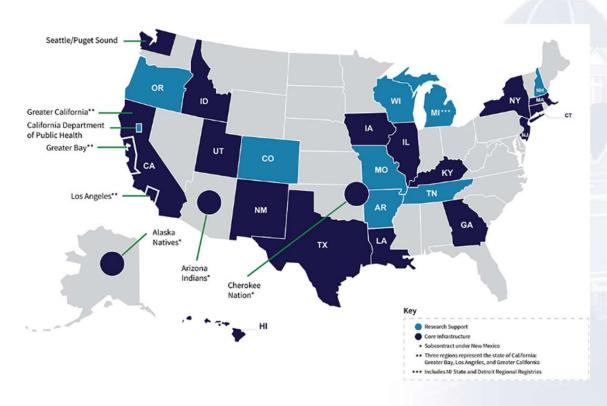
The National Cancer Act, December 23, 1971



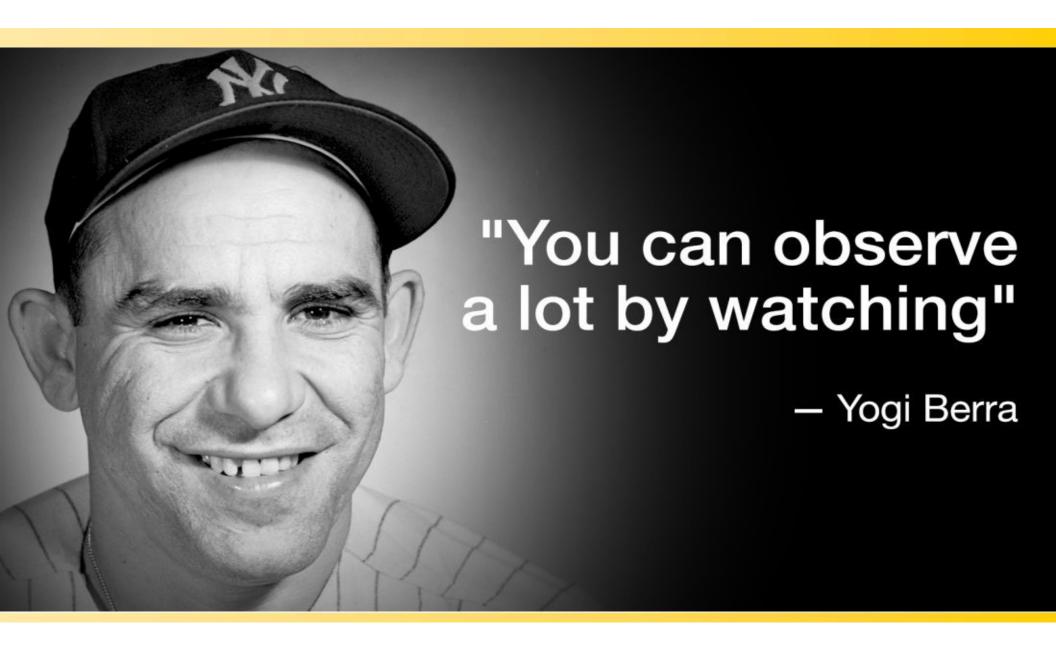
50 years of Cancer Biology



NCI Surveillance Epidemiology and End Results (SEER) Program

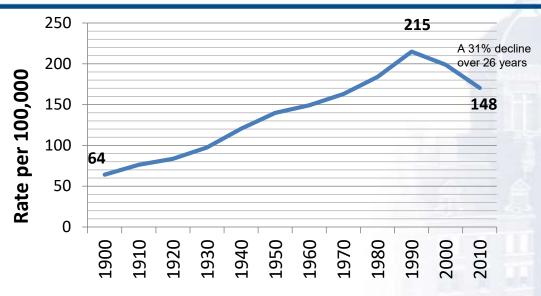






US Cancer Death Rate

1900 to 2018



Age Adjusted to 2000 Standard 1900-1970, US Public Health Service, Vital Statistics of the US, Vol. 1 and Vol 2; 1971-2020, US National Center for Health Statistics, Vital Statistics of the U.S



Cancer Mortality Reduction 1991 to 2020

	1991 Rate per 100,000	2020 Rate per 100,000	Percent Decrease
Lung	58.9	31.8	46%
Prostate	39.2	18.6	53%*
Breast	31.6	19.1	40%
Colorectal	23.3	12.6	46%**

Source: NCI SEER 2023

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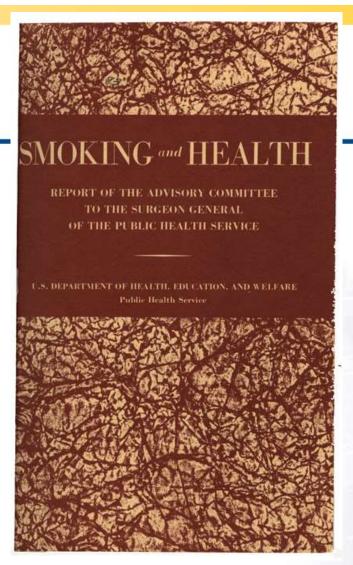
^{*}Prostate cancer rates may be affected by attribution biases associated with aging

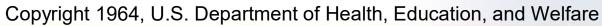
^{**}The colorectal mortality decline is 55% since 1980 Rates are age-adjusted to the 2000 standard

Causes of the Decline in Cancer Death Rates

- Prevention
- Treatment
- Screening







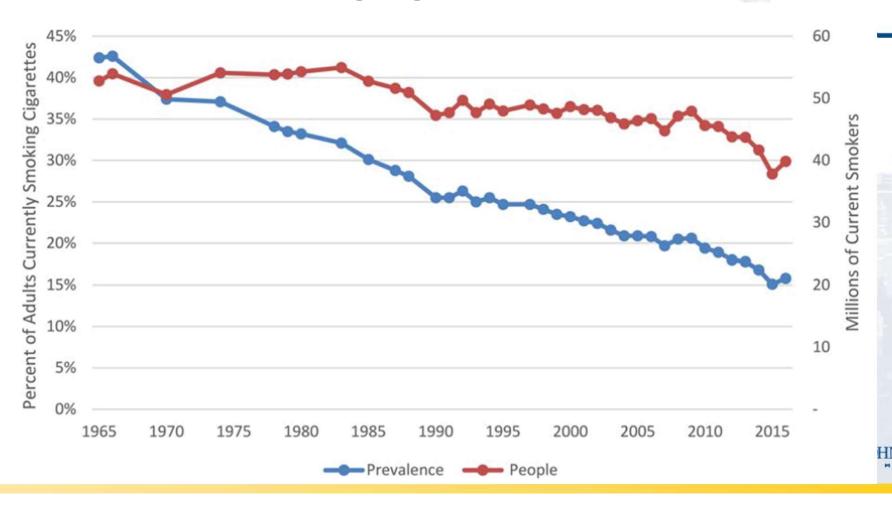
Cancers Associated with Tobacco Use

- lung,
- larynx,
- mouth,
- esophagus,
- throat,
- bladder,
- kidney,

- liver,
- stomach,
- · pancreas,
- colon and rectum,
- cervix,
- acute myeloid leukemia.

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Proportion and Absolute Number of Americans Smoking Cigarettes 1965-2018



Volume IV: Cardiovascular and Cerebrovascular Disease Part 1 Report of the Secretary's Task Force on

Black & Minority Health

U.S. Department of Health and Human Services

January 1986



THE EMPHASIS WAS ON RACE

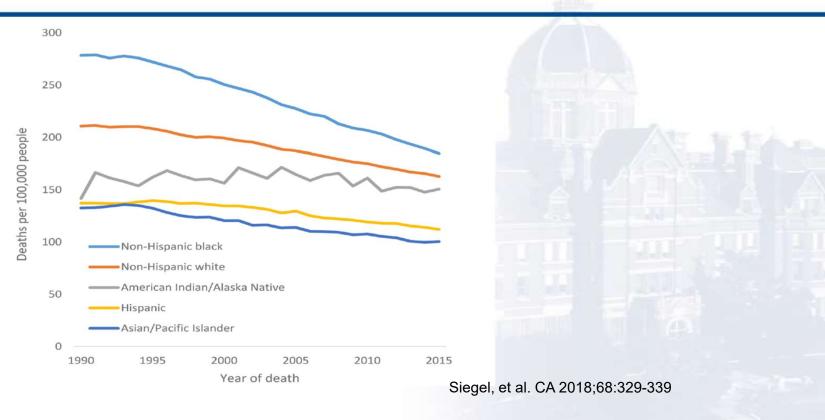
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Population Categorization

- Race is a broad sociopolitical construct.
- Race is not a biologic categorization.
- In some cases, race is often used as a biological categorization and that is racism.



Cancer Mortality by Race/Ethnicity from 1990 to 2017





"Poverty is a Carcinogen!"



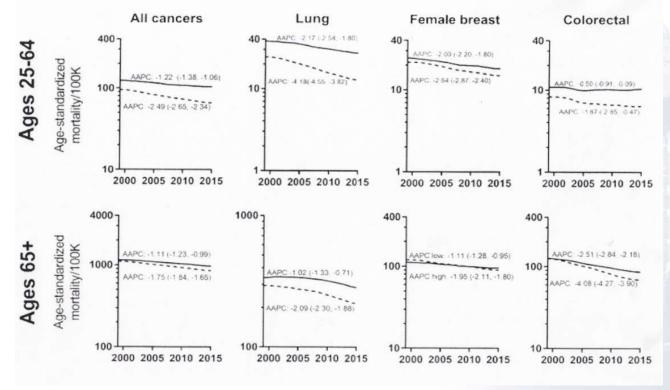
Samuel Broder

American Oncologist, AIDS Researcher and Philosopher Director of NCI, 1989-1995

November 8, 202



Trends in Cancer Mortality by Age, Group, and County-Level Income Quintile.

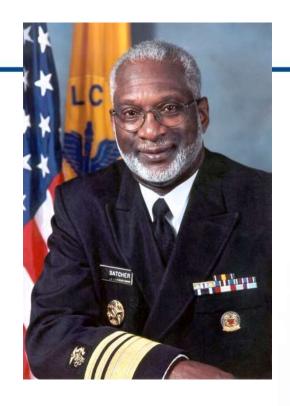




Poverty Rate by Race/Ethnicity US 2019

Race/Ethnicity	Proportion of US Population	Proportion of Racial/Ethnic Group in Poverty
White NH	60.1%	9.0%
Black NH	12.2%	21.2%
Hispanic	18.5%	17.2%
Asian/Pacific Islander NH	5.9%	9.7%
American Indian/Alaska Native NH	1.3%	24.2%

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David Satcher, MD, PhD 16th Surgeon General of the United States (1998-2002) 11th Assistant Secretary for Health (1998-2001)

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Disparities in Health

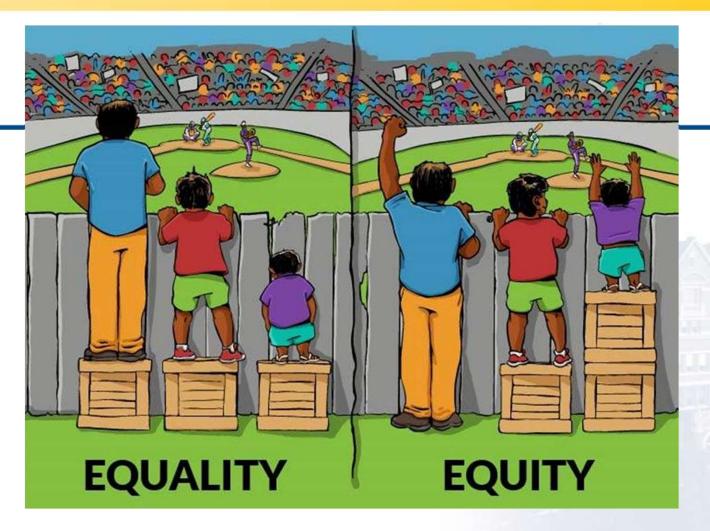
- The concept that some populations (however defined) do worse than others.
- Populations can be defined or categorized by:
 - Race
 - Ethnicity and Culture
 - Area of geographic origin
 - Socioeconomic Status



The Evolution of a Discipline

- Minority Health
- Special Populations Health
- Disparities in Health
- Health Equity
- Health Justice







Causes of the Decline in Cancer Death Rates

- Prevention
- Treatment
- Screening



CANCER SCREENING BE CAUTIOUS!!!!



Cancer Screening

- Screening is doing a test to determine if cancer might be present in an asymptomatic individual.
- Most distinguish mass screening versus screening within physician-patient relationship.
- Diagnostic tests are used when there are symptoms to cause a clinical suspicion of disease.



Principles of Screening

Finding disease is not a measure of success in cancer screening.

Increased survival is not a legitimate measure of success outside of a randomized clinical trial.

Reduction in mortality is the only true proof of effective screening. (Requires a randomized trial)



Principles of Screening

- There are several examples of cancer screening tests that have:
 - found localized disease,
 - increased the amount of disease found,
 - increased the proportion surviving five years and
 - Possibly increased risk of death.
- Some without changing the risk of death:
 - urine vanillylmandelic acid (VMA) screening for neuroblastoma.
 -Wood et al, NEJM, 2002
 - chest x-ray screening for lung cancer.
 - -Marcus et al, JNCI, 2006



Cancer Screening

- A series of tests with some uncertainties and some risk.
- Many do not appreciate the harms of screening.
- Often the harms are better proven than the benefits.



Harm?

- False Positive Findings
 - Anxiety
 - Negative diagnostic workup
- Morbidity
 - Pain
 - Hospitalizations
 - Death!!!!



To the Screening Epidemiologist

The worth of screening is really measured in a Benefit / Harm Ratio

A look at the forest and not just one tree!



Cancer Screening

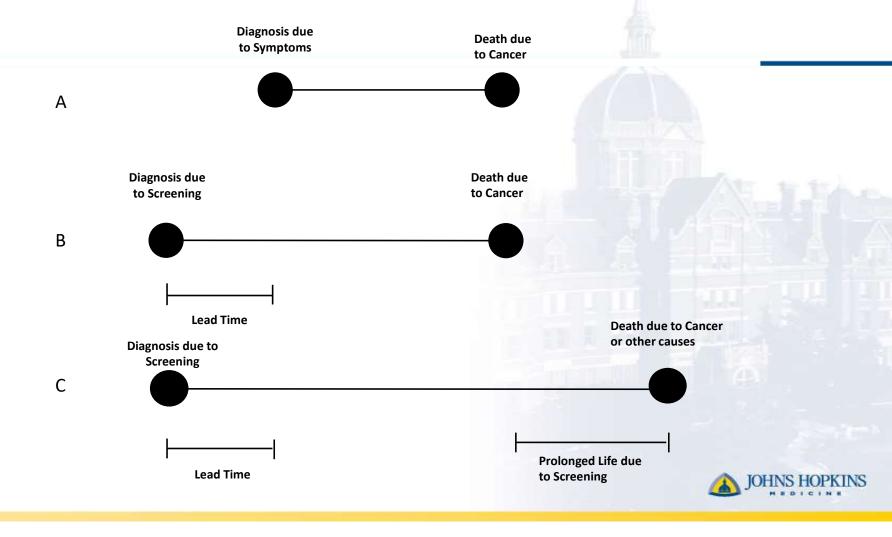
Lead time bias

Length bias

Overdiagnosis



LEAD TIME BIAS



Lead Time Bias

- Because of lead time bias, survival can increase without a decrease in mortality rate.
- Indeed, both survival and mortality increased in randomized trials of CXR and sputum cytology screening in the 1970's.

Marcus et al., JNCI, 2006



Length Bias

Biologic behavior of a cancer is key to its "screenability."

Slower growing, less deadly tumors are actually easier to find, treat, and cure.

Fast growing cancers are less likely to benefit from screening.



Overdiagnosis of Cancer a form of length bias

There are some small screen detected cancers that are not a clinical threat to the patient.

- We cure some cancers that do not need to be cured!!!!
- How to determine that these tissues are non-threatening is a major area of research.
 - Tumor profiling through genomics: Oncotype Dx, etc.
 - Using artificial intelligence to read the digital imaging of the biopsy



Overdiagnosis of Cancer

Thyroid Cancer in South Korea

	1993	2011
Incidence per 100,000	5	75
Mortality per 100,000	4	4

Ahn, Kim, and Welch NEJM 2014

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Overdiagnosis of Cancer (A Difficult Concept to Comprehend)

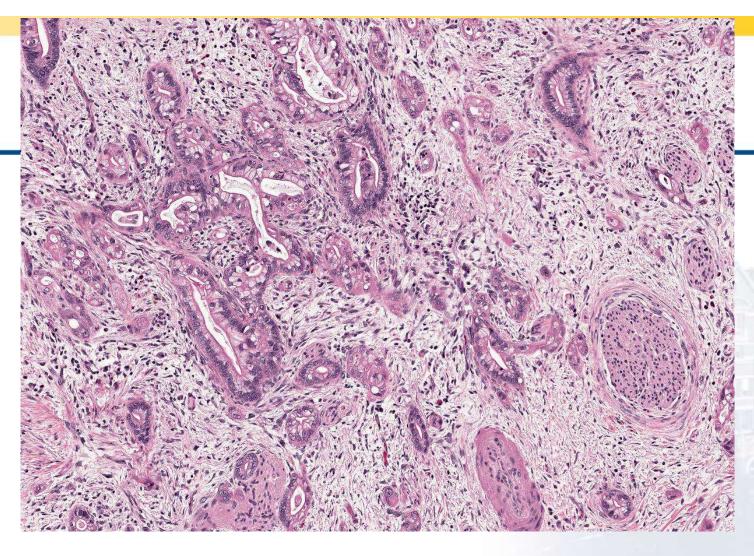
Estimates:

- 10 to 20% of radiologically detected lung cancers
- 10 to 50% of mammographically detected invasive breast cancers
- Up to 80% of Ductal Carcinoma In Situ of the breast
- 60 to 90%% of ultrasound detected thyroid cancers
- 60 to 80% of PSA detected prostate cancers

Thomas, Richards, Plescia, et al. MMWR 2015 3;64(12):324-7.







Adenocarcinoma

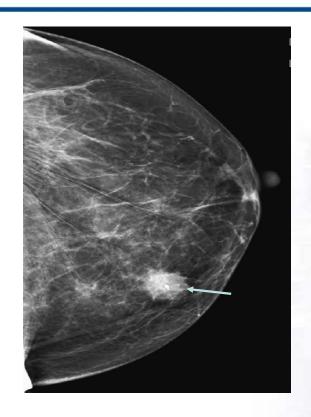


Advances in cancer diagnosis:

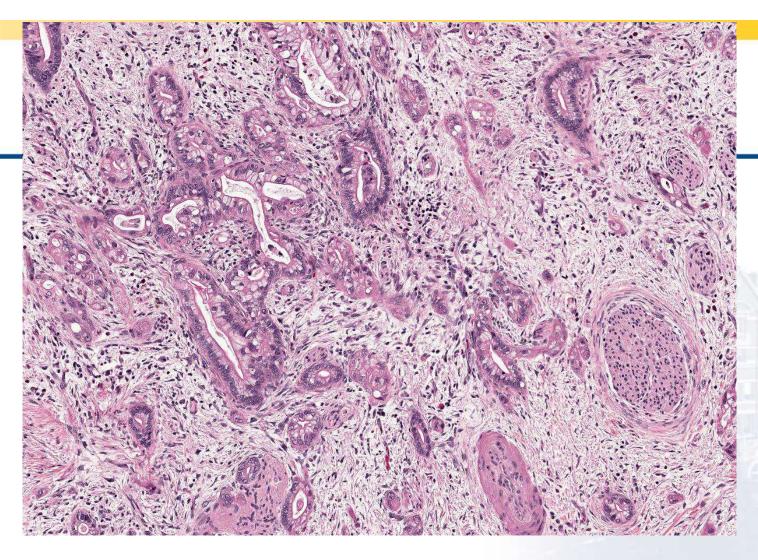
- X-ray 1890's
- Mammogram 1950's
- Ultrasound 1960's
- Computerized Tomography (CT) 1970's
- Magnetic Resonance Imaging (MRI) 1980's
- Stereotactic biopsy 2000's to present



Mammogram with a Ductal Carcinoma



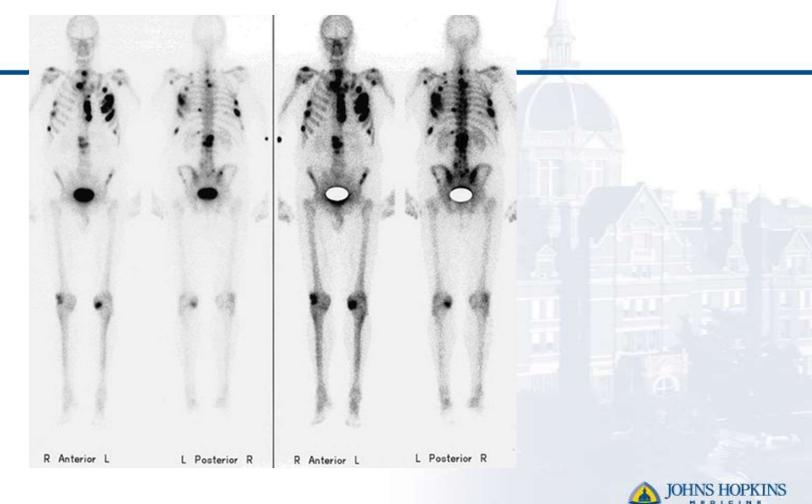








Bone Scan of Metastatic Adenocarcinoma



Overdiangosis

Overdiagnosis is the pathologic equivalent of "racial profiling."

It looks like something that has killed in the past; The assumption is if left alone it too will kill.



What is the Real Diagnosis?

Cancer is a subjective diagnosis!

When 49 pathologists look at 2940 biopsies, Inter-observer agreement rates were:

- 89% (95% CI 84-92) for invasive cancer,
- 79% (95% CI 76-81) for ductal carcinoma-in-situ,
- 43% (95% CI 41-45) for atypia, and
- 77% (95% CI 74-79) for benign without atypia.

Jackson et al. Ann Surg Oncology, 2016

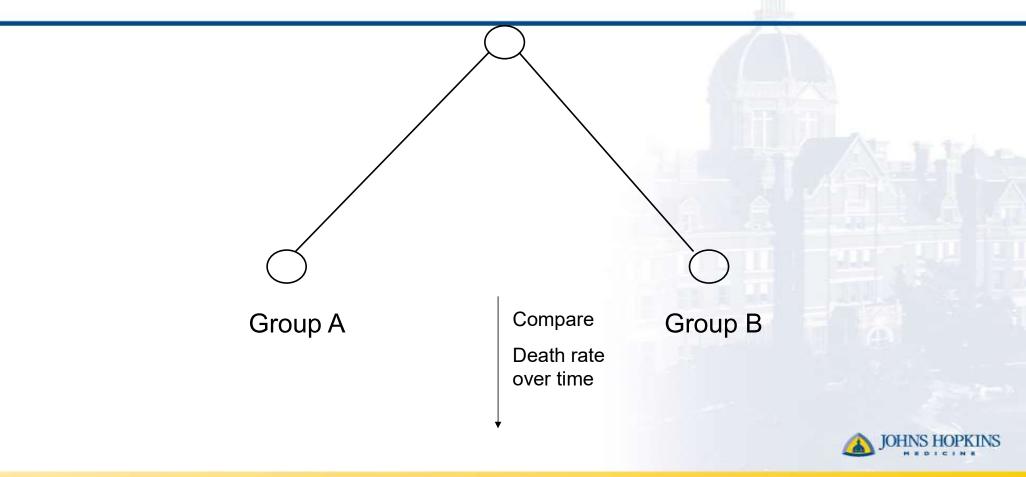


What is Cancer? The Evolution of Our Concept of the Disease

- Moving from a 19th Century definition to a 21st
 Century definition
- Moving from the biopsy to the biopsy and genomics



The Gold Standard in Clinical Science is a "Prospective Randomized Trial" Enrollee Randomization



Cancer Screening

Well designed clinical studies have demonstrated a mortality reduction through:

- Mammography for Breast Cancer
- Stool Blood Testing and Sigmoidoscopy for Colorectal Cancer
- Pap and Visual Screening for Cervical Cancer
- Low Dose Spiral CT screening in those at high risk for lung cancer





IMPORTANCE. Realizing the benefits of cancer screening requires testing of eligible individuals

In a survey of patients getting usual care, less than 23% of patients with an abnormal cancer screen completed diagnostic workup within 120 days.

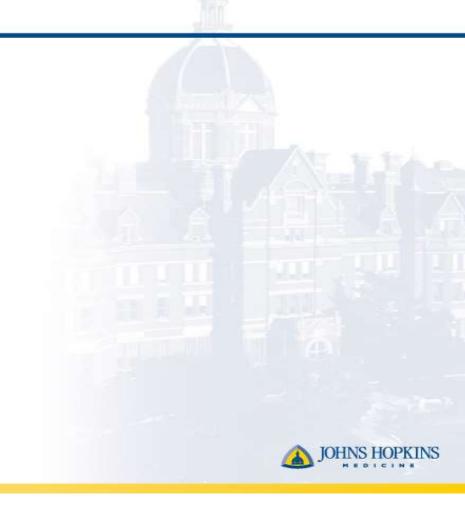
A navigation intervention moved that figure to 31%.

and processes to ensure follow-up of abnormal results.

Atlas et al JAMA 2023; 330(14):1348-1358

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BREAST CANCER



Breast Cancer

In 2019,

269,000 Diagnosed and 42,300 Deaths

There has been a 40% decline in age-adjusted female mortality from 1990 to 2016

Screening is attributed with 40% to 50% of the decline.

American Cancer Society Estimates 2019



Breast Cancer Screening

- Routine Mammography is recommended for normal risk women
- Controversies
 - Starting at age 40, 45, or 50 and over
 - Every year vs every two years
 - Quality of image and quality of radiologist
 - Importance of a program of routine screening and image comparison
- Clinical Breast Examination when mammography is not available.



Breast Cancer Screening

- Screening will miss some disease that we wish we could find especially among younger women with dense breasts.
- Screening will find some disease that does not need treatment (overdiagnosis).
- Overdiagnosis is a special question for 3D Mammography (The TMIST Trial)

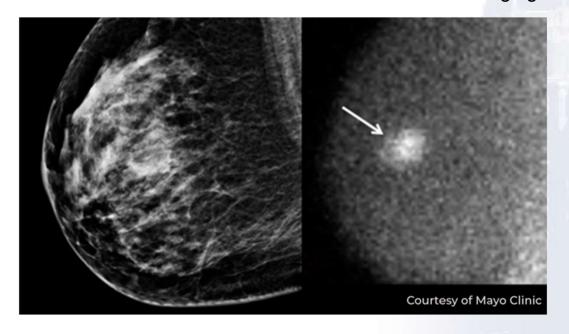
Smith RA et al, CA Cancer J Clin 2015



Molecular Breast Imaging



Molecular Breast Imaging



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Overemphasis on Screening

(and not enough emphasis on provision of adequate care)

CISNET Breast Cancer Modeling Estimates assessing annual and biannual screening.

- Failure to follow accepted screening guidelines accounts for 9.5 to 11.3% of all breast cancer deaths.
- Failure of the diagnosed to receive appropriate treatment accounts for 21.2 to 27.0% all of breast cancer deaths.
 - » Mandelblatt Stout, Schechter, et al, Cancer 2016
 - » Mandelblatt van Ravesteyn, Schechter, et al, Cancer 2011



Breast Cancer

In 2019,

269,000 Diagnosed and 42,300 Deaths

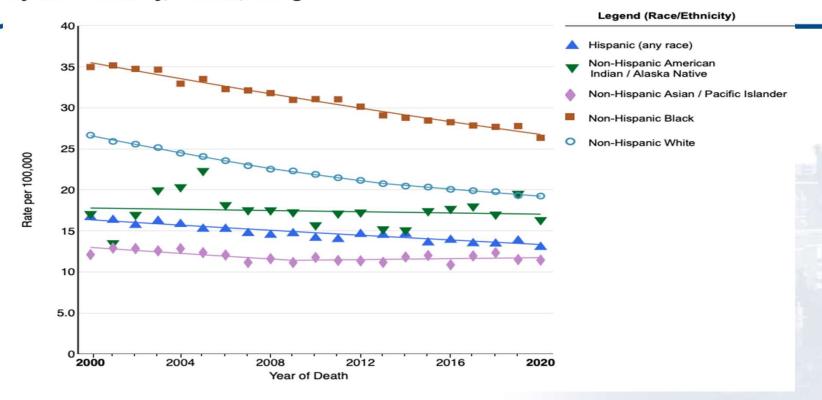
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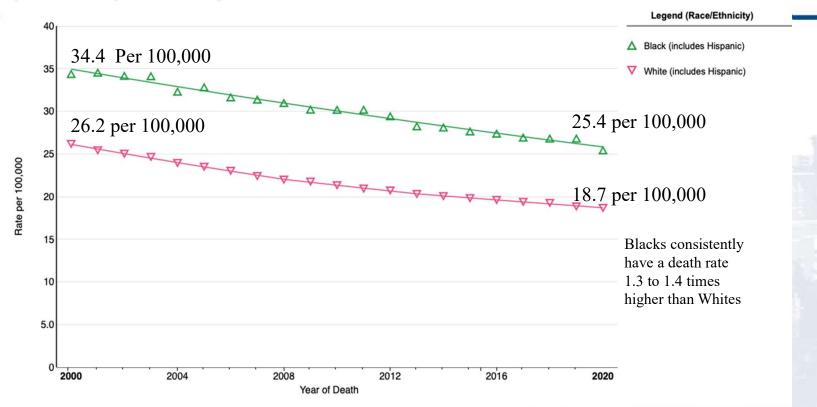


Breast Recent Trends in U.S. Age-Adjusted Mortality Rates, 2000-2020 By Race/Ethnicity, Female, All Ages





Breast Recent Trends in U.S. Age-Adjusted Mortality Rates, 2000-2020 By Race/Ethnicity, Female, All Ages





Varying Breast Cancer Mortality White Women by registry (2013-2017)

17.8 in Connecticut

Avg White Female 20.3 Range:

to

22.0 in Idaho

Rates are per 100,000 population age-adjusted to 2000 standard



Varying Breast Cancer Mortality Black/AA Women by registry (2014-2018)

Average Black Female 28.4 White Female 20.3

Black Female		
17.5	New Mexico	
18.3	Massachusetts	
19.8	Iowa	
20.3	Connecticut	
20.3	Minnesota	
21.7	Seattle-Puget Sound	
23.0	New York City	
25.1	Kentucky	
25.7	San Francisco Bay Ar	rea
28.3	Georgia	
28.8	Detroit	
29.8	Atlanta	Rates are per 100,000 population age-adjusted to 2000 standard
30.2	Los Angeles	
32.1	Louisiana	67

November 8, 2023

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Breast Cancer Mortality

- The B-W death rate is essentially equal in five states. They are among the lowest in the US.
- The White mortality rate in 11 states is higher than the rate for Black women in Massachusetts.

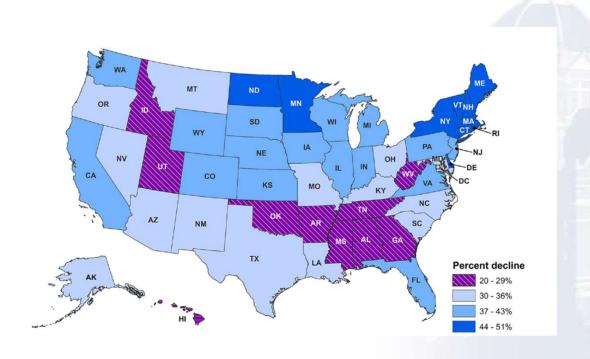
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US Breast Cancer Mortality

- There has been a 40% decline in US age-adjusted mortality from 1991 to 2020.
- The decline has varied by state.



Breast Cancer Mortality Decline from 1988-90 to 2013-2015 by State





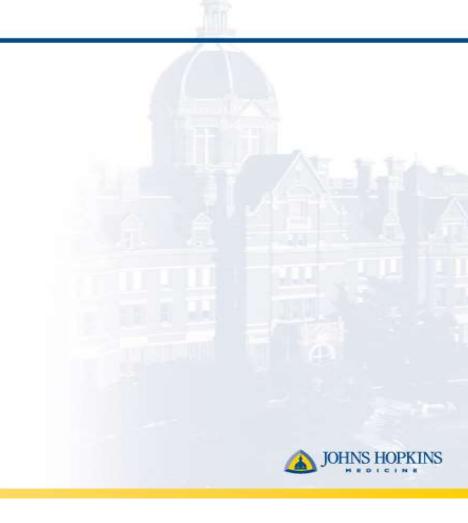
Overemphasis on Screening

(and not enough emphasis on provision of adequate care)

- A substantial proportion of women with breast cancer do not get adequate:
 - surgery,
 - chemotherapy,
 - hormonal therapy,
 - radiation therapy.



COLON CANCER



Colon Cancer Screening Clearly Reduces Mortality!!!

- Stool blood (human hemoglobin) testing, done annually with samples analyzed in a lab
 - Effective in several randomized trials and is really underappreciated
- Sigmoidoscopy (every three to five years)
 - Effective in several randomized trials



Colon Cancer Screening

- Stool DNA testing has become widely available in the past five years.
- The currently available test has some specificity issues and results in a high number of colonoscopies.



Colon cancer Screening

- Screening Colonoscopy (every ten years)
 - Widely accepted, indeed widely preferred, but to date no randomized trials,
 - Adopted because positive stool testing trials required a diagnostic colonoscopy.

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Colon Cancer Screening

- Colonoscopy has not been proven more effective than stool blood testing!
- · High tech (fiberoptic) is not necessarily better.



Colon Cancer Screening

- A positive stool test or polyps on sigmoidoscopy requires a diagnostic colonoscopy
- Colon screening with stool hemoglobin testing reduces risk of death by at least 35% and risk of cancer (through polypectomy) by 20%
- Colon screening is the least controversial of all screening tests.

Smith RA et al, CA Cancer J Clin 2019



Colon Cancer Quality of Surgery/Pathologic Assessment

A minimum of 12 lymph node should be examined in an adequate colorectal cancer pathology specimen

-About half of all colorectal cancer patients have 12 or more LN examined.

-Hispanics, Blacks and the poor have higher odds of receiving an inadequate dissection.

- Rhoads et al, Cancer 2012 Jan 15;118(2):469-77



Colon Cancer Quality of Surgery/Pathologic Assessment

-Inadequate examination is associated with the hospital where care was received.

-Inadequate staging leads to some Blacks with true stage 3 disease being labeled stage 2 and some of the talk that colorectal cancer is more aggressive among Blacks!!!

Rhoads et al, Cancer 2012 Jan 15;118(2):469-77



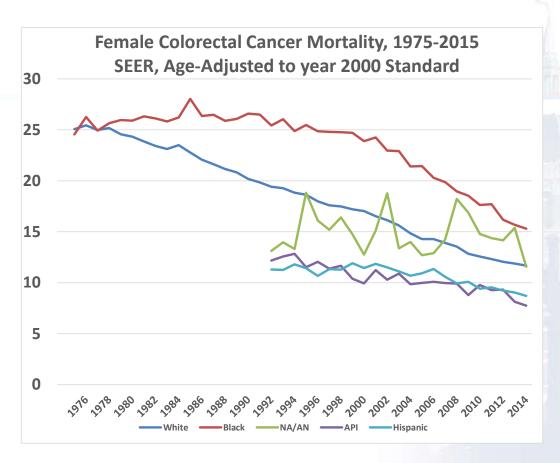
Colon and Rectal Cancer

In 2019,

- Diagnosed: 101,400 colonic and 44,200 rectal
- 51,000 Americans will die of colon and rectal cancer.
- Among the US Population as a whole, there has been a 50% decline in age-adjusted death rate since 1980.
- Screening is attributed with about 2/3 of the decline.

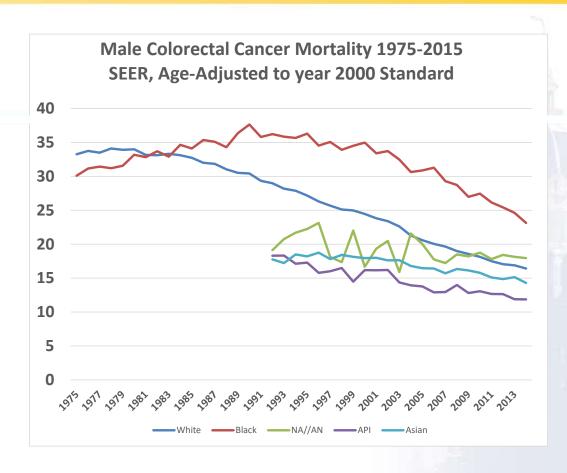
American Cancer Society Estimates 2019





Siegel, et al. CA 2018;68:329-339

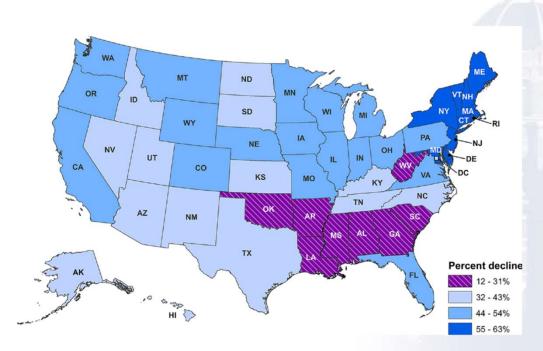




Siegel, et al. CA 2018;68:329-339



Colorectal Cancer Mortality Decline from 1980-82 to 2013-2015 by State



Siegel, et al. CA 2018;68:329-339

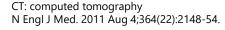


LUNG CANCER



The National Lung Screening Trial

- Nearly 54,000 at high risk enrolled in the trial
 - age 55 and above
 - 30 pack year or greater history of smoking; if quit, did so less than 15 years prior to trial entry
 - Reasonable health
- Subjects prospectively randomized to chest X-ray (sham) or low dose spiral CT (LDCT) yearly for three years
 - Done at 30 sites with lung cancer expertise
 - Analysis 10 years from start of screening showed LDCT associated with a 20% reduction in relative risk of death





The National Lung Screening Trial: A Closer Look

- In this high risk group, the benefit/risk ratio of 5.4 lives saved for:
 - Every 2 people with a complication due to an invasive procedure
 - Every 1 life lost prematurely due to diagnostic procedures
- This study was done in 30 of the best hospitals in the country
 - Results may differ as LDCT screening is adopted at other facilities.
 - The benefit-risk ratio may decrease



Lung Cancer Screening Recommendations

Six Respected Groups Recommend the Doctor "Consider" spiral CT for those:

- -Healthy aged 50 years and above,
- -H/0 20 pack years of smoking or more,
- -If quit smoking did so less than 15 years ago,
- –Who understand that there are risks of unnecessary diagnostic procedures and even death associated with screening.

Wender et al, CA Cancer J Clin 2013 ACS 2023 Guideline



An Efficient National Screening Program Applying Results of the NLST

- Approximately 160,000 Americans currently die of lung cancer every year.
- A screening program has potential of preventing 8,000 to 10,000 deaths per year!!!
- If done well screening would lead to 1,500 to 1,850 deaths secondary to diagnostic interventions (bronchoscopy, biopsy, etc.).



Lung Cancer Screening in the Real World

- Increasing volumes due to screening can tax and diminish the quality of care in other diseases.
- Lung screening consumes resources, especially in radiology and pathology.
- A lung cancer screening program can worsen or cause disparities in some hospital systems.

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PROSTATE CANCER



Prostate Cancer Screening

- There are positive and negative trials, all with significant biases tainting their results.
- It is likely that screening saves some lives but causes significant harm.
- The harms are better proven than the benefits.

Brawley OW, Annals of Internal Medicine, 2012



Prostate Cancer Screening A Complex Message

This is ripe for confusion and distrust

- Many (who mean well) promote screening and do not understand the nuances.
- Many promote screening because it is money making.

Confusion and distrust can cause disparities in receipt of care



The European Randomized Study of Screening for Prostate Cancer

- 162,389 men aged 55 to 69 in seven European countries,
- Randomized:
 - 72,890 to routine screening vs
 - 89,351 to the control group
- Results:
 - 520 prostate cancer deaths in the screened group
 - 793 prostate cancer deaths in the control group

Hugosson et al., Eur Urol. 2019 76(1): 43-51.



The European Randomized Study of Screening for Prostate Cancer

- PCa mortality reduction of 20% at 16 years
 RR =0.80 95% CI 0.72-0.89, p<0.001)
- Screening invitations to prevent one PCa death was 570
- Number Diagnosed to prevent one PCa death was 18

Hugosson et al., Eur Urol. 2019 76(1): 43-51.

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Applying ERSPC to the Population fourteen years of follow-up

Of 1000 men aged 55 to 69 screened regularly over a 16 year period

- 100 will be diagnosed with prostate cancer
- The number aggressively treated is declining in recent years
- 4 will die of the disease

ASCO Patient Consent, 2019



Applying ERSPC to the Population sixteen years of follow-up

Of 1000 men aged 55 to 69 who choose not to be screened over a 16 year period:

- 60 will be diagnosed with prostate cancer
- 5 will die of the disease



Applying ERSPC to the Population sixteen years of follow-up

A look at the absolute numbers

- 5 per 1000 dying going to 4 per 1000 is the 20% reduction in relative risk of death
- Screening saves 1 life in 1000 men screened regularly for 16 years, but at what cost?
- Of the 100 diagnosed through screening 96 think they are the 1 in 1000 whose life was saved.



Organizations Assessing Prostate Cancer Screening

- U.S. Preventive Services Taskforce
- American Cancer Society
- American Urology Association
- National Comprehensive Cancer Network
- American Society for Clinical Oncology
- European Urology Association
- Canadian Taskforce on the Periodic Health Examination
- American College of Preventive Medicine
- American College of Physicians
- American Academy of Family Physicians



American Urological Association*

Given the uncertainty that PSA testing results in more benefit than harm, a thoughtful and broad approach to PSA is critical.

Patients need to be informed of the risks and benefits of testing before it is undertaken. The risks of over detection and overtreatment should be included in this discussion.

AUA PSA Best Practice Statement 2009 and 2013



Prostate Cancer Treatment

Quality of Treatment is very important in outcome.

- Surgery
- Radiation therapy
- Observation for low grade lesions

Increasing volumes due to screening can tax and diminish the quality of a treatment program.



Fifteen-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer

Freddie C. Hamdy, F.R.C.S. (Urol.), F.Med.Sci., Jenny L. Donovan, Ph.D., F.Med.Sci., J. Athene Lane, Ph.D., Chris Metcalfe, Ph.D., Michael Davis, M.Sc., Emma L. Turner, Ph.D., Richard M. Martin, B.M., B.S., Ph.D., Grace J. Young, M.Sc., Eleanor I. Walsh, M.Sc., Richard J. Bryant, Ph.D., F.R.C.S. (Urol.), Prasad Bollina, M.B., B.S., F.R.C.S. (Urol.), Andrew Doble, F.R.C.S. (Urol.), et al., for the Protect Study Group*

After a median of 15 years follow-up of 1610 men with screen detected prostate cancer, (1/3 with intermediate or high-risk disease), the proportions were as follows:

Dying from Prostate Cancer		Developing Metastatic Disease
Active-monitoring	3.1%	9.4%
Prostatectomy	2.2%	4.7%
Radiotherapy	2.9%	5.0%



Prostate Cancer Treatment

Active Surveillance is the preferred management of low-risk prostate cancer.

- PSA less than 10 ng/ml,
- Gleason grade group 1,
- Clinical stage T1c or T2a.

In a survey of 349 US urology practices treating 20,800 patients with low-risk prostate cancer, rates of active surveillance were:

-26.5% in 2014

-59.6% in 2021

Cooperberg et al, JAMA Open Network 2023 6(3)



U.S. Health Care Spending (2019)

\$3.8 TRILLION

17.7% of US GDP (\$21.43 Trillion) \$10,000 per man, woman and child in the US

> Martin, Hartman, Lassman, et al. Health Aff, 2021



Health Expenditure as a percentage of Gross Domestic Product (GDP) 2019

•	United States	17.7%
•	Germany	11.7%
•	Switzerland	11.3%
•	France	11.1%
•	Japan	11.0%
•	Sweden	10.9%
•	Canada	10.8%
•	Belgium	10.7%
•	Norway	10.5%
•	United Kingdom	10.2%
•	Netherlands	10.2%
•	Finland	9.2%
•	Israel	7.5%

Health expenditure as share of GDP by country | Statista



Disparities in Health

The Concept of Medical Gluttony

- Some consume too much
 - (Unnecessary care is given meaning increased risk of harm)
- Some consume too little
 - (Necessary care not given and harm results)
- We could decrease the waste and improve overall health!!!!



Causes of the Decline in Disease Mortality

The Spectrum of Disease Control

Appropriate

In the US, the emphasis is too much on screening, diagnosis and treatment and not enough emphasis is placed on disease prevention (or risk reduction).

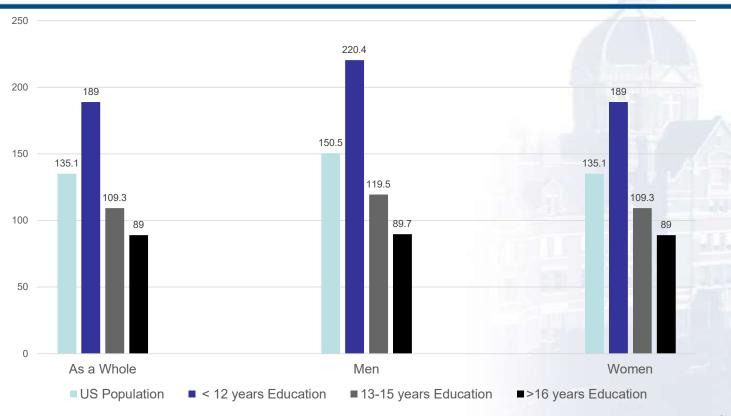
JOHNS HOPKINS

THE TRUE COST OF AMERICAN HEALTHCARE (FROM A CANCER DOC!)



Cancer Mortality by Education

Age Adjusted Rates per 100,000



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Applying Known Science (Prevention and Treatment)

- It is estimated that about 600,000 Americans will die of cancer this year.
- If all Americans had the cancer death rate of college educated Americans, 22% would not die.
- More than one in five cancer deaths (132,000 Americans) would not occur!

Siegel, et al. CA 2018;68:329-339



Applying Known Science (Prevention and Treatment)

- At least 132,000 (22% of the more than 600,000) deaths per year are preventable if all Americans received known medical prevention and treatment.
- The United States leads the western world in preventable cancer deaths.
- Most of these preventable deaths are among white Americans.
- The issue of disparities in health are not just a racial minority health issue.

Siegel, et al. CA 2018;68:329-339



Key Point!!!

The Most Important Question in Cancer Control

How can we provide adequate high-quality care (<u>to include preventive services</u>) to populations that so often do not receive it?

- Unnecessary care consumes limited resources and interferes with abilities to provide necessary care.
- The provision of unnecessary care is a cause of health disparities.



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