



Northwest Colorectal Cancer Task Force Meeting

February 17, 2026



Agenda

- Welcome & Introductions
- Land Acknowledgment
- Presentations
- Sharing Updates & Events
- Wrap up

Welcome & Introduction

Please introduce yourself by typing in the chat your
Name, Organization and Title



Presentation 1

Vaccines to Treat and Prevent Cancer

Presenter: **Dr. Nora Disis, MD**

Director & Founder, UW Cancer Vaccine Institute

Helen B. Slonaker Endowed Professor for Cancer Research

A photograph of the Space Needle tower in Seattle, Washington, set against a sunset sky with orange and purple hues. The tower is illuminated with blue lights.

Vaccines to treat and prevent cancer

Nora Disis, MD

Director & Founder, UW Cancer Vaccine Institute
Helen B. Slonaker Endowed Professor for Cancer Research



CANCER VACCINE INSTITUTE
UW Medicine

Vaccines have had a profound impact on human health



Polio



Smallpox



Measles

Decrease in cases → 100%

100%

99%

Many diseases that cause serious harm or death 50 years ago have almost been eliminated by vaccines

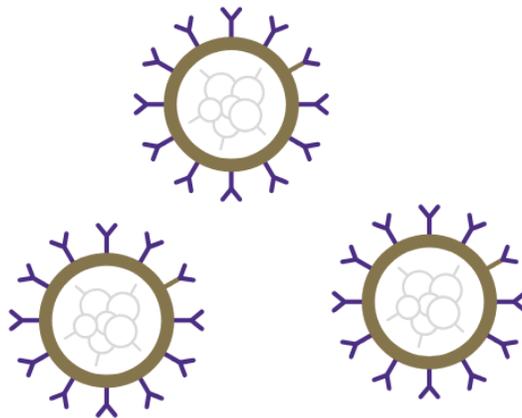
Vaccines train the immune system to recognize and destroy foreign threats

1



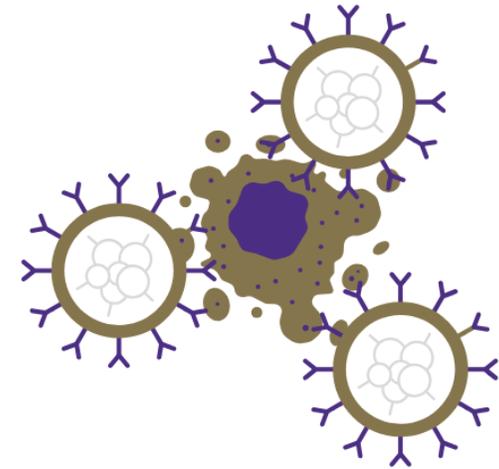
Patient receives DNA or mRNA that encodes proteins found at high levels in cancer

2



Immune system creates cells that are trained to recognize cancer proteins as foreign and dangerous

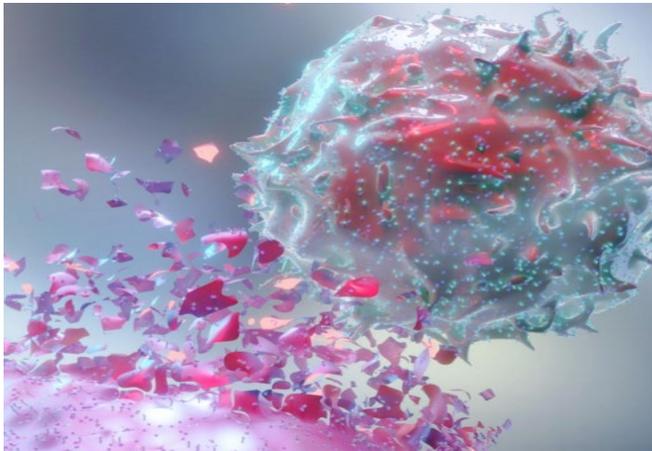
3



Trained immune cells search and destroy cancer cells, for decades after the vaccine

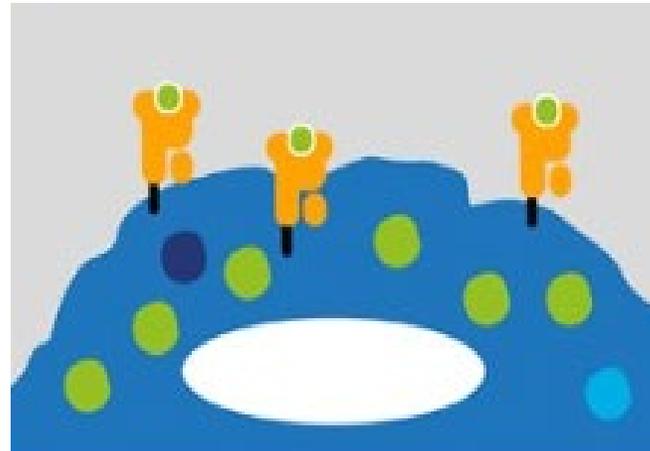
We are at a tipping point for cancer vaccines

We know the type of immune response we need to kill cancer



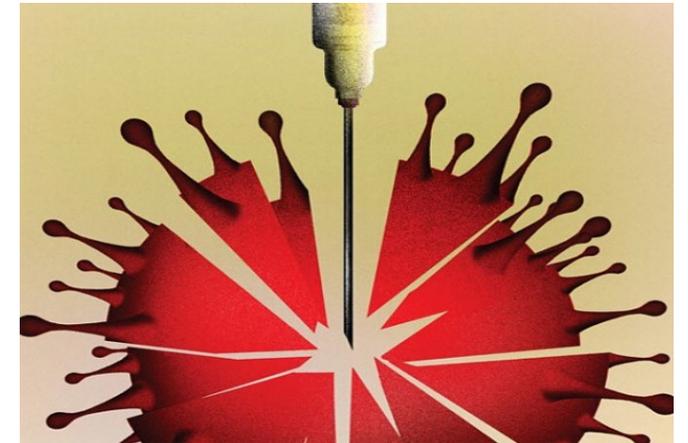
Type I T-lymphocytes

We know what parts of a cancer can stimulate the immune system



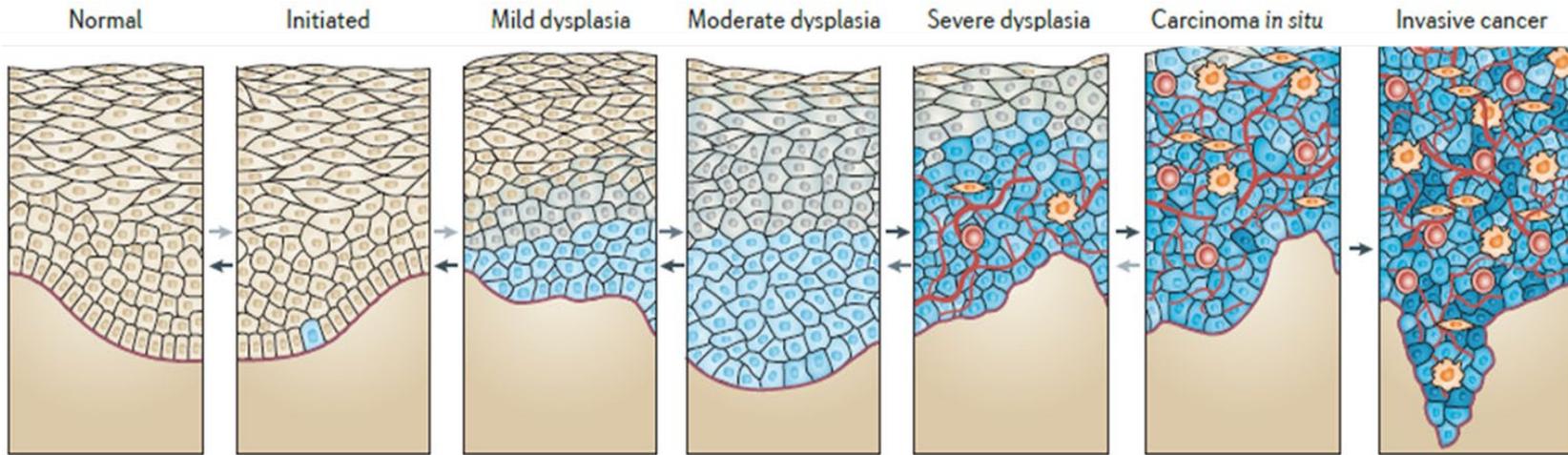
Hundreds of tumor “antigens”

New vaccine technology makes immunization more effective



DNA and RNA: nucleic acid based

Vaccines to prevent cancer and cancer recurrence



Adapted from Umar, Nat Rev Ca, 2012

Prostate: Intraepithelial neoplasia

Colon: Adenomatous polyps

Lung: Bronchial dysplasia

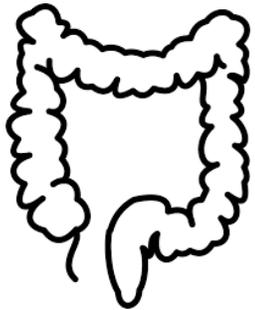
Ovary: Serous tubal
intraepithelial carcinoma

Breast: Ductal carcinoma in situ

Bladder: Carcinoma in situ

- Account for +50% of cancer diagnosis and cancer deaths
- Associated with increased risk of recurrence
- Have defined pre-malignant lesions
- Have a defined and motivated high-risk population for early intervention

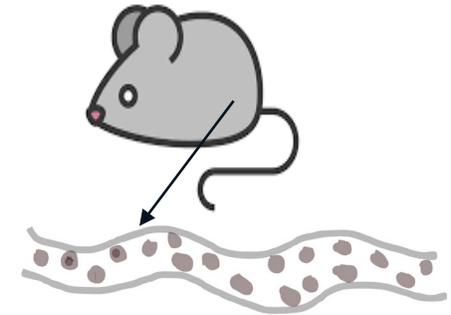
COLOVAC - Vaccine for intercepting colon cancer



Identified proteins
expressed at high levels
in colon polyps and
cancer

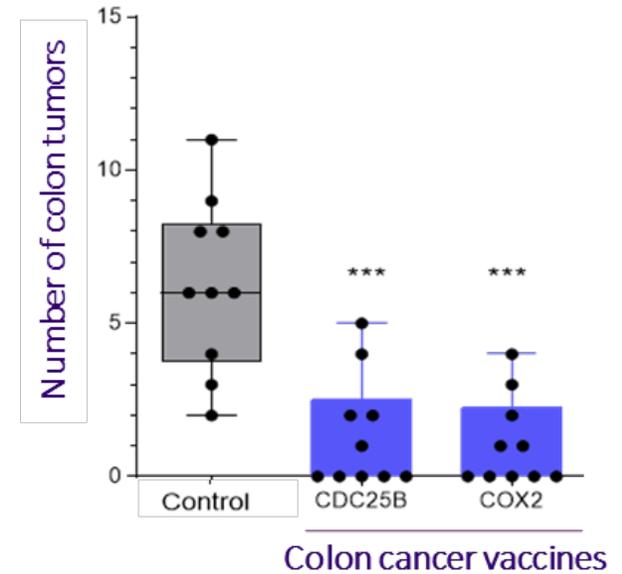
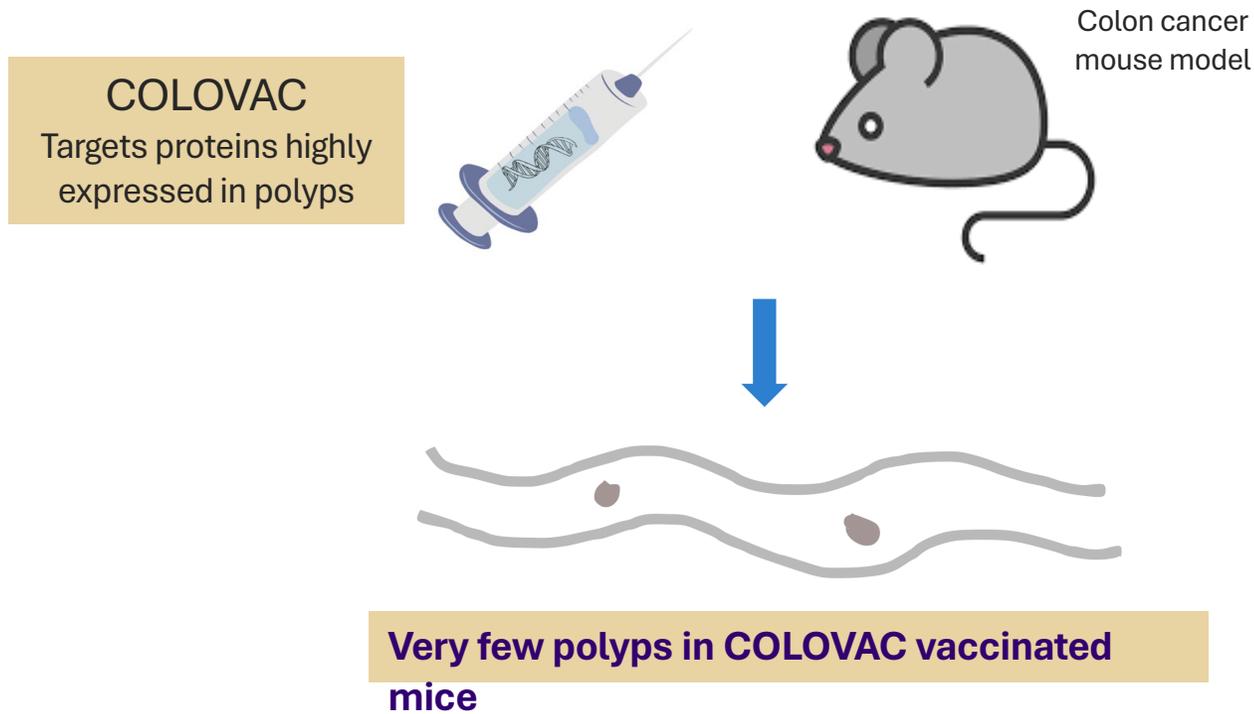


COLOVAC
Vaccine



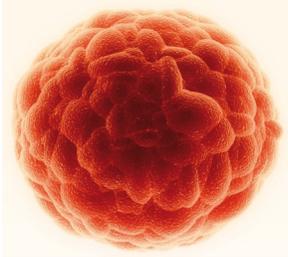
Can we reduce polyps
in mouse models of
colon cancer with
COLOVAC?

COLOVAC - Vaccine for intercepting colon cancer



Targeting cancer stem cells to prevent cancer: STEMVAC vaccination

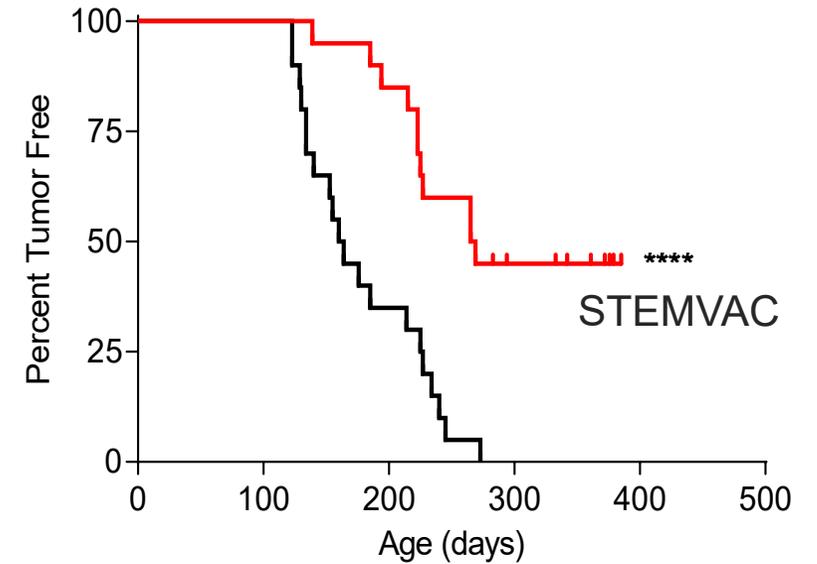
Cancer Stem Cell



Resistance to therapy
Recurrence
Metastasis



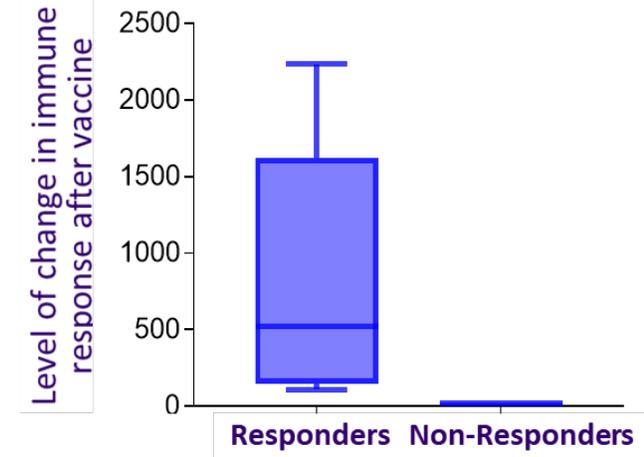
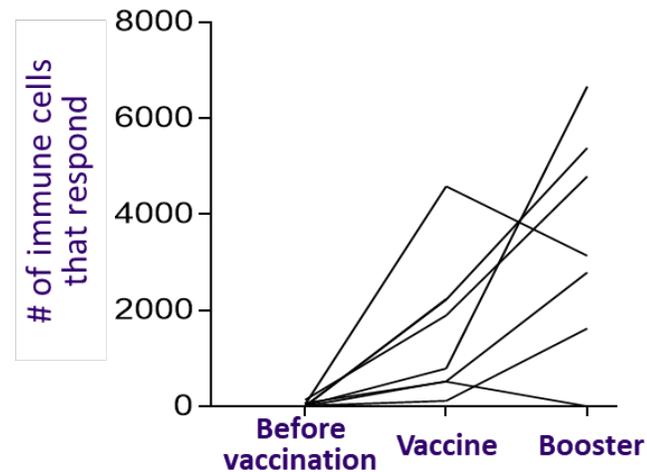
STEMVAC DNA vaccine
Targets 5 stem cell proteins



Effective in preventing breast
cancer in mice

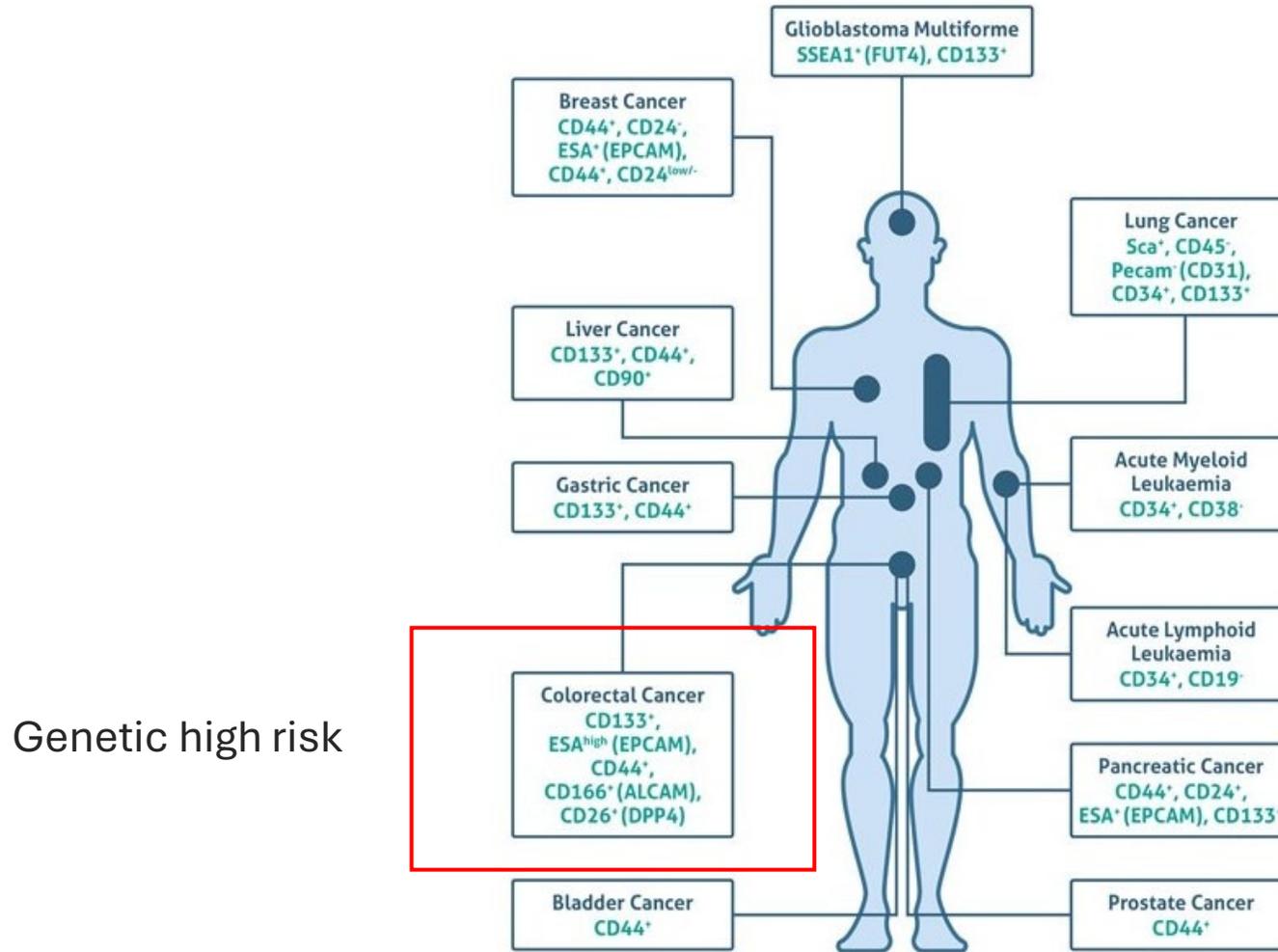
STEMVAC generated a strong immune response in cancer patients

Clinical Trial
Phase I, dose escalation
3 doses of vaccine
Stage III/IV Breast Cancer Hormone receptor positive or Triple Negative
30 patients (10 per dose)
3 vaccines 1 month apart, id
Boosters at 3 and 9 months



- ✓ We detected an immune response to all 5 stem cell proteins
- ✓ Boosters increase level of response
- ✓ Very high levels of STEMVAC immunity

STEMVAC may be effective to prevent cancer



Vision for a cancer-free future



Intermediate Risk
Chronic inflammation



Vaccines to target risk factors to prevent cancer



High Risk
Genetic mutations or precancerous lesions



Vaccines to intercept or prevent cancer



Very High Risk
Cancer diagnosed



Vaccines to treat cancer & prevent recurrence

UW Medicine Cancer Vaccine Institute

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Supported by: National Cancer Institute, Department of Defense Breast, Lung, and Ovarian Cancer Programs, Komen Foundation, American Cancer Society, Breast Cancer Research Foundation, Kuni Foundation, Wings of Karen, Breast Cancer Alliance, Valley Girls & Guys, and the Helen B. Slonaker Professorship in Cancer Research

Presentation 2

CRC Data Dashboard

Presenter: **Derrik Zebroski**

Mobile Outreach Program Coordinator

Knight Cancer Institute, OHSU

Presentation 3

MyGeneRisk Colon

Presenters: **Li Hsu & Robert Steifelder**

Fred Hutch Cancer Research Center



MyGeneRisk Colon - Colorectal Cancer Risk Assessment Tool

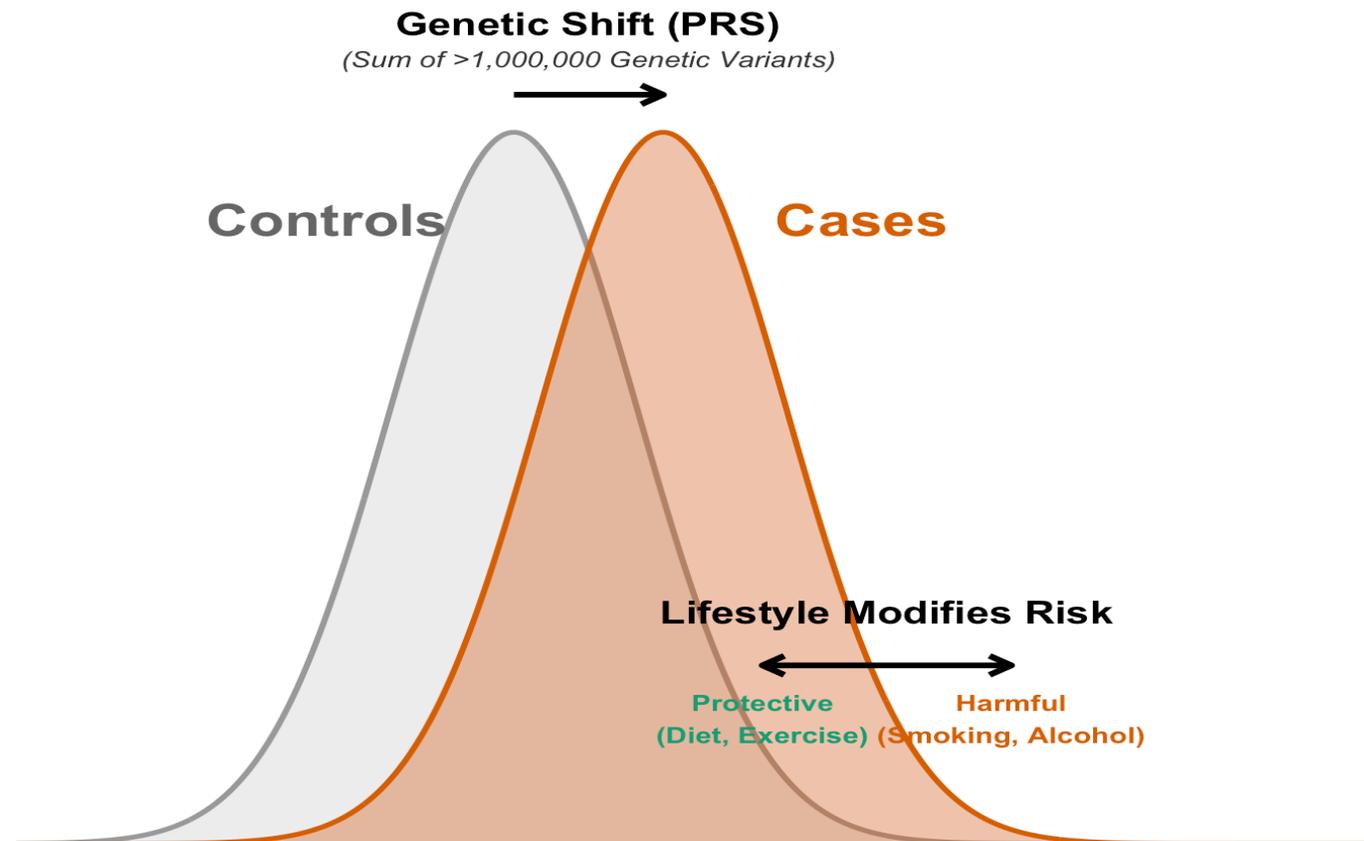
Li Hsu, PhD and Robert Steinfeld, PhD

Genetic and Epidemiology Colorectal Cancer Consortium (Riki Peters)
Public Health Sciences

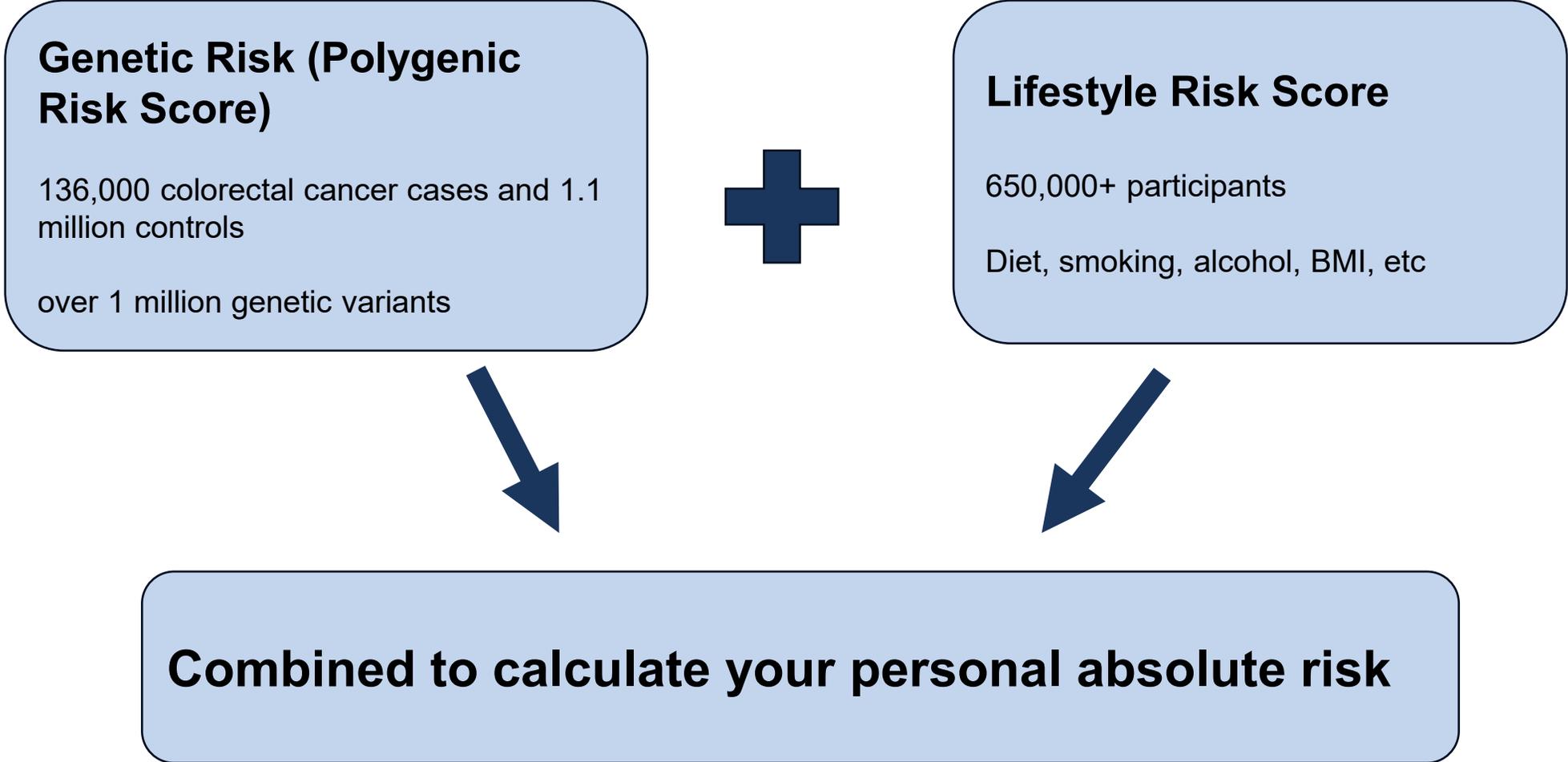
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Both Genetics and Lifestyle Contribute to Colorectal Cancer Risk

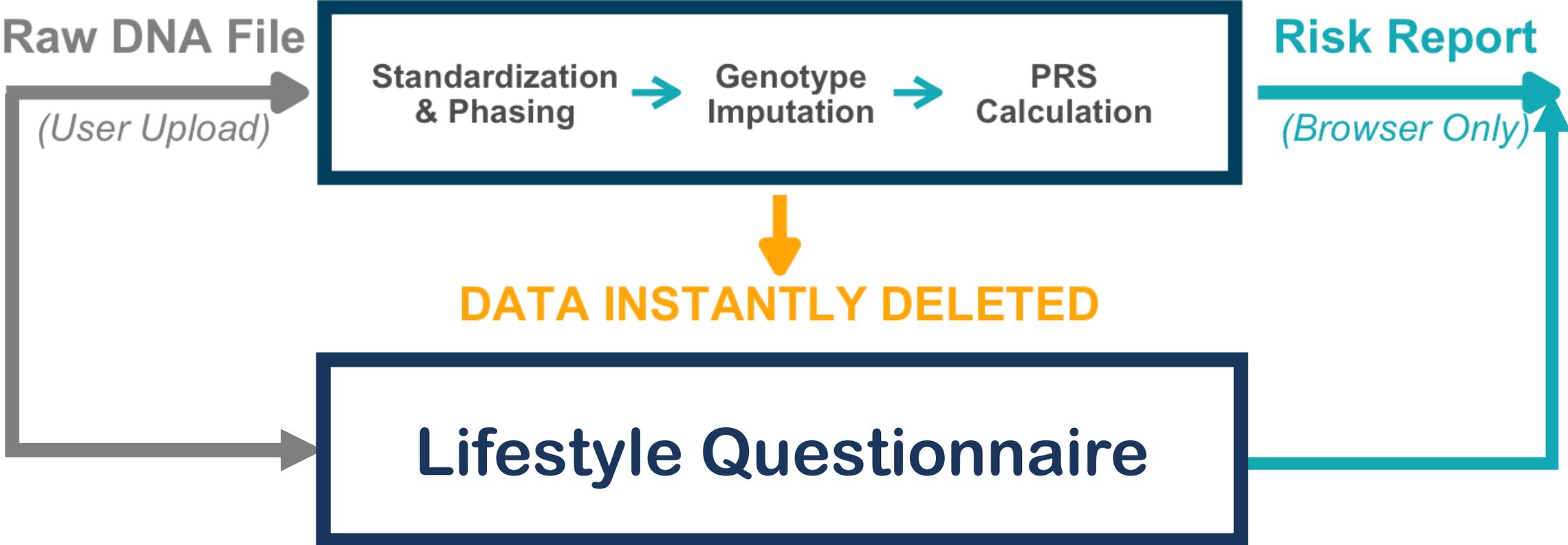


How We Estimate Your Colorectal Cancer Risk



Robert Steinfeld

Secure Ephemeral Cloud



Raw DNA File
(User Upload)

Standardization & Phasing → Genotype Imputation → PRS Calculation



DATA INSTANTLY DELETED

Lifestyle Questionnaire

Risk Report
(Browser Only)

<https://mygenerisk-colon.fredhutch.org/>

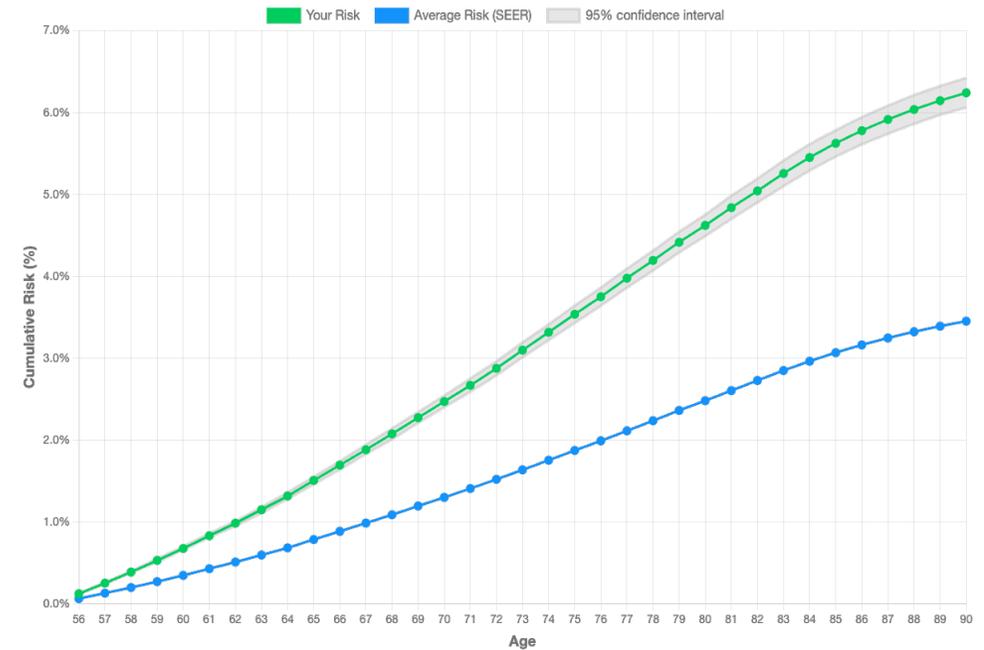
Colorectal Cancer Risk Assessment Tool

Fred Hutch
Cancer Center



Get Your Colorectal Cancer Risk Report in 5 Minutes

Fred Hutch Cancer Center



Genetics and Epidemiology of Colorectal Consortium – GECCO (PI: Riki Peters)



Fred Hutch Cancer Center

R01-CA059045, U01-CA137088, U19-CA148107, U01-CA164930, R01-CA176272, U01-CA185094, R01-CA201407, R01-CA206279 , R21-CA230486 X01-HG006196, X01-HG006662, X01-HG007585, X01HG009781, JUNO Therapeutics , R01-CA244588, R01-CA248857, R37-CA276306, P50-CA285275





Thank you





BREAK



5 Minutes

Presentation 4

Colorectal Cancer and Nutrition

Speaker: **Margaret Chaykin, MPH, CHES, RDN, CD**

Breast, Cervical and Colon Health Program Manager

WA State Department of Health



PREVENTION, TREATMENT, AND SURVIVORSHIP



Margaret Chaykin, MPH, CHES, RDN, CD
Breast, Cervical, and Colon Health Program Manager
WA State Department of Health

Learning Objectives

By the end of this session participants will...

Identify cancers strongly linked to nutrition and inflammatory conditions

Describe evidence-based dietary patterns for prevention

Understand nutrition priorities during treatment

Apply survivorship nutrition guidance

Connect equitable nutrition access as cancer prevention

Why Nutrition Matters

Diet and physical activity influence cancer risk and outcomes

Adherence to cancer prevention guidelines are associated with **14% lower total cancer risk.**

Significant risk reductions seen for colorectal, breast, kidney, esophageal, and uterine cancers incidence.

Nutrition Mediated Cancers

Convincing evidence links nutrition to:

Colorectal

Postmenopausal breast

Endometrial

Esophageal adenocarcinoma

Pancreatic

Kidney

Liver

Probable links:

Ovarian, prostate, thyroid, gallbladder, and likely others

Inflammatory conditions, including BMI >40, is linked to **≥13 cancers** including stomach, myeloma, and meningioma



Cancer Prevention and Nutrition

Nutrition-Specific Risk Factors

Dietary exposures with strong evidence

Processed meat → ↑ colorectal cancer

Red meat → probable colorectal risk

Low fiber/whole grains → ↑ colorectal risk

Alcohol → increased cancer risk

Sugar-sweetened beverages →

Nutrition-Specific Risk Reduction

≥ 5 servings fruits/vegetables daily

Emphasize plant foods

Limit ultra-processed foods

Limit red meat

Avoid processed meat

Avoid sugar-sweetened beverages

Limit alcohol

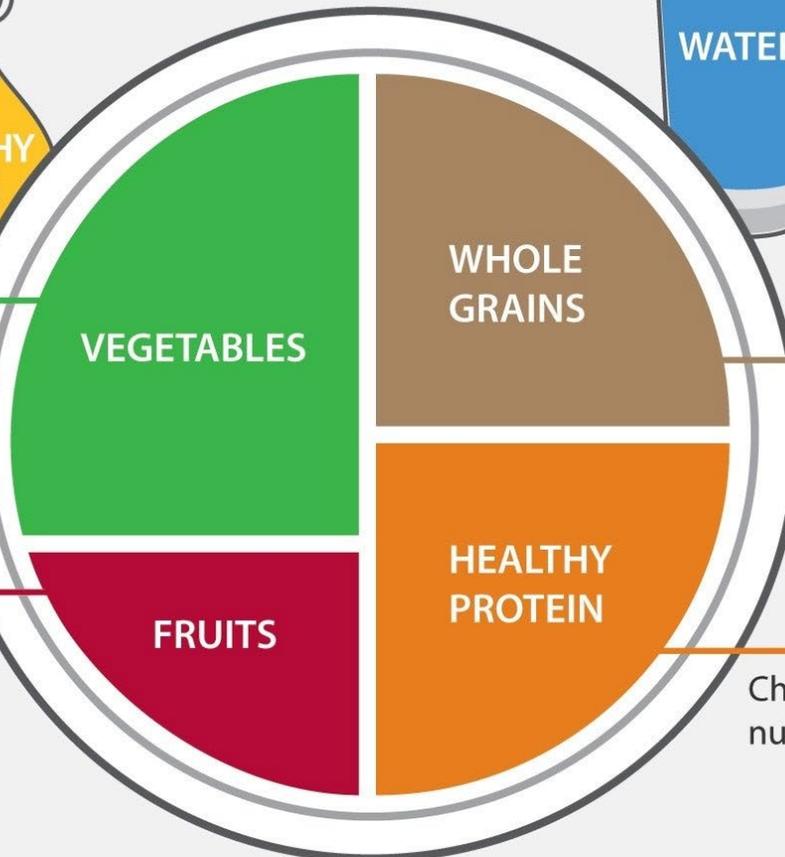
HEALTHY EATING PLATE

Use healthy oils (like olive and canola oil) for cooking, on salad, and at the table. Limit butter. Avoid trans fat.



Drink water, tea, or coffee (with little or no sugar). Limit milk/dairy (1-2 servings/day) and juice (1 small glass/day). Avoid sugary drinks.

The more veggies – and the greater the variety – the better. Potatoes and French fries don't count.



Eat a variety of whole grains (like whole-wheat bread, whole-grain pasta, and brown rice). Limit refined grains (like white rice and white bread).

Eat plenty of fruits of all colors.

Choose fish, poultry, beans, and nuts; limit red meat and cheese; avoid bacon, cold cuts, and other processed meats.



STAY ACTIVE!

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The Nutrition Source
www.hsph.harvard.edu/nutritionsource

Harvard Medical School
Harvard Health Publications
www.health.harvard.edu



Ultra-Processed Foods & Risk



We can not say UPFs cause cancer, however...



Observational evidence:



UPF's seem to carry risk relational to exposure. Every 10% increase in UPF intake → 12% higher associated risk increase for cancer.

Food Category*	Example Products	Choose Often			Choose Sometimes			Choose Rarely		
		Saturated Fat	Sodium	Added Sugar**	Saturated Fat	Sodium	Added Sugar**	Saturated Fat	Sodium	Added Sugar**
Fruits and Vegetables	Fresh, canned, frozen, and dried fruits and vegetables, frozen broccoli with cheese sauce, apple sauce, tomato sauce, 100% juice, 100% fruit popsicle	≤2 g	≤230 mg	0 g	All 100% juice and plain dried fruit			≥2.5 g***	≥480 mg	≥12 g
					≥2.5 g***	231-479 mg	1-11 g			
Grains	Bread, rice, pasta, grains with seasoning mixes	First ingredient must be whole grain AND meet following thresholds:			≥2.5 g***	231-479 mg	7-11 g	≥2.5 g***	≥480 mg	≥12 g
		≤2 g	≤230 mg	≤6 g						
Protein	Animal (beef, pork, poultry, sausage, deli meats, hot dogs, eggs) and plant proteins (nuts, seeds, veggie burgers, soy, beans, peanut butter)	≤2 g	≤230 mg	≤6 g	2.5-4.5 g	231-479 mg	7-11 g	≥5 g	≥480 mg	≥12 g
Dairy	Milk, cheese, yogurt	≤3 g	≤230 mg	0 g	3.5-6 g	231-479 mg	1-11 g	≥6.5 g	≥480 mg	≥12 g

THE “OFTEN” FOODS

FRUITS AND VEGETABLES

- Fresh, frozen, and canned fruits and vegetables with NO added sugar or sodium(salt)
- Low-sodium(salt) vegetables
- Fruit canned in 100% juice or in water

GRAINS

- Whole Grains
- Whole wheat pasta/breads
- Whole grain cereal with less than 6 grams of added sugar
- Plain oatmeal

PROTEIN

- Dried beans
- Low-sodium(salt) canned beans
- Nuts
- Fresh/ Frozen poultry
- Fish
- Low-sodium(salt) canned tuna
- Canned salmon

DAIRY

- Skim, 1%, 2% milk
- Fat-free and reduced fat cheeses

BEVERAGES

- Plain water
- Flavored and unflavored sparkling water
- Plain coffee
- Unsweetened tea

THE “SOMETIMES” FOODS

FRUITS AND VEGETABLES

- 100% juice
- Fruit canned in light syrup
- Canned vegetables
- Plain dried fruit

GRAINS

- Refined grain products
- Oatmeal with added sugar
- Whole or non-whole grain cereal with 7-11 grams of total added sugar

PROTEIN

- Canned beans
- Regular canned fish
- Pork

DAIRY

- Some reduced fat or whole milk cheeses
- Whole Milk

BEVERAGES

- Diet soft drinks
- Diet iced teas

PROCESSED/ PACKAGED SNACKS

- Plain popcorn
- Whole wheat crackers
- Unsalted whole grain pretzels

THE “RARELY” FOODS

FRUITS AND VEGETABLES

- Dried fruit with sugar added
- Fruit canned in heavy syrup
- Tomato sauce with added sugar
- Vegetables canned with high sodium(salt)

GRAINS

- Rice and pasta with salt-based seasoning mixes
- Whole or non-whole grain cereal with greater than 12 grams of sugar
- Most bakery items

PROTEIN

- Refried beans
- Deli meat
- Sausage
- Bacon
- Most red meat

DAIRY

- Full-fat cheese

BEVERAGES

- Sweetened energy drinks
- Sports drinks
- Regular sodas
- Non-100% juice drinks with added sugar
- Processed/packaged snacks
- Pretzels
- Cheese crackers
- Potato chips

Mechanistic Pathways of Nutrition-Cancer Risk Influence

Insulin resistance & adipokines

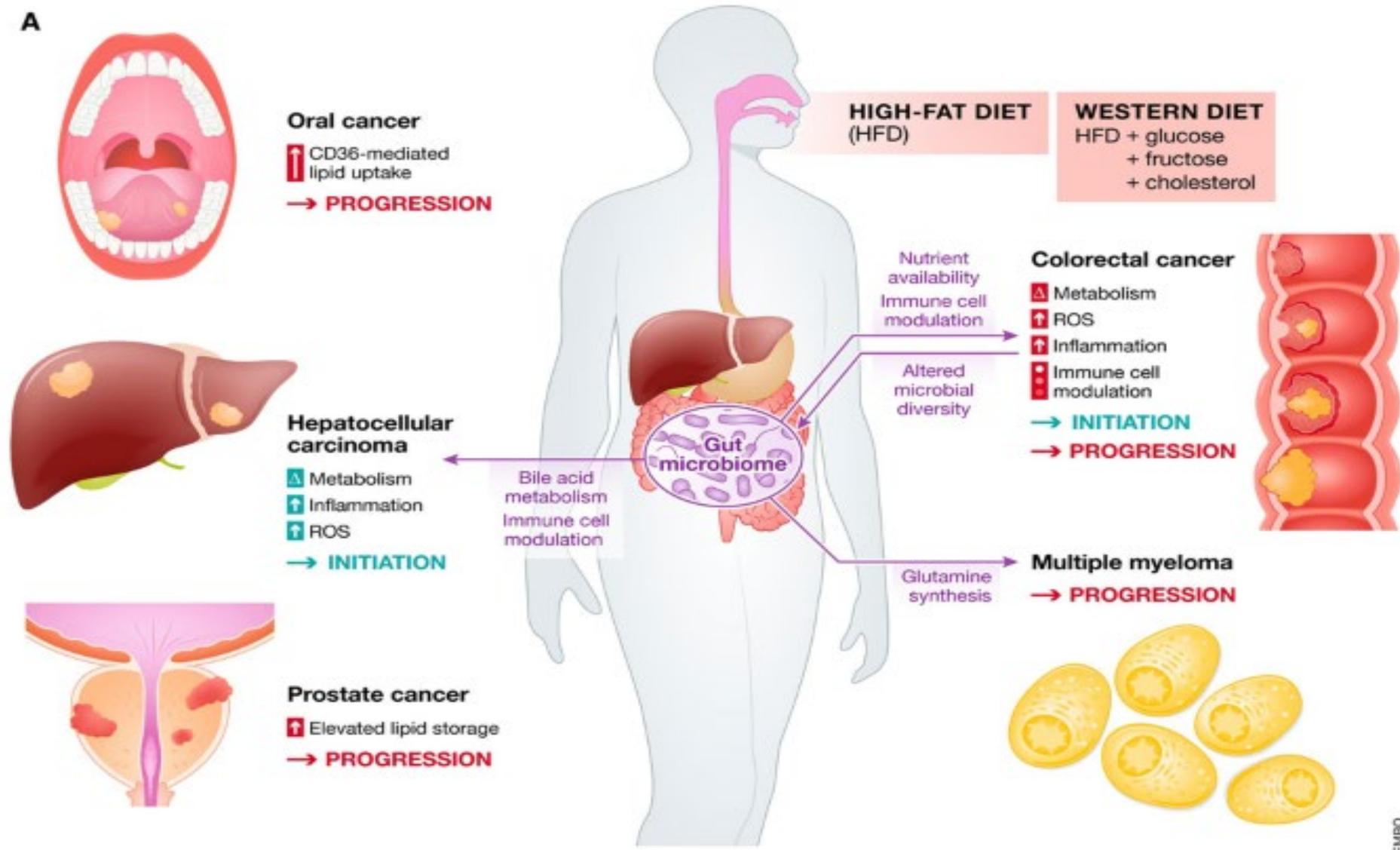
Chronic inflammation

Hormone modulation

Microbiome effects

Cell proliferation opportunity

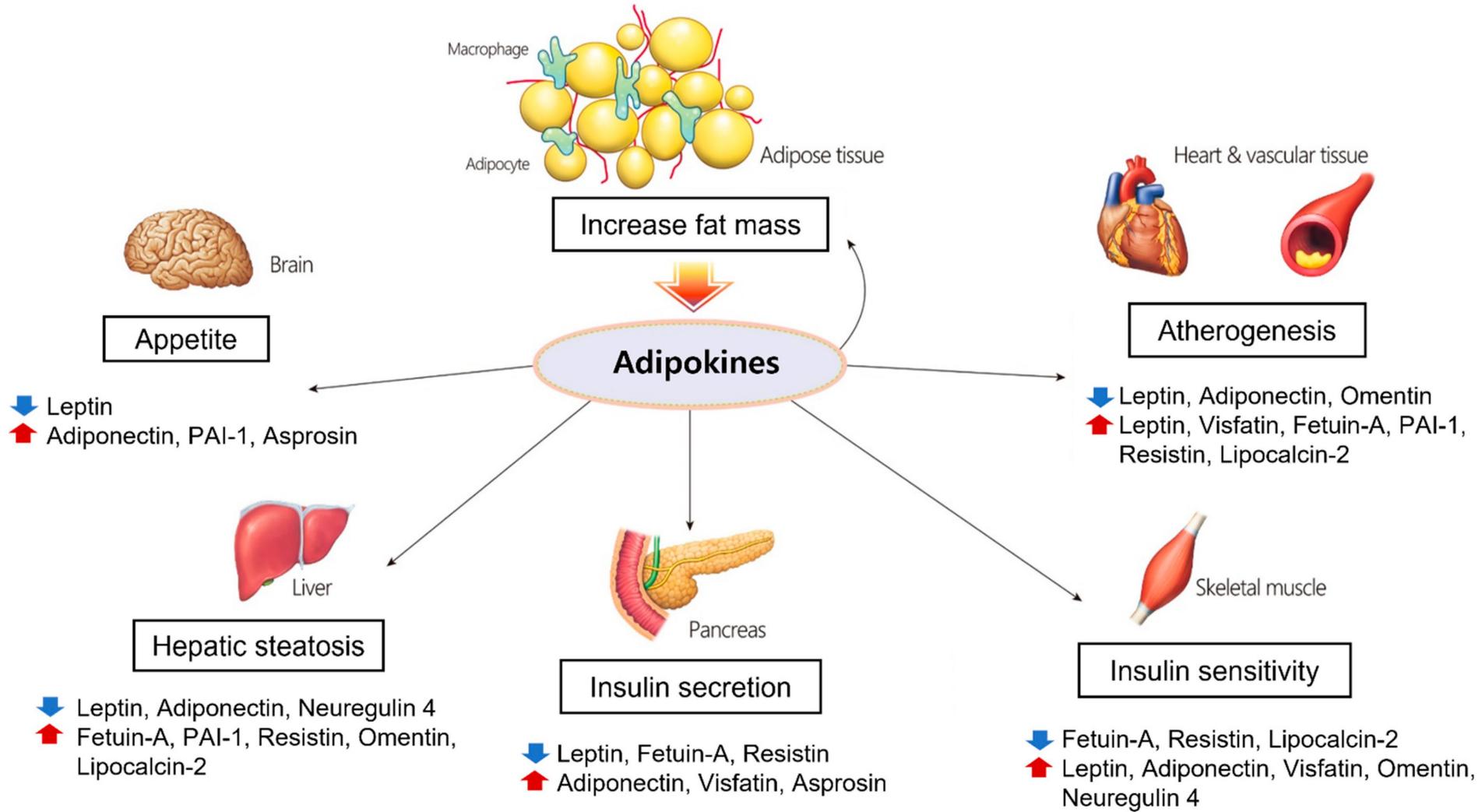
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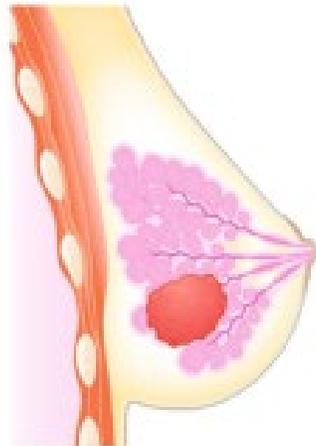
Key Mechanisms Behind ROS Production from UPFs

- **Mitochondrial Overload:** The high-energy density and metabolic load of UPFs force mitochondria to work harder, resulting in excess production of ROS.
- **Additives and Ingredients:** Components like emulsifiers, artificial colors, and preservatives can metabolically trigger ROS.
- **Advanced Glycation End Products (AGEs):** Processing creates these compounds, which are known to cause damage, inflammation, and ROS production.
- **Reduced Antioxidant Defense:** A high-UPF diet is usually low in antioxidants (vitamins, fiber), reducing the body's ability to neutralize free radicals.
- **Gut Microbiota Dysbiosis:** The lack of dietary fiber disrupts gut health, promoting systemic inflammation that increases ROS production.

Chronic consumption of UPFs leads to a vicious cycle of inflammation and oxidative stress – a prime driver of chronic conditions like HLD, HTN, and T2DM.

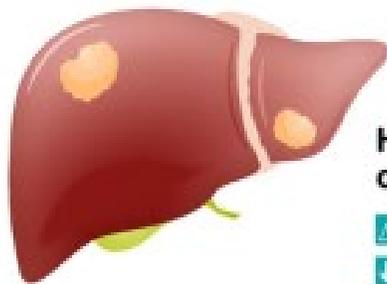


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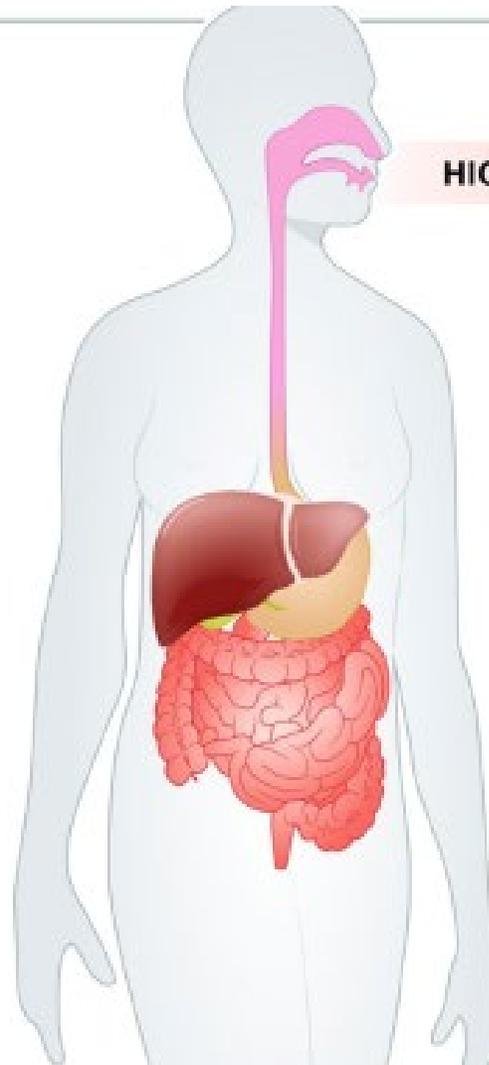
Breast cancer

- ⬇ Glucose metabolism
- ⬇ LOX signaling
- PROGRESSION

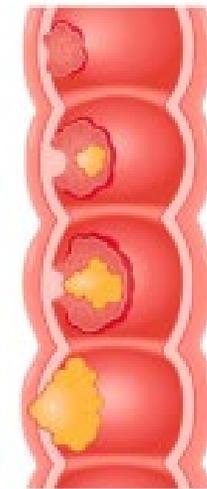


Hepatocellular carcinoma

- ⬆ Insulin signaling
- ⬆ ROS scavenging
- INITIATION



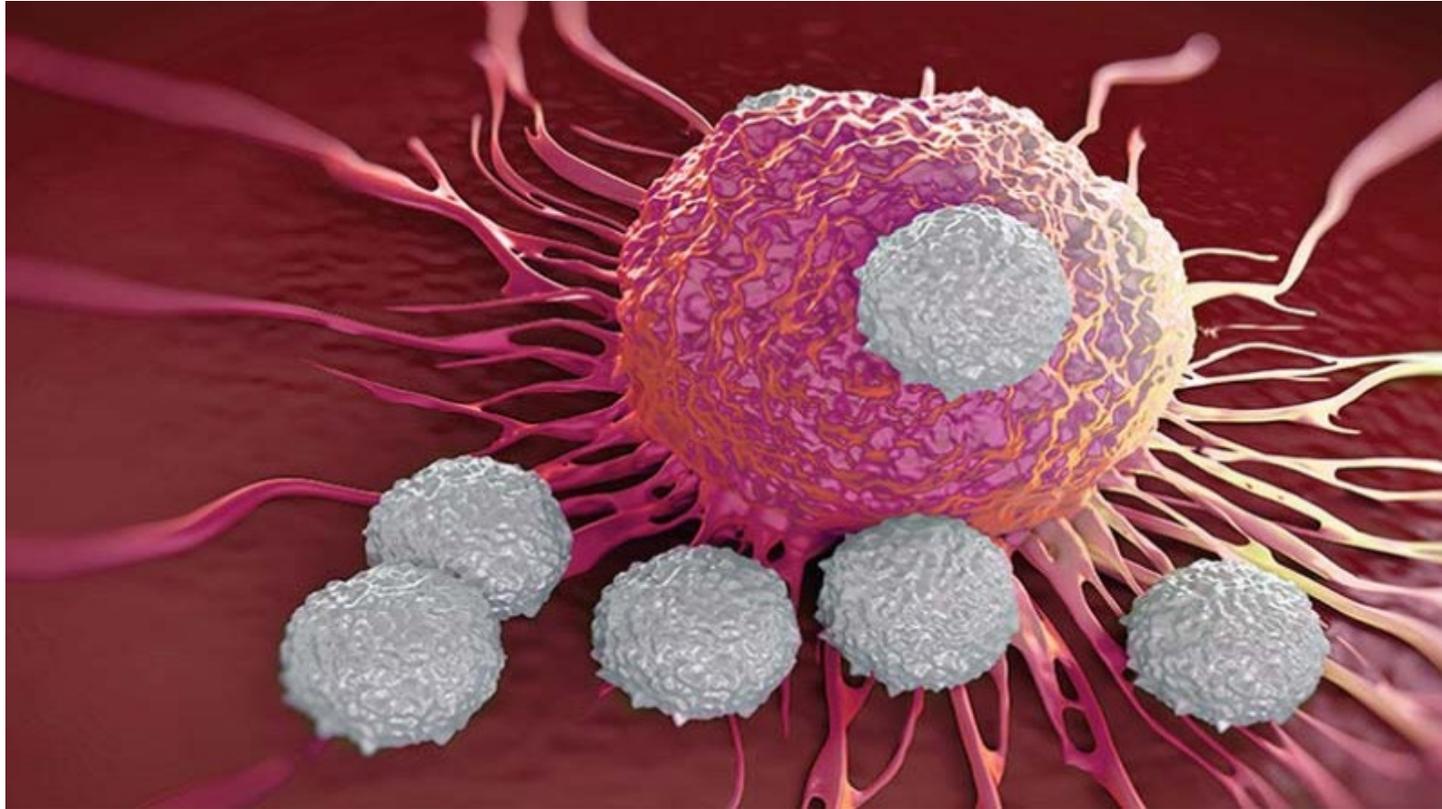
HIGH-FRUCTOSE DIET



Colorectal cancer

- ⬆ Glucose metabolism
- ⬆ De novo lipogenesis
- PROGRESSION

Cancer & Treatment



Nutrition Priorities During Cancer Treatment

Prevent	Prevent malnutrition
Maintain	Maintain lean mass
Manage	Manage symptoms
Support	Support treatment tolerance

Treatment Nutrition Principles

Best practice (clinical consensus)

- Individualized energy/protein support
- Symptom-targeted adjustments
- Flexible dietary restrictions
- Enteral/parenteral nutrition if needed
- Multidisciplinary care
- Nutrition status influences inflammation and outcomes – limit ROS+ Foods and increase ROS- foods, as able and tolerated.

Micronutrients & Supplements

Evidence-based guidance

Meet needs
through food

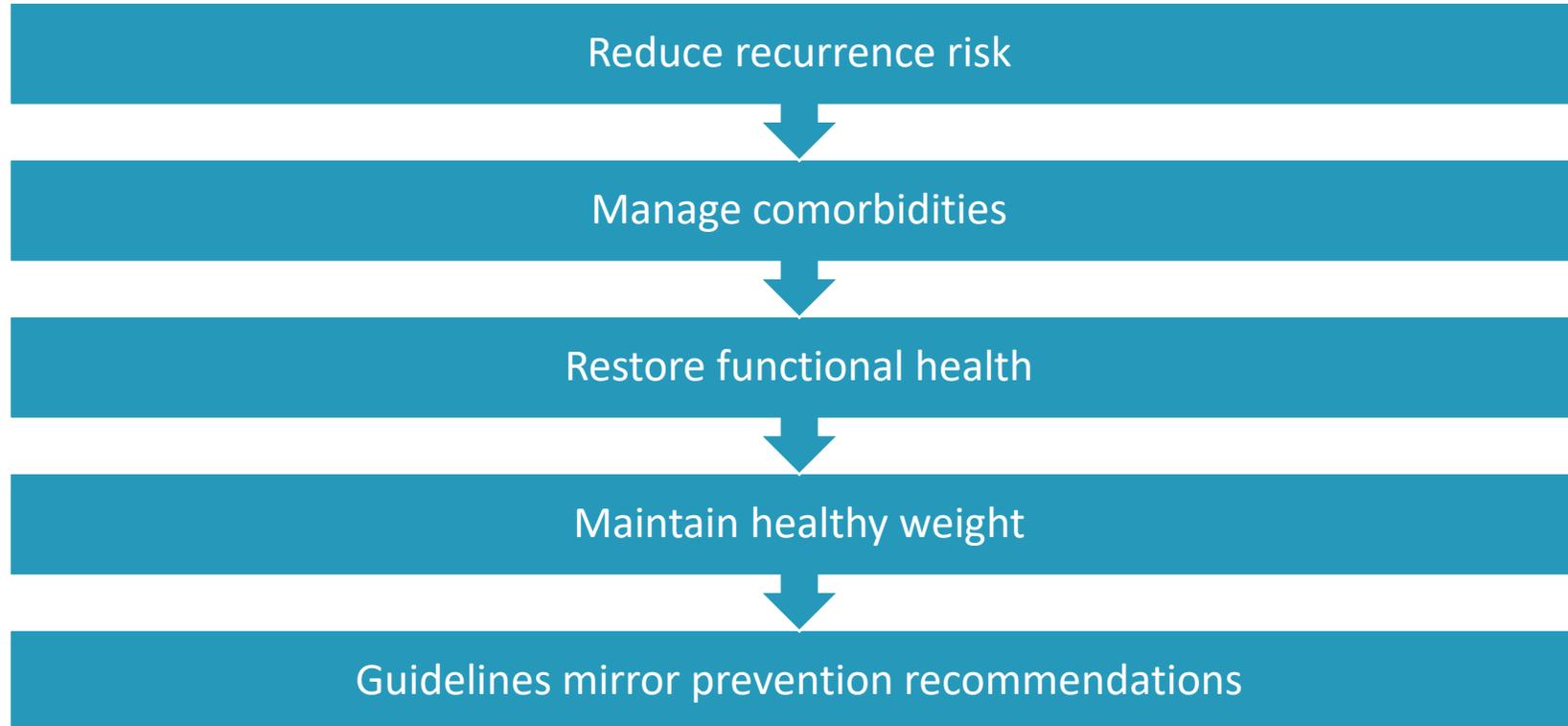
Avoid high-
dose
supplements

No
preventive
evidence

SURVIVORSHIP



Survivorship Nutrition Goals



Evidence in Survivorship

Dietary Pattern following recommendations associated with:

Reduced recurrence risk patterns

Lower risk of new occurrence of nutrition-mediated cancers

Improved long-term outcomes

Opportunities for Population-level Nutrition-Mediated Cancer Risk Reduction Across the Lifespan

Prenatal & Early Life

- Maternal nutrition (WIC, SNAP)
- Breastfeeding (breastfeeding support)
- Healthy complementary feeding (SNAP-Ed, WIC)
- Inflammation/ROS –prevention(WIC, SNAP, SNAP-Ed)

Childhood & Adolescence

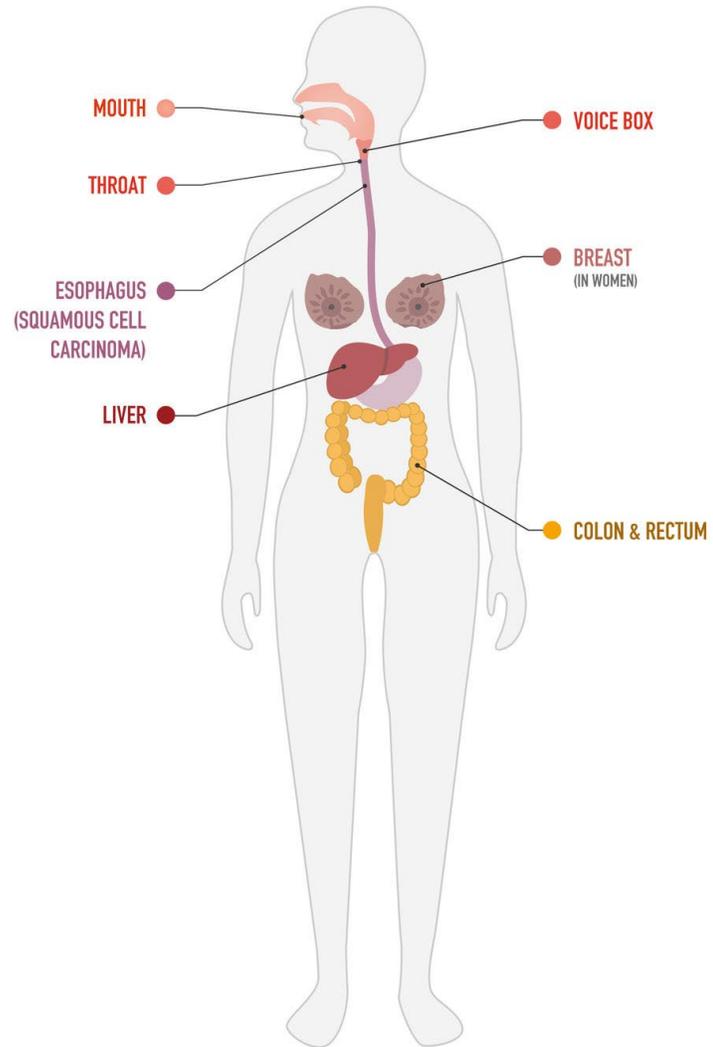
- School food policy (Universal School Lunch, Breakfast Before the Bell, Farm-to-School)
- Sugary beverage reduction
- Physical activity access
- Nutrition education

Opportunities for Population-level Nutrition-Mediated Cancer Risk Reduction Across the Lifespan

Late Adolescence/Young Adulthood

- Address Western patterns
- Support fruit, vegetable, and whole-grain intake
 - Food preparation resources and education
- Promote fiber intake
- Limit ultra-processed foods
 - Support nutrition access and education
- Alcohol messaging
 - Alcohol increases risk of cancer. Period. No matter how much of a “social lubricant”, that does not remove the evidence that alcohol is a known, classified carcinogen, similar to tobacco and asbestos.

Cancers Associated with Drinking Alcohol



cancer.gov/alcohol-fact-sheet

Opportunities for Population-level Nutrition-Mediated Cancer Risk Reduction Across the Lifespan

Midlife

- Concurrent chronic disease management
- Screening uptake (Medicaid)
- Nutritional integrity maintenance (SNAP)
- Maintaining PA through later adulthood

Older Adults

- Maintain muscle mass
- Nutritional adequacy (SNAP)
- Comprehensive chronic disease management (SNAP, Medicare/Medicaid)
- Appropriate screening (Medicare + Medicaid)

Key Public Health and Cancer Prevention Messaging

Key messages for patients:

Physical Activity is Prevention

Plant-forward pattern

Fiber & whole grains

Limit processed/red meat

Limit alcohol

Summary

Nutrition significantly influences cancer risk



Strongest links seen via nutrition-mediated pathways
with strong associations with inflammatory conditions



Prevention and survivorship guidance are aligned for
best public health practice



Nutrition supports treatment — and is not a cure



Evidence base continues to evolve

Margaret Chaykin MPH, CHES, RDN, CD

Pronouns: She/Her/Hers

Breast, Cervical, and Colon Health Program Manager
Community Healthcare Improvement & Linkages

Prevention and Community Health Division

Washington State Department of Health

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Presentation 5

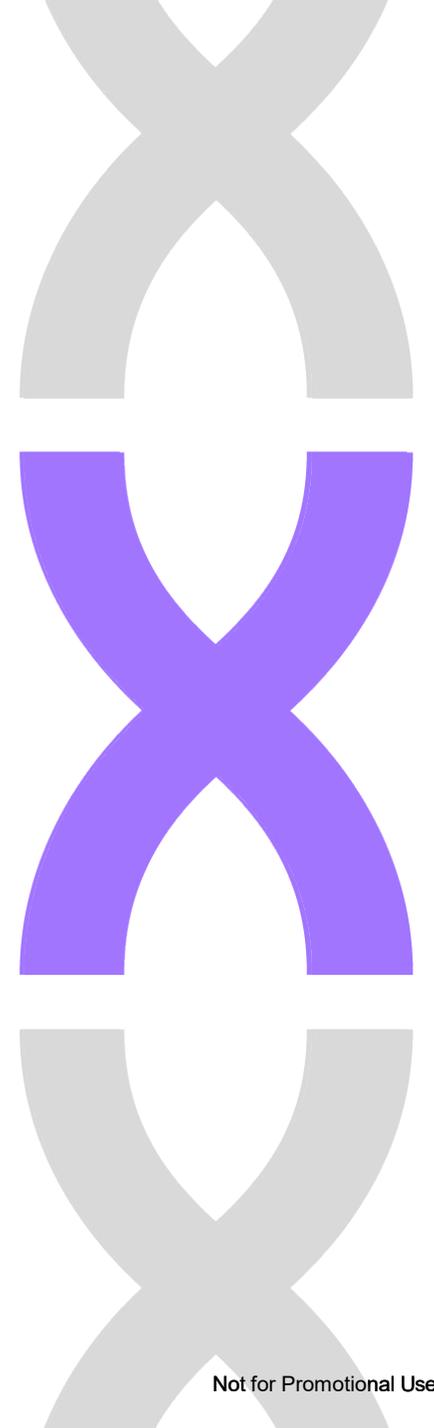
Cologuard Updates

Speaker: **Paul Dorsey, MS, CGC**

Medical Science Liaison

Exact Sciences

The Multi-Target Stool DNA Test: A Colorectal Cancer Screening Option



The Cologuard[®] test and Cologuard Plus[™] test are intended for adults 45 and older at average risk for colorectal cancer and not for those at high risk. All positive results should be followed by colonoscopy.

Do you have any questions related to the Cologuard products' Indications, Contraindications or Warnings and Precautions that I can answer?

The Cologuard[®] Test

Clinical Validation of the Cologuard® Test: DeeP-C Study

DeeP-C was a prospective, cross-sectional, multicenter pivotal study evaluating the performance of the Cologuard test vs FIT* in asymptomatic adults (N=9989) between the ages of 50 and 84, who were considered at average risk for CRC, and who were scheduled to undergo screening colonoscopy

Participants

Key Inclusion Criteria

- Average risk for CRC development
- Age 50 to 84 years
- Able and willing to undergo a screening colonoscopy within 90 days of enrollment

Key Exclusion Criteria

- Had a colonoscopy within the previous nine years
- History of CRC or adenoma
- Had a positive FOBT or FIT within the previous six months

Study Design

Participants provided a **single stool sample**[†]



Laboratory performed the **Cologuard test** and **FIT*** on each stool sample

Participants also underwent screening **colonoscopy**[†] (reference standard)

Outcomes

Primary Endpoint

- Ability of the **Cologuard** test to detect CRC (i.e., adenocarcinoma)
- Disease stage determined by the AJCC staging system

Secondary Endpoint

- Ability of the **Cologuard** test to detect advanced precancerous lesions[‡]
- Comparison of the **Cologuard** test vs commercially available FIT[†] performance in the detection of both CRC and advanced precancerous lesions

*OC FIT-CHEK, Polymedco, Inc.

[†]Done within 90 days of providing informed consent.

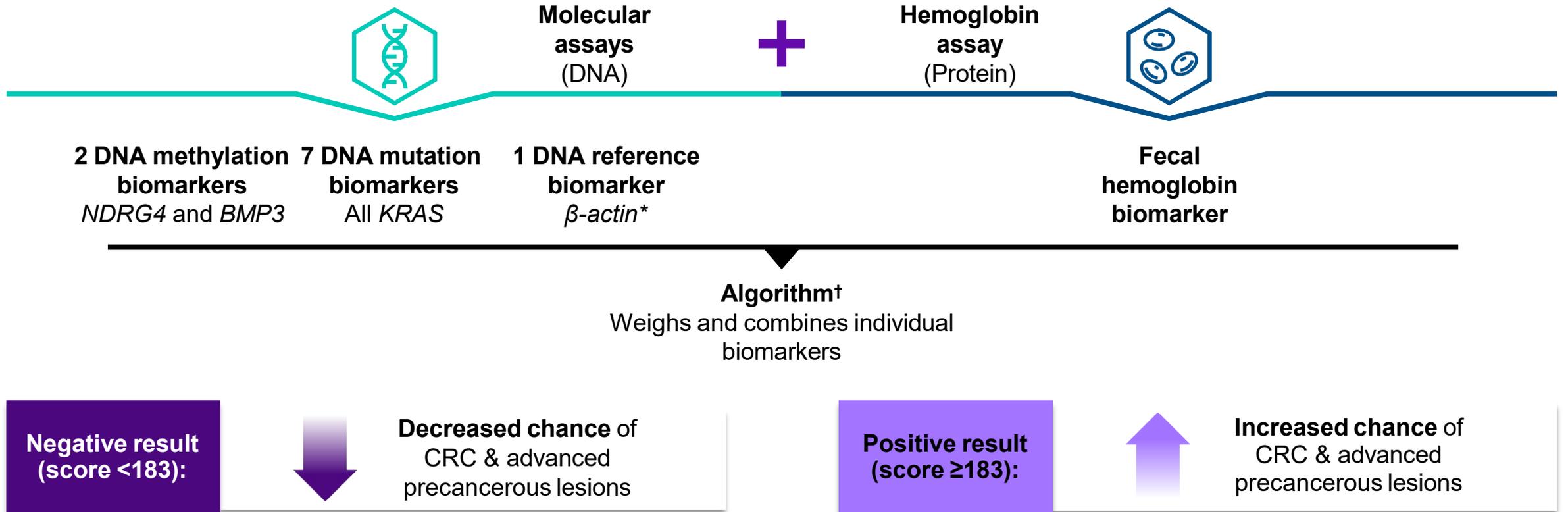
[‡]Advanced precancerous lesions were defined as: adenoma with carcinoma in situ/high grade dysplasia, any size; adenoma, villous growth pattern (≥25%), any size; adenoma ≥1.0 cm in size; or serrated lesion, ≥1.0 cm in size.

AJCC: American Joint Committee on Cancer; **CRC**: colorectal cancer; **FIT**: fecal immunochemical test; **FOBT**: fecal occult blood test.

Imperiale TF, et al. *N Engl J Med*. 2014;370(14):1287-1297.

How the Cologuard[®] Test Works^{1,2}

The multi-target stool DNA (mt-sDNA) test is a noninvasive test which looks for the presence of **10 DNA biomarkers plus hemoglobin** in a stool sample²



*Reference gene for human DNA quantity. †If a result cannot be obtained due to insufficient sample size, low DNA capture, etc., the Exact Sciences Laboratory will automatically request a second sample, at no additional cost to the patient.

AA: advanced adenoma; **BMP3:** bone morphogenetic protein 3; **CRC:** colorectal cancer; **KRAS:** Kirsten rat sarcoma; **mt-sDNA:** multitarget stool DNA; **NDRG4:** N-myc downstream-regulated gene 4.

1. Imperiale TF, et al. *N Engl J Med.* 2014;370(suppl1):1-10,s2-s3. 2. Cologuard Clinician Brochure. Exact Sciences Corporation. Madison, WI.

Sensitivity and Specificity of the Cologuard® Test vs FIT

Most Advanced Finding	Colonoscopy	Cologuard Test (n=9989)		FIT* (n=9989)	
	n	Positive Results, n	Sensitivity, % (95% CI)	Positive Results, n	Sensitivity, % (95% CI)
CRC					
Any	65	60	92.3 (83.0-97.5)	48	73.8 (61.5-84.0)
Stage I-III†	60	56	93.3 (83.8-98.2)	44	73.3 (60.3-83.9)
CRC and high-grade dysplasia	104	87	83.7 (75.1-90.2)	66	63.5 (53.5-72.7)
Advanced precancerous lesions‡	757	321	42.4 (38.9-46.0)	180	23.8 (20.8-27.0)
Nonadvanced adenoma	2893	498	17.2 (15.9-18.6)	220	7.6 (6.7-8.6)
			Specificity, % (95% CI)		Specificity, % (95% CI)
All nonadvanced adenomas, non-neoplastic findings, and negative results on colonoscopy	9167	1231	86.6 (85.9-87.2)	472	94.9 (94.4-95.3)
Negative results on colonoscopy	4457	455	89.8 (88.9-90.7)	162	96.4 (95.8-96.9)

*OC FIT-CHEK, Polymedco, Inc.

†These stages of CRC, as defined by the AJCC, are associated with an increased rate of cure.

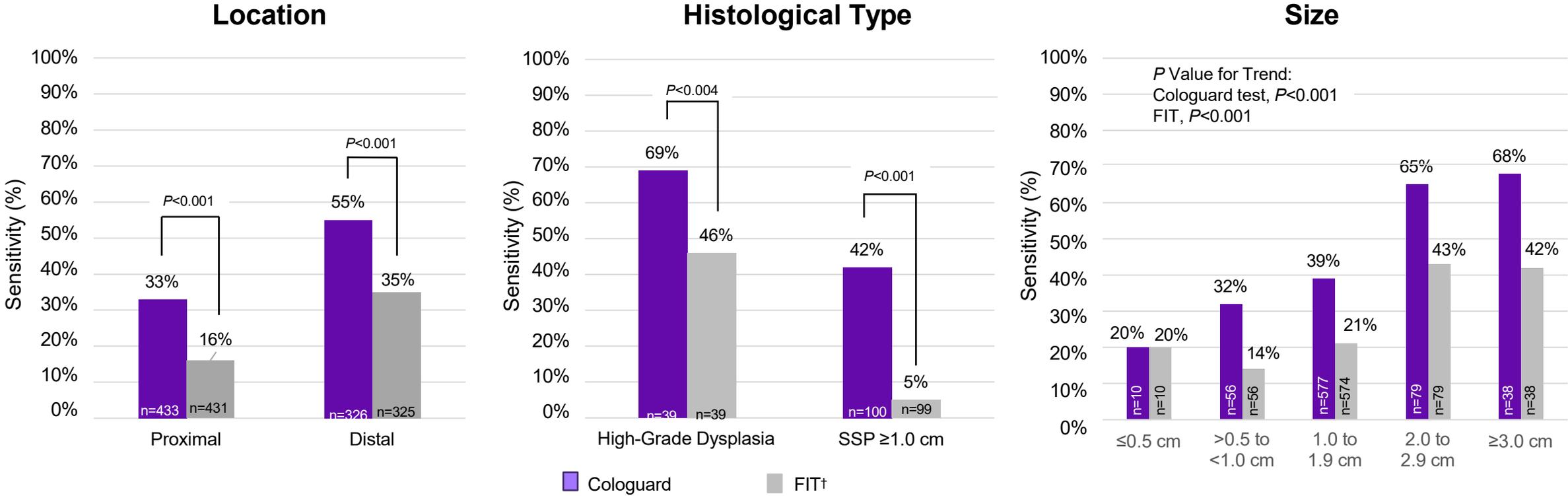
‡Advanced adenoma: colorectal adenoma or sessile serrated adenoma/polyp ≥1.0 cm in diameter, or adenoma with high-grade dysplasia or ≥25% villous component, of any size.

CI: confidence interval; **CRC**: colorectal cancer; **FIT**: fecal immunochemical test.

Imperiale TF, et al. *N Engl J Med.* 2014;370(14):1287-1297.

Sensitivity of the Cologuard® Test and FIT* According to Subgroup

Advanced Precancerous Lesion Sensitivity by Lesion Characteristic^{1,2}



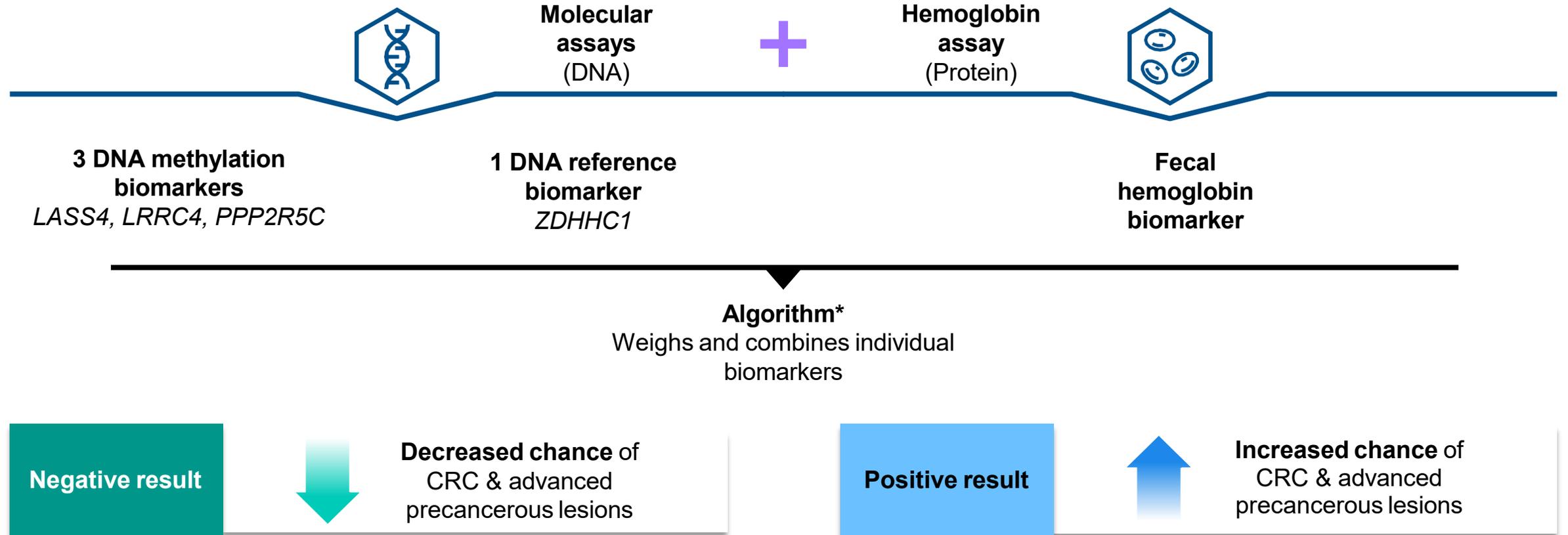
The Cologuard test had higher advanced precancerous lesion sensitivity in both proximal and distal locations, in high-grade dysplasia and SSPs, and in larger lesions compared to FIT.*

*False positives and false negatives did occur in this pivotal study. 13% of patients without colorectal cancer or advanced adenomas received a positive result (false positive), and 8% of patients with cancer received a negative result (false negative)
[†]OC FIT-CHEK, Polymedco, Inc.
AA: advanced adenoma; **CRC:** colorectal cancer; **FIT:** fecal immunochemical test; **SSP:** sessile serrated polyps.
 1. Cologuard Clinician Brochure. Exact Sciences Corporation. Madison, WI. 2. Imperiale TF, et al. *N Engl J Med.* 2014;370(14):1287-1297.

The Cologuard Plus™ Test

How the Cologuard Plus™ Test Works

The multi-target stool DNA (mt-sDNA) test is a noninvasive test which looks for the presence of **4 DNA biomarkers plus hemoglobin** in a stool sample



*If a result cannot be obtained due to insufficient sample size, low DNA capture, etc., the Exact Sciences Laboratory will automatically request a second sample, at no additional cost to the patient.

LASS4: ceramide synthase 4 gene; **LRRC4**: leucine-rich repeat-containing protein 4 gene; **PPP2R5C**: serine-threonine protein phosphatase 2A 56-kDa regulatory subunit gamma isoform gene; **ZDHHC1**: reference marker zinc finger DHHC-type containing 1 gene.

Cologuard Plus Clinician Brochure. Exact Sciences Corporation. Madison, WI.

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Clinical Validation of the Cologuard Plus™ Test: BLUE-C Study

BLUE-C was a prospective, cross-sectional study (N=20,176) that assessed the sensitivity for CRC and specificity for advanced neoplasia using colonoscopy as the reference standard.^{1,2}

Participants (N=18,911) for the FDA-approved label were average risk, asymptomatic adults 45-86 with no first-degree relative with CRC.²

Participants¹

Key inclusion criteria

- Asymptomatic adults ≥40 years of age
- Scheduled for screening colonoscopy

Key exclusion criteria

- Personal history of CRC or APLs
- Medical/Family history of hereditary CRC syndromes
- Inflammatory bowel disease or Cronkhite–Canada syndrome
- A positive result for the Cologuard® test within 2 years or positive FIT or fecal occult blood test within 6 months
- Colonoscopy within 9 years
- Rectal bleeding within 30 days

Study Design^{1,3}

Participants provided a **single stool and blood sample**



Laboratory performed the **Cologuard Plus™ test (including hemoglobin component)** and a separate **FIT*** on each stool sample

Participants also underwent screening **colonoscopy** (reference standard)

Outcomes¹

Primary outcomes

- Sensitivity for CRC
- Specificity for advanced neoplasia (*i.e.*, CRC or APLs[†])

Secondary outcomes

- Sensitivity for APLs[†]
- Comparison of sensitivity for CRC and APLs[†] between the Cologuard Plus™ test and commercial FIT*
- Specificity for non-neoplastic findings or negative colonoscopy

*Polymedco OC-Auto® Micro 80 iFOB Test; positivity cutoff: hemoglobin >100 ng/mL.

†Adenomas with high-grade dysplasia/carcinoma in situ of any size; adenomas with villous growth pattern (≥25%) of any size; adenomas ≥10 mm; serrated lesions ≥10 mm; or hyperplastic polyps ≥10 mm.

CRC: colorectal cancer; **FDA:** Federal Drug Administration; **FIT:** fecal immunochemical test.

1. Imperiale TF, et al. *N Engl J Med.* 2024;390(11):984-993. 2. Cologuard Plus Clinician Brochure. Exact Sciences Corporation. Madison, WI. 3. Imperiale TF, et al. *N Engl J Med.* 2024;390(suppl):S1-S46.

Sensitivity and Specificity of the Cologuard Plus™ Test vs FIT*

Most Advanced Finding	Colonoscopy	Cologuard Plus Test (n=18,882)		FIT* (n=18,882)	
	n	Positive Results, n	Sensitivity, % (95% CI)	Positive Results, n	Sensitivity, % (95% CI)
CRC					
Any	85	81	95.3 (88.4-98.7)¹	60	70.6¹ (59.7-80.0)²
Stage I-III [†]	69	65	94.2 (85.8-98.4) ¹	47	68.1 (55.8-78.8) ³
Advanced precancerous lesions [‡]	1962	849	43.3 (41.1-45.5)¹	457	23.3¹ (21.5-25.3)²
High-grade dysplasia	106	78	73.6 (64.1-81.7) ¹	51	48.1 (38.3-58.0) ³
Sessile serrated lesions ^{**}	235	116	49.4 (42.8-55.9) ³	11	4.7 (2.4-8.2) ³
		(Negative Results)	Specificity, % (95% CI)	(Negative results)	Specificity, % (95% CI)
Absence of advanced neoplasia ^{††}	16,864	15,297	90.7 (90.3-91.1) ¹	15,958 (n=16,837)	94.8 ¹ (94.4-95.1) ²
Non-neoplastic or negative colonoscopy	10,361	9609	92.7 (92.2-93.2) ¹	NR	NR

Age-weighted to the US Population Specificity: 94% (95% CI, 93.2-94.5).²

CRC: colorectal cancer; **FIT:** fecal immunochemical test; **NR:** not reported.

*Polymedco OC-Auto® Micro 80 iFOB Test; positivity cutoff: hemoglobin >100 ng/mL. [†]These stages of CRC, as defined by the AJCC, are associated with an increased rate of cure. [‡]Advanced precancerous lesions: high-grade dysplasia greater ≥10 adenomas, any size; tubulovillous adenoma, any size; tubular adenoma ≥10 mm; sessile serrated lesion with dysplasia; traditional serrated adenoma; conventional adenoma with serrated architecture; sessile serrated lesion ≥10 mm.

**Sessile serrated lesion with dysplasia (SSLD); Traditional serrated adenoma (TSA), Conventional adenoma with serrated architecture, Sessile serrated lesion; ≥10 mm.

††All nonadvanced adenomas, non-neoplastic findings, and negative results on colonoscopy.

1. Cologuard Plus Clinician Brochure. Exact Sciences Corporation. Madison, WI. 2. Data on File. FIT sensitivity and specificity. [October 11, 2024]. Exact Sciences Corporation. Madison, WI. 3. Cologuard Plus Instructions for Use. Exact Sciences Corporation. Madison, WI.

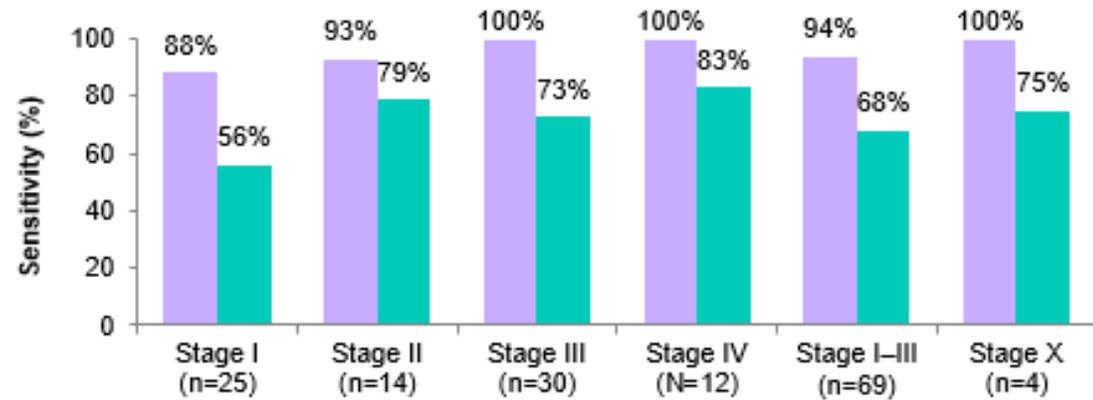
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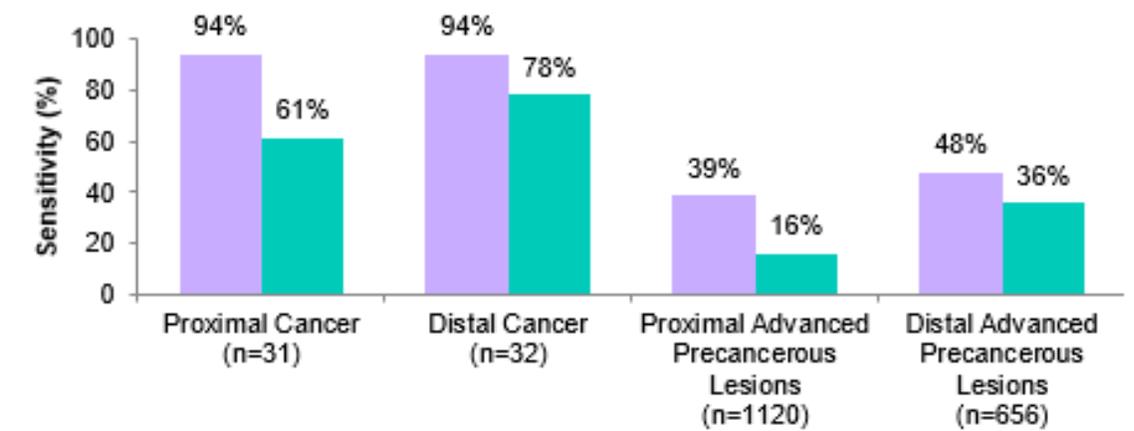
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Sensitivity of the Cologuard Plus™ Test and FIT,* According to Subgroup

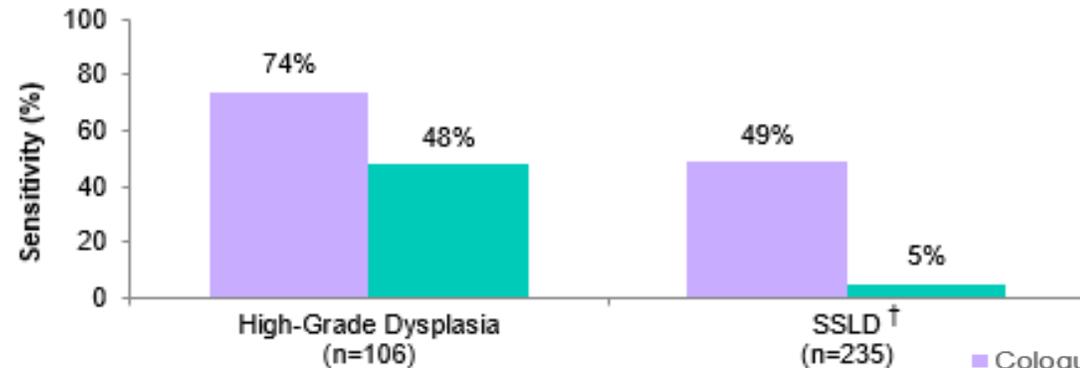
CRC According to Stage[‡]



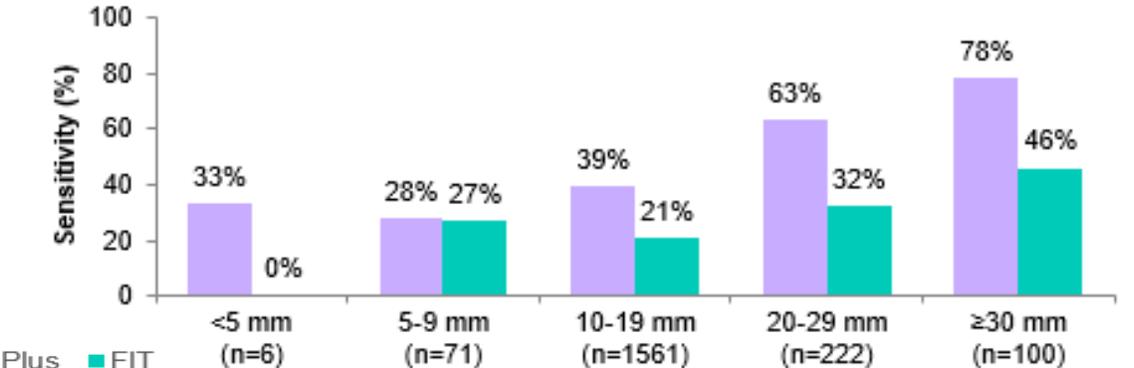
CRC and Advanced Precancerous Lesions[§] According to Location



Higher-Risk Types Among Advanced Precancerous Lesions



Advanced Precancerous Lesions According to Size of Largest Lesion



*Polymedco OC-Auto® Micro 80 iFOB Test; positivity cutoff: hemoglobin >100 ng/mL.

[†]SSLD defined as sessile serrated lesion with dysplasia, traditional serrated adenoma, conventional adenoma with serrated architecture, sessile serrated lesion ≥10mm. [‡]These stages of CRC, as defined by the AJCC, are associated with an increased rate of cure. [§]Advanced precancerous lesions: high-grade dysplasia; greater ≥10 adenomas, any size; tubulovillous adenoma, any size; tubular adenoma ≥10 mm; sessile serrate lesion with dysplasia; traditional serrated adenoma; conventional adenoma with serrated architecture; sessile serrated lesion ≥10 mm.

Colorectal Cancer Screening Adherence by Modality

Data presented in this table were collected in separate studies and are not direct evidence comparing these different screening modalities

Patient Adherence Rate	Colonoscopy	38% ¹ (28–62%) ¹⁻⁴
	The Cologuard [®] Test	71% ⁵
	FIT	39% ⁶ (12–47%) ^{3,7}

FIT: fecal immunochemical test.

1. Singal AG, et al. *JAMA*. 2017;318(9):806-815. 2. Inadomi JM, et al. *Arch Intern Med*. 2012;172(7):575-582. 3. Khalid-de Bakker C, et al. *Endoscopy*. 2011;43(12):1059-1086. 4. Turner BJ, et al. *Ann Intern Med*. 2004;140(7):528-532. 5. Le QA, et al. *Int J Colorectal Dis*. 2025;40(1):16. 6. Vahdat V, et al. Adherence to colorectal cancer screening with fecal immunochemical testing with and without outreach: a systematic review and meta-analysis. Poster presented at: Digestive Disease Week; May 3-6, 2025; San Diego, CA. 7. Dore D, et al. Adherence to FIT-based colorectal cancer screening by health facility type: a systematic review and meta-analysis. Abstract presented at: Digestive Disease Week; May 3-6, 2025; San Diego, CA.

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The mt-sDNA Tests are Included in Major Quality Measures



Uniform Data Systems (UDS) Clinical Quality Measures¹



Healthcare Effectiveness and Information Set (HEDIS[®])^{2,*}



Adult Health Care Quality Measures for Medicaid (Adult Core Set)^{3,4}



ACO Medicare Shared Savings Program (MSSP)⁵



Merit-based Incentive Payment System (MIPS) & Advanced Alternative Payment Model (AAPM)⁶



Electronic Clinical Quality Measures (eCQM)⁷



Medicare Advantage Stars Rating Program⁸

The National Committee for Quality Assurance (NCQA) includes the mt-sDNA test within its HEDIS[®]* quality measures with **3 years** of credit. Blood-based tests are not included in HEDIS[®] quality measures at this time.²

*HEDIS is a registered trademark of the NCQA. Third-party guidelines and quality measures do not specifically “endorse” commercial products, and inclusion in same does not imply otherwise.

ACO: Accountable Care Organization.

1. HRSA Health Center Program. Uniform data system (UDS) clinical quality measures 2025. Accessed June 11, 2025. <https://bphc.hrsa.gov/sites/default/files/bphc/compliance/2025-uds-manual.pdf> 2. NCQA. Colorectal Cancer Screening (COL-E). Accessed July 14, 2025. <https://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality-report/colorectal-cancer-screening-col-e/> 3. CMS. 2025 Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set). Accessed July 14, 2025. https://www.medicaid.gov/medicaid/quality-of-care/downloads/2025-adult-core-set.pdf?sm_vck=4tSF052Q0F527MJk2T52nD6ZJN2DnVnn3FqN3qsFH6N05fnfs475 4. CMS. 2025 Quality Rating System measure technical specifications. April 2024. Accessed July 14, 2025. <https://www.cms.gov/files/document/2025-quality-rating-system-measure-technical-specifications.pdf> 5. CMS. HHS Finalizes Physician Payment Rule Strengthening Access to Behavioral Health Services and Whole-Person Care. Press Release. November 1, 2022. Accessed July 14, 2025. <https://www.cms.gov/newsroom/press-releases/hhs-finalizes-physician-payment-rule-strengthening-access-behavioral-health-services-and-whole> 6. CMS Quality Payment Program. Quality performance category: traditional MIPS requirements. Performance year 2025. Accessed July 14, 2025. <https://qpp-cm-prod-content.s3.amazonaws.com/uploads/31116/2025-Quality-Quick-Start-Guide.pdf> 7. eCQM Resource Center. Colorectal cancer screening 2025 Performance Period. Last Updated May 13, 2025. Accessed July 14, 2025. <https://ecqi.healthit.gov/ecqm/ec/2025/cms0130v13> 8. CMS. Announcement of calendar year (CY) 2025 Medicare Advantage (MA) capitation rates and Part C and Part D payment policies. April 2, 2024. Accessed July 14, 2025. <https://www.cms.gov/files/document/2025-announcement.pdf>

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Thank You!

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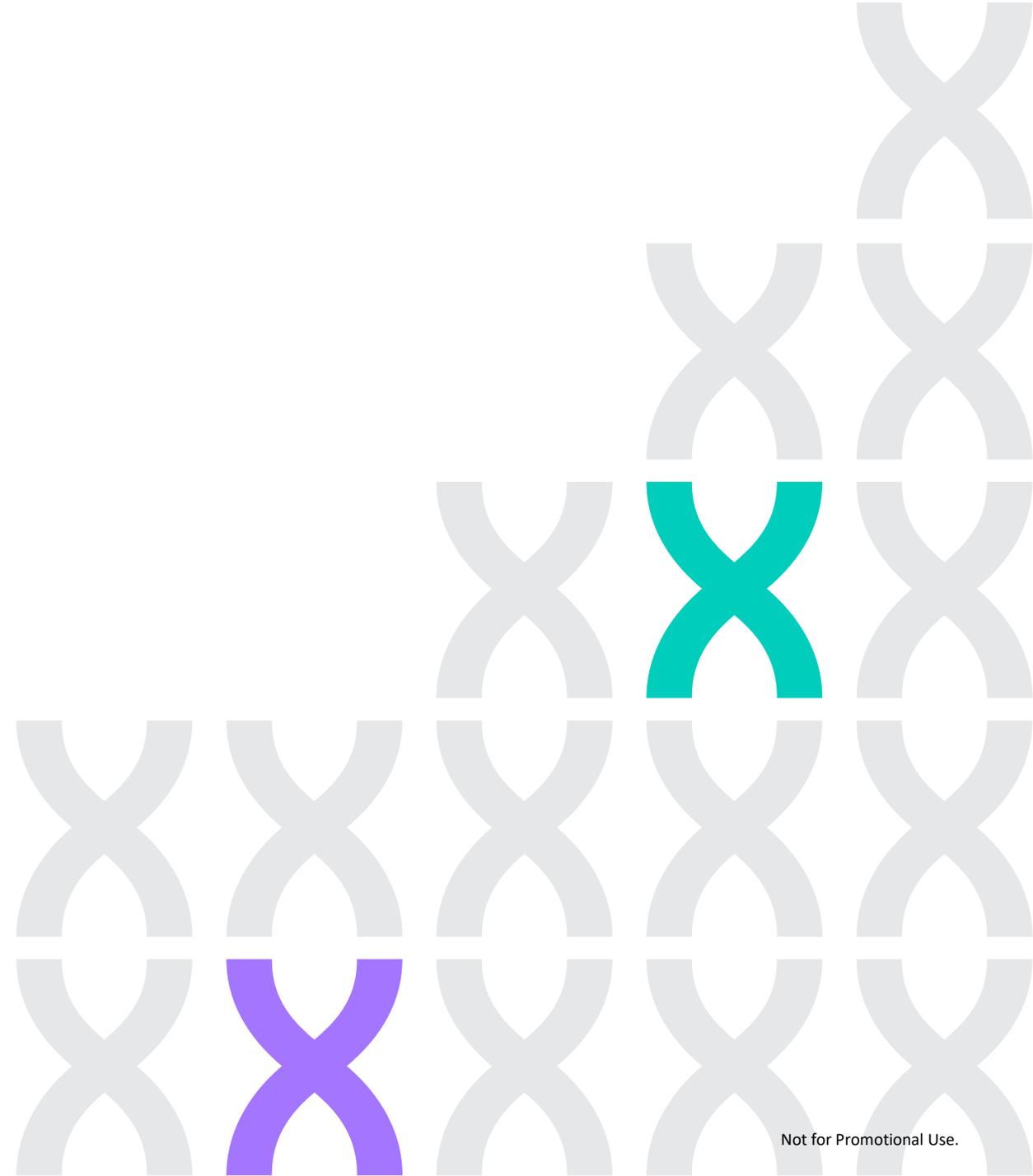
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Cologuard® Indications and Important Risk Information

Indications for Use

The Cologuard® test is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by a colonoscopy. The Cologuard test is indicated to screen adults of either sex, 45 years or older, who are at typical average-risk for CRC. The Cologuard test is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.

Contraindications

The Cologuard® test is intended for use with patients, age 45 years and older, at average risk who are typical candidates for CRC screening. The Cologuard test was not clinically evaluated for the following types of patients:

- Patients with a history of colorectal cancer, adenomas, or other related cancers.
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.
- Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to: Inflammatory Bowel Disease (IBD), Chronic ulcerative colitis (CUC), Crohn's disease, Familial adenomatous polyposis (FAP), or Family history of colorectal cancer.
- Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome, (HNPCCC or Lynch syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcots (or Crails) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis.

Cologuard® Indications and Important Risk Information

Warnings and Precautions

- The performance of the Cologuard® test has been established in a cross sectional study (i.e., single point in time). Programmatic performance of the Cologuard test (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with a Cologuard test. Non-inferiority or superiority of the Cologuard test programmatic sensitivity as compared to other recommended screening methods for CRC and AA has not been established.
- The clinical validation study was conducted in patients 50 years of age and older. ACS Guidelines recommend screening begin at age 45. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.
- CRC screening guideline recommendations vary for persons over the age of 75. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with a healthcare provider. Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program with another recommended screening method. The screening interval for this follow-up has not been established.
- The Cologuard test may produce false negative or false positive results. A false positive result occurs when the Cologuard test produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps. A false negative result occurs when the Cologuard test does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.
- Patients should not provide a sample for the Cologuard® test if they have diarrhea or if they have blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation).
- To ensure the integrity of the sample, the laboratory must receive the patient specimens within 96 hours of collection. Patients should send stool samples to the laboratory according to the instructions stated in the Cologuard Patient Guide.
- Patients should be advised of the caution listed in the Cologuard Patient Guide. Patients should NOT drink the preservative liquid.
- The risks related to using the Cologuard Collection Kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain.

RX Only.

CRC: colorectal cancer; **AA:** advanced adenoma; **mt-sDNA:** multi-target stool DNA.
Cologuard Clinician Brochure. Exact Sciences Corporation. Madison, WI.

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Cologuard Plus™ Indications and Important Risk Information

Indications for Use

- The Cologuard Plus™ test is a qualitative in vitro diagnostic test intended for the detection of colorectal neoplasia-associated DNA markers and for the presence of occult hemoglobin in human stool. The Cologuard Plus test is performed on samples collected using the Cologuard Plus Collection Kit. A positive result may indicate the presence of colorectal cancer (CRC) or advance precancerous lesions (APL) and should be followed by a colonoscopy. The Cologuard Plus test is indicated to screen adults 45 years or older who are at average risk for CRC. The Cologuard Plus test is not a replacement for diagnostic colonoscopy in high-risk individuals.
- The Cologuard Plus test is performed at Exact Sciences Laboratories, Madison, WI.

Contraindications

The Cologuard Plus test is not indicated for use in patients who have the following:

- A personal history of CRC or APLs.
- A positive result from another CRC screening method within the last 6 months, or:
 - 12 months for a fecal occult blood test (FOBT) or a fecal immunochemical test (FIT)
 - 36 months for a FIT-DNA test
- A family history of CRC, defined as having a first-degree relative (parent, sibling, or child) with a CRC diagnosis at any age.
- Personal history of any of the following high-risk conditions for CRC:
 - A diagnosis of Inflammatory Bowel Disease (Chronic Ulcerative Colitis, Crohn's Disease).
 - A diagnosis of a relevant familial (hereditary) cancer syndrome or other polyposis syndrome, including but not limited to: Familial adenomatous polyposis (FAP or Gardner's), Hereditary non-polyposis colorectal cancer syndrome (HNPCC or Lynch), Peutz-Jeghers, MYH-Associated Polyposis (MAP), Turcot's (or Crail's), Cowden's, Juvenile Polyposis, Cronkhite-Canada, Neurofibromatosis, or Serrated Polyposis.

Cologuard Plus™ Indications and Important Risk Information

Warnings and Precautions

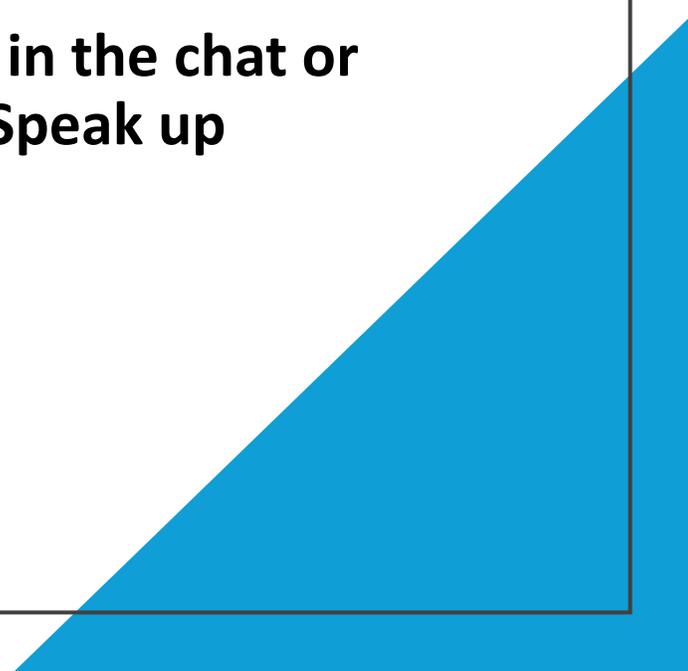
- Patients should not provide a sample if they are experiencing diarrhea or have known blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstrual bleeding). Unexpected bleeding should be discussed with your healthcare provider.
- Reference national guidelines for the recommended screening ages for colorectal cancer. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with your healthcare provider. Cologuard Plus test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- The Cologuard Plus test may produce false negative or false positive results. A false positive result occurs when the Cologuard Plus test produces a positive result, even though a colonoscopy will not find CRC or APL. A false negative result occurs when the Cologuard Plus test does not detect an APL or CRC even when a colonoscopy identifies either of these findings.
 - Out of every 100 patients testing positive, approximately 3 patients will have CRC, 34 patients will have APL, 33 will have a non-advanced adenoma, and 30 will have no neoplastic findings.
 - Out of every 10,000 patients testing negative, approximately 2 will be falsely assured that they do not have CRC. Out of every 100 patients testing negative, approximately 7 patients will be falsely assured that they do not have APL.
- A negative Cologuard Plus test result does not guarantee the absence of CRC or APL. Patients with a negative Cologuard Plus test result should continue participating in colorectal cancer screening programs, at the appropriate guideline recommended intervals.
- The performance of the Cologuard Plus test has been established in a cross-sectional study (i.e., single point in time). Programmatic performance of the Cologuard Plus test (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Non-inferiority or superiority of the Cologuard Plus test's programmatic sensitivity as compared to other recommended screening methods for CRC and APL has not been established.
- To ensure the integrity of the sample, the laboratory must receive the patient specimens within 144 hours of collection. Patients should send stool samples to the laboratory according to the instructions included in the Cologuard Plus Collection Kit.
- Patients should be advised of the caution listed in the Cologuard Plus Collection Kit instructions. Patients should NOT drink the preservative liquid.
- The risks related to using the Cologuard Plus Collection Kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain. Fecal samples should be treated as if they are potentially infectious.

Rx Only.

Share Updates & Upcoming Events

Do you have any Upcoming CRC Events
that you would like to share with the CRC
Task Force Members?

**Feel free to type it in the chat or
Unmute and Speak up**

A blue triangular graphic is located in the bottom right corner of the slide, pointing towards the top right.

March: Colorectal Cancer Awareness Month

• Topic Briefers from NW CRC Task Force :

- What is CRC? Risk Factors, Facts and Figures
- All about CRC Screening
- Early onset of CRC, Lynch Syndrome & Genetic Risk Factors
- Stigma, Fear and Embarrassment about CRC Screening, Culturally and Linguistically Appropriate Resources
- Summary and Prevention Strategies
- Available on: <https://waportal.org/health-initiatives/washington-cares-about-cancer-partnership/northwest-colorectal-cancer-task-force>

• GWU CRC Awareness Month Campaign Toolkit

- <https://cancercontroltap.org/news/colorectal-cancer-awareness-month-campaign/>

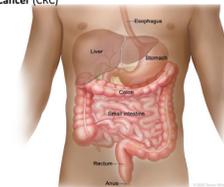
Are there any new materials or resources you would like to share with the Task Force members?

MARCH 2025 COLORECTAL CANCER AWARENESS MONTH

Weekly Topic Briefer

WHAT IS COLRECTAL CANCER (CRC)?

- The **colon** is the large intestine
- The **rectum** connects the colon to the anus and holds waste until it is eliminated from the body
- Cancer that begins in the colon or rectum is called **Colorectal Cancer (CRC)**



Source: National Cancer Institute

HOW DOES IT DEVELOP?

- CRC usually begins as a small **growth or polyp** in the lining of the **colon or rectum**
- Over time these **polyps** can develop into **cancer**
- Many people with polyps or CRC do **NOT** experience any symptoms
- When a **polyp** (noncancerous growth in the lining of the **colon or rectum**) progresses to cancer, it usually grows into the wall of the **colon or rectum**, where it may invade blood or lymph nodes.
- The extent to which cancer has spread at the time of the diagnosis is described as its **stage**.
- **Stages** according to the **Surveillance, Epidemiology and End Results (SEER)** summary system are:
 - **Localized**, grown into the wall of the **colon or rectum** but not into nearby tissue.
 - **Regional**, spread through the wall of the **colon or rectum** and **invading nearby tissues or lymph nodes**.
 - **Distant**, spread to other parts of the body (e.g. liver or lung)



Source: National Cancer Institute

1/2

Northwest CRC Task Force

WEEK: 1 Facts and Figures

- CRC is the **2nd** leading cause of cancer death in the US in both men and women combined (ACS)
- Approximately 153,000 people are diagnosed with CRC in the US annually. (ACS)
- About 52,500 people die annually from CRC in the US. (ACS)

Anyone can get it!

- Men: About 42 new cases per 100,000
- Women: About 31 new cases per 100,000
- Compared to White Americans (about 36 cases per 100,000), we see a higher number of cases among:
 - Alaska Natives (about 89 new cases per 100,000)
 - American Indians (46 new cases per 100,000)
 - Black/African Americans (about 42 new cases per 100,000)

(Data Source: ACS CRC Facts & Figures 2023-2025.)



Source: National Cancer Institute

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Northwest CRC Task Force

MARCH 2025 CRC Awareness Month-Weekly Topic Briefer

WEEK: 3

LYNCH SYNDROME?

- Some colorectal cancers (CRC) are inherited. About 3-5% of all CRCs are due to an **inherited** condition called **Lynch Syndrome**.
- **Lynch Syndrome** (previously referred to as hereditary nonpolyposis colorectal cancer, HNPCC) is an **inherited disorder** that **increases the risk for colorectal, endometrial, and many other types of cancer**.
- Lynch Syndrome is caused by **autosomal dominantly inherited mutations** in the mismatch repair (MMR) genes MLH1, MSH2, MSH6 and PMS2. Most individuals with Lynch Syndrome are undiagnosed.
- **Most individuals** with Lynch Syndrome are **undiagnosed**.
- Individuals with Lynch Syndrome have a significant **increased risk of developing colorectal cancer**.
- **First-degree relatives** of individuals identified with a Lynch Syndrome gene mutation also have a **50% chance** to carry the **mutation**.
- It is **crucial to identify patients with Lynch Syndrome** and their relatives to allow them to **take advantage of interventions** that can significantly **reduce their risk of cancer in the future**.



CLICK ON THE LINKS BELOW TO LEARN MORE:

- [Lynch Syndrome | Washington State Department of Health](#)
- [Cancer Can Run in the Family](#)
- [My Family Health Portrait](#)
- [Hereditary Cancer Resources for Providers](#)
- [Genetic Clinics in Washington and Portland, OR](#)
- [Family Cancer Syndromes | American Cancer Society](#)

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SIGNS OF CANCER SYNDROMES

- Multiple family members with the same type of cancer
- Startle about cancer running in the family
- Family members developed cancer at a young age
- Family members with more than one type of cancer

WHAT IF I HAVE A CANCER SYNDROME?

- You may not have signs or symptoms, but you are at higher risk of developing certain types of cancer
- However, not everyone who inherits a cancer syndrome will develop cancer

UNDERSTAND & REDUCE YOUR RISK

- If cancer runs in your family:
 - Collect your family history of cancer
 - Talk to your doctor about it
 - Encourage family members to talk to their doctors
 - Talk to a genetic counselor about if genetic testing may be right for you
 - Reduce your risk by getting screened for cancer

Image sourced from DODD Lynch Syndrome Integrative.

Facts and Figures

- It is estimated that **1 in 279 individuals** has **Lynch syndrome** but **over 98% are undiagnosed**.
- The **lifetime risk** for colorectal cancer for individuals with Lynch syndrome is **10-80%**, while for an individual without Lynch syndrome, it is 5.5%.
- The risk for a second primary colorectal cancer is 15%-20% at 10 years.
- **Females** with Lynch Syndrome also have a **28%-60% lifetime risk for endometrial cancer**.
- Identifying these undiagnosed individuals has the potential to reduce rates of morbidity and mortality from colorectal cancer.



Cancer Action Plan of Washington

April 2026 Virtual Gathering

- Date: **Thursday, April 30, 2025**
- Time: **10:00 am – 12:00 pm**
- Registration Link: [Meeting Registration - Zoom](#)
- Contact: info@canceractionplanofwashington.com



**Cancer Action Plan
of Washington**

Statewide Coalition

Save the Dates!

- **Northwest CRC Task Force's Upcoming Meetings**
 - May 19th , 2026 (Tuesday) 9:00 am- 11:00 am
 - October 13th , 2026 (Tuesday) 9:00 am- 11:00 am

All meetings will be virtual on Zoom



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Thank you!

