EMORY

WINSHIP CANCER INSTITUTE

A Cancer Center Designated by the National Cancer Institute

Ethical Considerations in Assessing Cancer Screening Benefits and Risks

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No Conflicts of Interest

Identifying the Risks and Benefits is not an Ethical Question

It is a scientific question:

- Identify benefits and measure accurately accounting for lead time, length bias, etc.
- Identify risks such as overdiagnosis, false positives, psychological distress.

Jatoi and Brawley et al. The history of cancer screening; Current Problems in Surgery 56 (2019) 138–163

Weighing the Risks and Benefits is Partly Statistical

- How many lives saved by screening?
- Quantify the reductions to treatment morbidity due to early detection.
- Quantify the harms e.g. of radiation, over diagnosis, false positives, false negatives, unnecessary procedures.

Weighing the Risks and Benefits has an Ethical Component

- How important to people are these benefits and harms?
- Involve experts but also have lay input.
- Use Citizen Juries or Deliberative Democracy techniques.
- Ensure diversity in the Citizen Juries.

Den Broeder et al, Health Promot Int. 2018
Safaei J; Journal of Healthcare Leadership; 2015
https://www.epa.gov/international-cooperation/public-participation-guide-citizen-juries

Citizen Jury used to Evaluate PSA Screening

- 15 citizens were selected and balanced for sex, age, and education.
- Pre-meeting received an information booklet.
- Two-day meeting with nine experts.
- Question:“Should the National Health Service discourage or recommend PSA as an individual screening test for prostate cancer in men 55–69 years old?”

Format

- Experts gave talks and answered questions
- Morning of Day 2 had a debate between a clinician and a health policy-maker on the pros and cons of opportunistic PSA screening.
- Ended with a four-hour closed-doors juror deliberation session facilitated by psychologist expert in group facilitation.

Results

- 12/15 recommended discouraging use of PSA in 55–69 year-old men.
- Main concerns: false positives and negatives, overdiagnosis and bad side effects of treatment, cost/benefit ratio.
- Before the meeting, 60% of jurors and all the male jurors would have recommended the test to a relative.
- After the meeting, these percentages fell to 15% and 12%.

Mosconi P et al; (2016) PLoS ONE

ONCE THE RISKS AND BENEFITS ARE WEIGHED, YOU STILL HAVE AN ETHICAL CONUNDRUM

The Ethical Conundrum of Screening

- Should Public Health or Clinical Ethics Principles apply?

- Ethical Principle of Beneficence:
  - Benefit for whom? The population or the individual?

- Ethical Principle of Non-maleficence:
  - Can we harm an individual if the program benefits the population?

Must Use Principles from Both

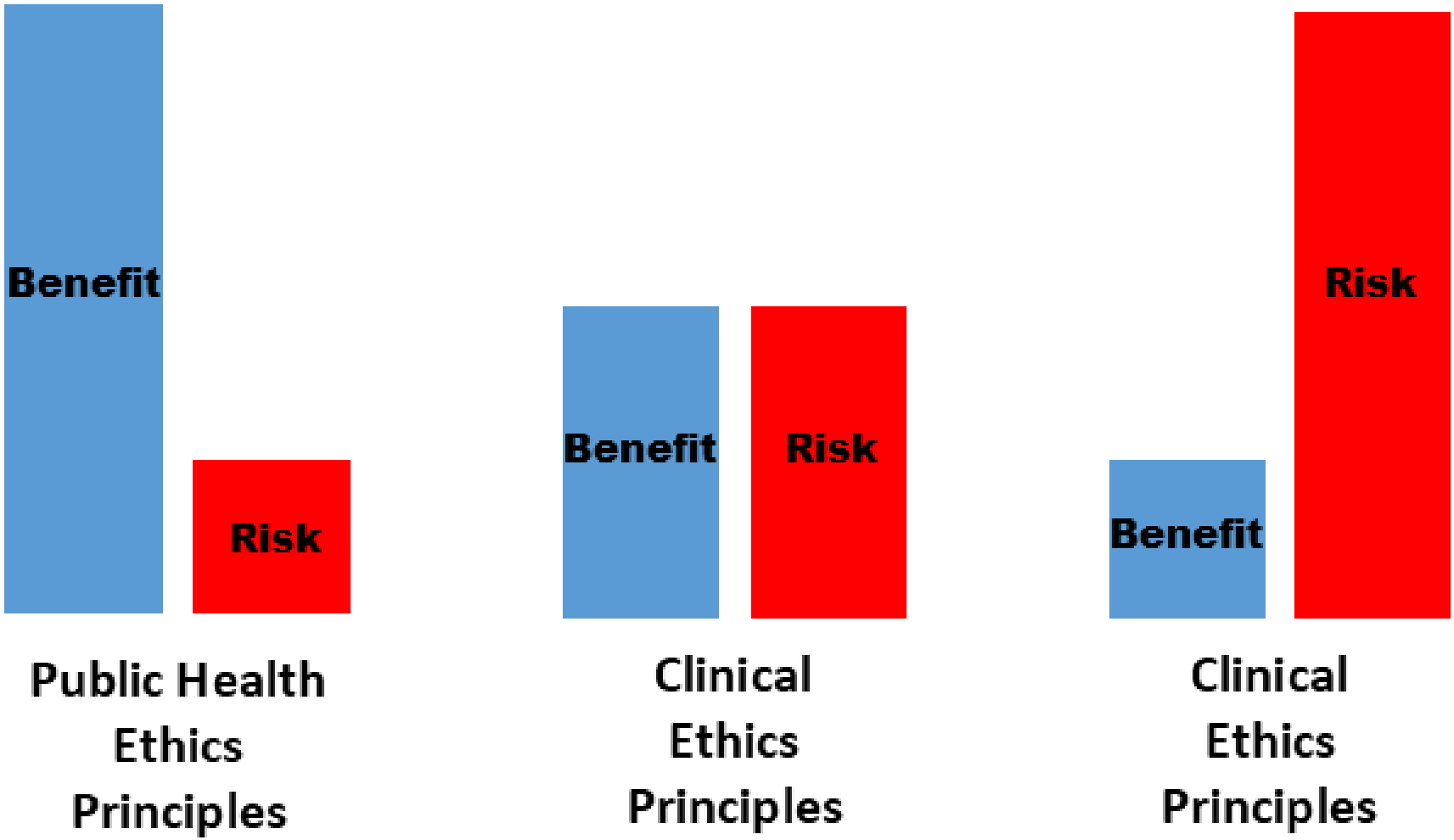
Clinical Ethics Principles:

- Beneficence, non-maleficence, autonomy and justice

Public Health Principles:

- Beneficence, Non-maleficence, Justice for the population
- Transparency and honest communication
- Reciprocity

•Parker et al, Breast Cancer Screening. Elsevier Inc. 2016 http://dx.doi.org/10.1016/B978-0-12-802209-2.00014-0


Benefit
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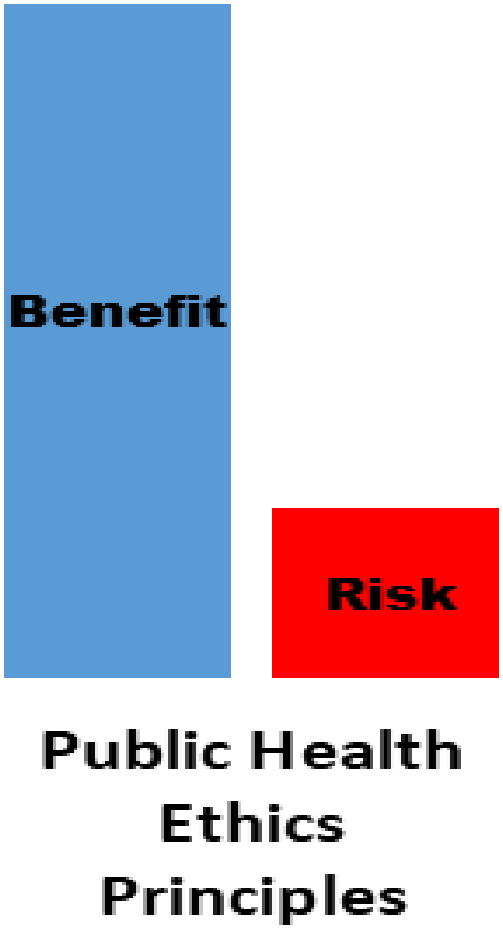
High Benefit/ Low Risk

- **<u>Beneficence/Non-Maleficence apply to the Population</u>**

- Low risk that anyone will be harmed, but this risk is outweighed by the high benefit to the population



High Benefit Scenario

- Need an organized system of screening with regular contact and follow-up system wide.
- Provisions included for appropriate follow-up care.
- Not “opportunistic screening which depends on encounters with health care providers or on individuals who initiate cancer screening on their own.”

Wender and Brawley et al.Blueprint for Cancer Screening and Early Detection: Advancing Screening’s Contribution to Cancer Control; CANCER J CLIN 2019;69:50–79

Justice

Access must be facilitated both for screening and for follow-up care.

Justice – So Many Barriers

Individuals with lower income, lower education, and without insurance are less likely to be up to date with screening.

- Carney PA, et al. Cancer. 2012;118:6217-6225
- White A, et al; MMWR Morb Mortal Wkly Rep. 2017;66:201-206
- Damiani G, et al. Prev Med. 2015;81:281-289

Justice – So Many Barriers

- Health services unavailable in area
- No resources to pay for cancer treatment if found
- A legacy of self-reliance – I can take care of these symptoms myself

Drew, E et al, Deconstructing Fatalism; Med Anthropol Q. 2011 June ; 25(2): 164–182.

- Fatalism (higher in low SES groups)

Beeken, RJ; Cancer fatalism: deterring early presentation and increasing social inequalities?:Cancer Epidemiol Biomarkers Prev. 2011 ; 20(10): 2127–2131.

Justice – So Many Barriers

Mistrust of medical system contributes to lower Colorectal Cancer Screening among Blacks

Adams LB et al, Medical Mistrust and Colorectal Cancer Screening Among African Americans J Community Health. 2017 October ; 42(5): 1044–1061. doi:10.1007/s10900-017-0339-2

But must be cautious. We do not experience this in our research in Atlanta

Pentz, RD, Billot L, Wendler D. Research on Stored Biological Samples: Views of African American and White American Cancer Patients. **American Journal of Medical Genetics**. 2006:140A:733-739. PMID: 16523508.

Justice Demands that We Attempt to Remove these Barriers to Access

Transparency and Honesty

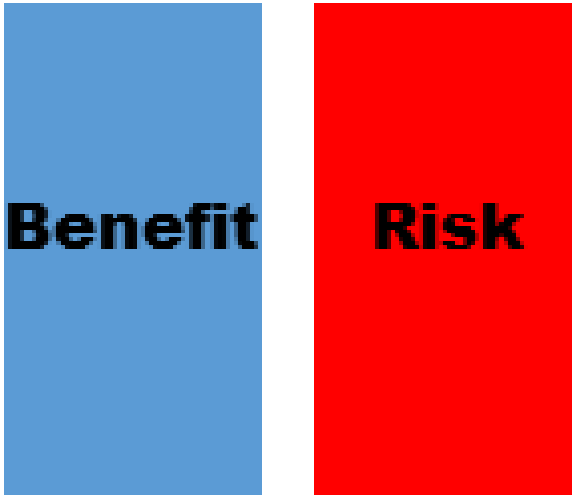
Currently, communicating about screening with transparency and honesty is challenging:

- Must distinguish this high benefit scenario from the other two.
- Screening and early detection are intuitive and have been sold aggressively.
- Harms of screening not obvious to the public.
- Systems have to be kept up to date with the most recent guidance. I still get my annual mammogram notice.

Reciprocity

In a perfect world, people who are harmed by screening, e.g.with false positives and overdiagnosis, should be compensated.

Equally Balanced Benefit/Risk Scenario



Clinical Ethics Principles

Beneficence and Non-Maleficence apply to the Individual

Autonomy applies: Shared decision making with the physician.

This is tough

Phase of Shared Decision Making	Definition
Bearings	Discusses the current health state and how screening fits in. Ensures shared understanding of the present situation.
Pathways	Explains both risks and benefits of screening
Amplification	Gives the patient the opportunity to express their reactions, thoughts, feelings, and to ask questions
Declaration	Provider makes an explicit screening recommendation
Enunciation	Patient articulates decision or delegates the decision to the provider
Enactment	Implements decision or describes next steps
Emphasizing the Importance of the Patient's Opinion	Invite the patient to become involved in the decision-making process and affirm the patient's opinion

Bomhof-Roordink H et al; *Psycho-Oncology.* 2019
Brown RF et al. *Social Science & Medicine.* 2004;

Explaining Risks and Benefits is Difficult

- Lay people have difficulty understanding risk calculations
- Even when given absolute risk, heuristics and framing may lead a patient to over or under emphasize small risks
- Some suggest that numbers do not play a role in human decisions about risk

Reyna VF.. Curr Dir Psychol Sci. 2004;13(2):60-6

Lloyd AJ. Qual Saf Health Care.2001;10:14i–8

Research shows that individuals overestimate the benefits and underestimate the possible risks of screening

Schwartz and Meslin, The Ethics of Information J Gen Intern Med 23(6):867-70

And to top it off, providers may have biases:

- Providers do not want to think that the tests they order could harm their patients.
- Fee-for-service system encourages testing.

ANYA PLUTYNSKI, Journal of Medicine and Philosophy, 2012

Next Steps for Equally Balanced Scenarios

- Increase media portrayal of balanced risks and benefits.
- Educate providers.
- Research on how best to do shared decision making for screening: Develop simple decision tools to overcome heuristics???
- We have found that short animated videos are helpful.

This Week's NY Times

THE NEW YORK TIMES, TUESDAY, FEBRUARY 25, 2020

Well

PERSONAL HEALTH | JANE E. BRODY

Debating the Value of PSA Screening

How should the test results be interpreted, and just when is other testing warranted?

WE'VE LONG BEEN schooled on the lifesaving value of early detection of a potentially deadly cancer. So when a simple blood test was introduced in 1994 that could detect the possible presence of prostate cancer, the second-leading cause of cancer deaths among American men, it's not hard to understand why it quickly became popular.

Suddenly, in the decades after approval of the test known as the PSA, for prostate-specific antigen, the number of men receiving a diagnosis of prostate cancer skyrocketed, along with the number undergoing biopsies of this walnut-size gland between the bladder and penis that produces the seminal fluid to nourish sperm.

The goal of screening is to find aggressive cancers early enough to reduce the risk of death, and national health statistics seem to justify the popularity of PSA screening. Today, 90 percent of prostate cancers are found while the disease is still confined to the gland and its nearby neighbors, when nearly 100 percent of men with the disease survive five or more years. And indeed, the death rate from prostate cancer has dropped by more than half since the PSA was approved as a screening tool by the Food and Drug Administration.

Nonetheless, controversy over the true value and necessity of annual PSA testing for most men has flourished for several reasons. In many men identified as having prostate cancer after PSA screening, the disease is neither aggressive nor likely to kill them before something else does. In fact, a previously unknown prostate cancer is found at autopsy in more than a third of men who die in their 70s or older from some other cause.

Yet when a biopsy after an elevated PSA reveals cancer, even a cancer considered indolent, it can provoke considerable anxiety, and some men may choose to undergo unnecessary treatment that can cause impotence, incontinence or both.

The not-inconsequential problems of prostate-related symptoms should have a PSA test and how often, how the test results should be interpreted, and when follow-up biopsy and other testing is warranted.

As Dr. Henry Rosevear, a urologist who endorses the value of the PSA, wrote in Urology Times, "Not everyone needs to be screened, not everyone found to have an elevated PSA needs to be biopsied, and Lord knows that not everyone with prostate cancer needs aggressive treatment."

In most cases, prostate cancer is slow-growing, and a PSA level of less than 4 nanograms per milliliter of blood is considered within the range of normal. But when the PSA level rises precipitously, say from 4 to 6 or higher in a year's time, doctors are likely to suggest a biopsy. Among men with

> 'Not everyone needs to be screened, not everyone found to have an elevated PSA needs to be biopsied, and Lord knows that not everyone with prostate cancer needs aggressive treatment.'
> DR. HENRY ROSEVEAR

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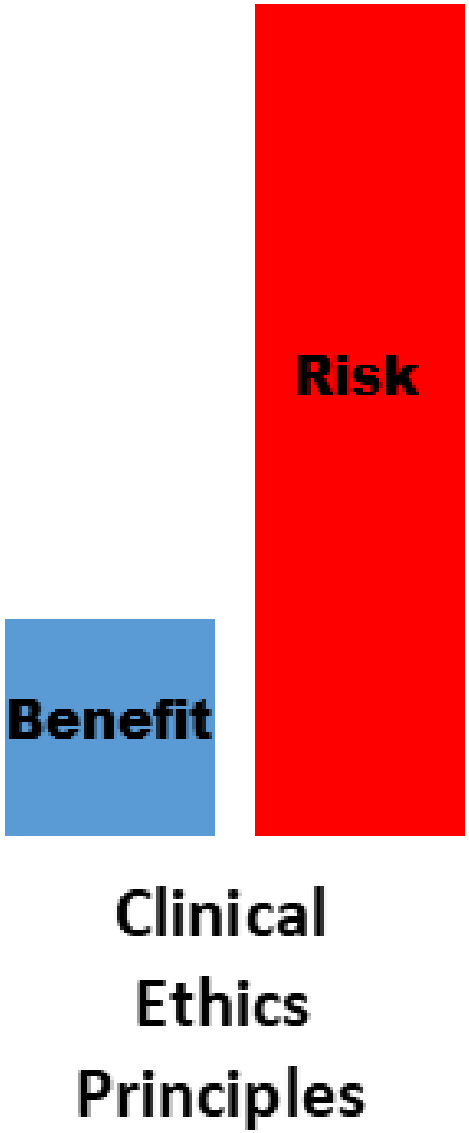
High Risk/Low Benefit Scenario



- Do not offer screening to average patient.
- Beneficence and Non-maleficence require that harmful procedures not be offered, unless this patient has unique risk.

Providers are Not Coke Machines

Only offer beneficial treatments or screenings

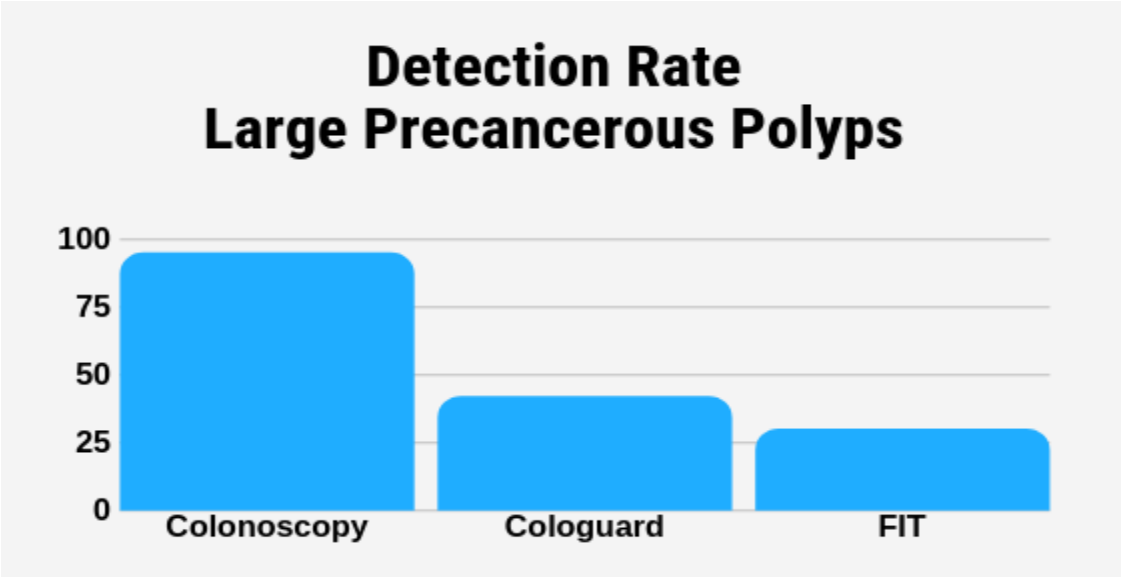
Special Challenges of the New Screening Methods

- Since new, the risks and benefits need further study.
- Using good scientific methods to establish the risks and benefits is ethically required.

- Bad Science is Bad Ethics

"Ulrich, that's bad science and you know it!"

Cologuard Test – Is detecting precancerous lesions a benefit or harm?



Imperiale TF et al, N Engl J Med 2014; 370:1287-1297;
https://www.gastroconsa.com/the-truth-about-cologuard-tests/

Breast Screening

- New breast imaging techniques may be better. Further study needed.
- For example Digital breast tomosynthesis and 10 minute MRI may be better for an underserved population: Black women with dense breasts

Desounis, SV et al, AJR Am J Roentgenol. 2015 Feb;204(2):261-4.

Rochman, S; *JNCI: Journal of the National Cancer Institute*, 107:10; 2015,

Comstock CE, al. *JAMA.* 2020;323(8):746–756.

Access is a problem. Newer imaging may not be available and costs more.

Newman, L; JAMA Surg. 2020. doi:10.1001/jamasurg.2020.0280

Low Uptake of Lung Cancer Screening

Public not aware of new tests: Need public education programs

https://www.healthline.com/health-news/2-percent-heavy-smokers-get-lung-cancer-screenings#1

Richards TB, et al 2017. MMWR Morb Mortal Wkly Rep 2020;69:201–206.

Plus the same recurring issues:

- Fear of disease and the treatment
- Fatalism – either I will get it or I won't
- Fear of false-positives
- Practical barriers
- Expense

Carter-Harris L et al, *Family Practice*, 2017, Pages 239–244, https://doi.org/10.1093/fampra/cmw146

Low Dose CT for Lung Cancer has Incidental Findings

- Pulmonary e.g. COPD, Interstitial Lung Abnormalities, Pulmonary Infections.
- Pleural (plaques, effusion)
- Mediastinal : cardiovascular, thyroid, mediastinal masses, lymph nodes, esophagus
- Upper Abdominal: malignant and non-malignant

Tsai, EB et al, Science Direct; 2018

Incidental Findings

- The new ethical consensus is that incidental findings that are medically actionable must be reported and acted upon.
- Issue: what counts as medically actionable? Need SOP on what and how to respond to IFs.
- Cost: "nearly half (46.2%) of the calculated $817 per-patient reimbursement associated with lung cancer screening was related to the evaluation and treatment of incidental findings."

L. Morgan, H. Choi, M. Reid, *et al.* Ann Am Thorac Soc, (2017)

Artificial Intelligence has Unique Barrier to Use

Patients worry that their uniqueness - unique characteristics, circumstances and symptoms - will not be captured, so they don't trust AI to see them as they really are

Logoni et al. Journal of Consumer Research, (2019), https://doi.org/10.1093/jcr/ucz013

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