



Understanding Interval Breast Cancers that are Missed by Mammogram Screening

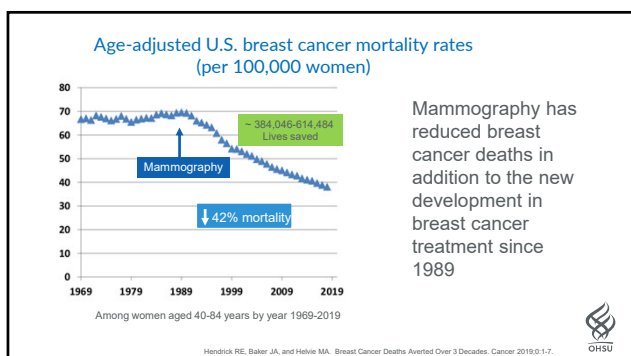
DATE: March 12, 2021 PRESENTED BY: Zhenzhen Zhang, PhD, MPH, MMed

Outlines

- Background of Interval Breast Cancer
- Overview of Women's Health Initiative Study
- Previous Published Research Results
- New Unpublished Research Results
- Ongoing Hospital-based Case-Control Study

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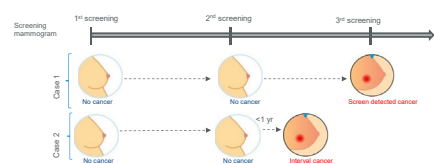
Current Mammogram Screening Guideline

	ACR/SBI	ACS	ACOG	AMA	NCCN	USPSTF
Age to start mammogram	40	45 Option to start at age 40	Offer at 40, no later than 50	40	40	50
Age to stop mammogram	No age limit; tailor to individual health status	When life expectancy is < 10 yrs	Age 75, then shared decision	Not stated	Not stated	74 years
Mammogram interval	Annual	Annual 45-54; Every 1 or 2 yrs 55 and older	Every 1 or 2 years	Annual	Annual	Every 2 years
View on Tomosynthesis (3D) mammogram	Improve cancer detection, reduced recall rates	Improvement in detection, lower chance of recall	Not stated	Not stated	Improves cancer detection, reduces recall rates	Insufficient evidence to support routine use: Grade *1)

Stapleton et al. Race/Ethnicity and Age Distribution of Breast Cancer Diagnosis in the United States. JAMA Surg. 2015. Black, Hispanic, and Asian women have peak incidence of breast cancer in their 40s and should begin screening at least by age 40.
Reference: <https://www.breastcancer.org/about-mammogram-screening-guidelines>



Interval breast cancer

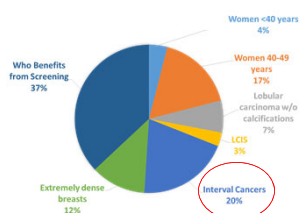


- Definition of Interval cancers:

- Breast cancers that emerge after a non-suspicious mammogram, but before the patient's next scheduled screen (i.e. detected between mammographic screenings with no previous evidence of abnormal findings).



Mammographic screening detects indolent cancers but misses more life-threatening breast cancers



- The percentage of Interval Breast Cancers detected range between 12-26% for annual screens, 17-33% for biennial screens and 32-38% for triennial
- It is expected that the prevalence of Interval Breast Cancers may decrease in coming years due to the increased use of supplemental MRI screening.
- It's sudden appearance identifies interval breast cancer as uniquely aggressive & rapidly progressing disease.
- Factors: tumor biology, masking, life styles





- Largest women's health prevention study ever
- Represented US population, high response rate
- Diverse in geography, socioeconomic status, race/ethnicity
- Multiple time point of mammogram results available for each participant and other repeated interim measures
- Long term follow up data available with comprehensive, standardized assessment of outcomes



What role do hormones and diet play in a woman's risk of getting heart disease, breast and colon cancer, and osteoporosis? You can help find the answer by volunteering to be a study participant in the NIH-funded Women's Health Initiative, the largest studies ever done on women's health. We need your help now — 1997 is the last year for women to join the study. If you're in your 50s or 70s, call today for information. And help take some of the mystery out of the most talked-about women's health study.

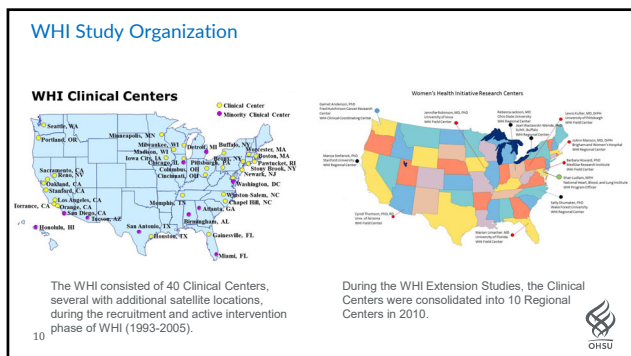
Here's your chance to make a big difference in the lives of women for generations to come. Join us in the Women's Health Initiative, one of the largest studies ever done exclusively on women's health issues.

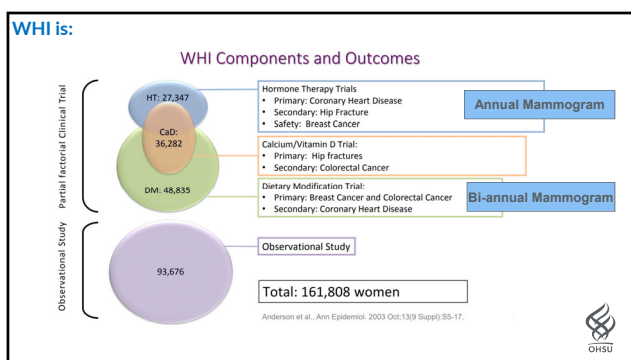
be part of the answer call 1.800.54.WOMEN

Postmenopausal
women aged
50-79 at
enrollment

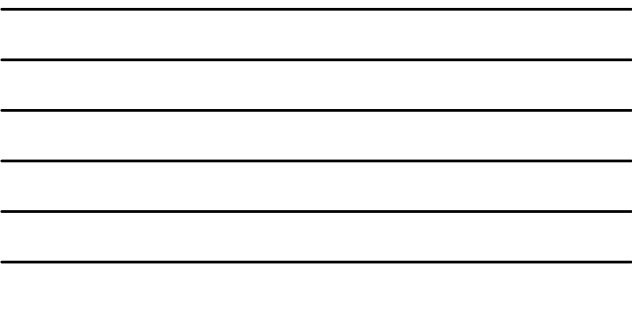
- Initial study period: **1993-2005**
- WHI Extension I: **2005-2010**
- WHI Extension II: **2010-2020**
- Recruitment efforts:
 - Local level at the clinical centers
 - National level at NIH

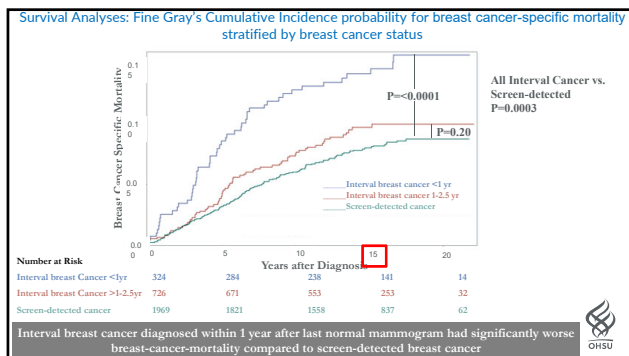












Survival Analysis

Model	Screening-detected	Interval breast cancer <1 yr HR (95% CI)	Interval breast cancer 1-2.5 yr HR (95% CI)
Model 1 ¹	1.00 (reference)	1.13 (1.02-1.25)	1.17 (0.88-1.56)
Model 2 ²	1.00 (reference)	1.21 (1.12-2.29)	1.12 (0.84-1.50)
Model 3 ³	1.00 (reference)	1.22 (1.12-2.33)	1.17 (0.86-1.60)
Model 4 ⁴	1.00 (reference)	1.22 (1.12-2.33)	1.17 (0.86-1.60)
Model 5 ⁵	1.00 (reference)	1.25 (1.03-2.08)	1.12 (0.82-1.53)
Model 6 ⁶	1.00 (reference)	1.24 (0.96-1.65)	1.13 (0.83-1.55)
Model 7 ⁷	1.00 (reference)	1.24 (0.87-1.79)	1.09 (0.78-1.51)

- ¹ This table reports a series of sequential multivariate models where a new variable is added to each model. Numbers in cells represent the Hazard Ratios and 95% confidence intervals computed from the Fine-Gray competing risk model. Time is calculated as the time between diagnosis date and end-of-follow-up. Interval breast cancers were subdivided by their time-screening period: those diagnosed within 1 year of last screen or 1 – 2.5 years since last screen.
- ² Model 1: Fine-Gray Competing Risk Models for breast cancer-specific mortality by breast cancer type adjusting for molecular subtypes in the covariate.
- ³ Model 2 includes all variables in model 1 with additional adjustment for histology.
- ⁴ Model 3 includes all variables in model 2 with additional adjustment for hormone replacement therapy clinical trial arm and dietary modification trial arm.
- ⁵ Model 4 includes all variables in model 3 with additional adjustment for WHR.
- ⁶ Model 5 includes all variables in model 4 with additional adjustment for tumor size.
- ⁷ Model 6 includes all variables in model 5 with additional adjustment for lymph node involvement.
- ⁸ Model 7 includes all variables in model 6 with additional adjustment for other common risk factors for breast cancer (age at diagnosis, race/ethnicity, family history of breast cancer, comorbidity, total number of mammograms before diagnosis, age at menarche, age at first birth, income, education, smoking status, alcohol intake and BMI).
- ⁹ If adding the common risk factors in Model 7 before adding tumor size and lymph node into the model, the corresponding HR (95% CI) = 1.64 (1.14-2.34) for interval breast cancer <1 yr and 1.16 (0.84-1.59) for interval breast cancer 1-2.5 yr.

HR=1.64; 95% CI=1.14-2.33

The elevated risk of death for IBC_{1yr} was dependent on increased tumor size and lymph node involvement, as differences were no longer statistically significant after further controlling for these tumor phenotypes

Clinical Tumor Characteristic Analyses

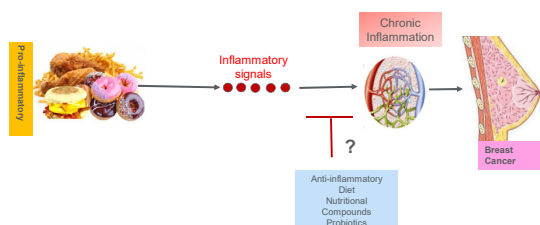
Participant Characteristics	Screening-detected BCa (N=1,867)	All Interval BCa (N=1,882)	p	Interval BCa <1 yr (N=324)	p	Interval BCa 1-2.5 yr (N=728)	p
Tumor size, cm	Mean: 1.62 [1.42 (1.23)]	Mean: 1.65 [1.45]	<0.001	Mean: 1.87 [1.63]	<0.001	Mean: 1.61 [1.45]	0.18
Stage							
In Situ	414 (21.25)	178 (9.44)	<0.001	38 (11.60)	<0.001	140 (19.69)	1.00
Localized	1187 (63.59)	616 (32.69)		180 (56.07)		436 (61.32)	1.00
Regional	336 (17.25)	221 (11.75)		91(28.35)		130 (18.28)	1.00
Distant	11 (0.58)	17 (0.91)		12 (3.74)		5 (0.70)	1.00
Grade							
Well diff	417 (24.51)	210 (11.18)	0.66	58 (17.90)	0.10	183 (25.47)	1.00
Moderately diff	719 (42.03)	394 (20.99)		113 (34.89)		281 (43.30)	1.00
Poorly diff	431 (25.34)	247 (13.11)		88 (27.14)		163 (25.12)	1.00
Anaplastic	138 (8.11)	80 (4.26)		17 (5.23)		52 (8.01)	1.00
LN involvement							
No	1593 (83.01)	802 (42.62)	0.01	223 (68.84)	<0.001	679 (91.90)	1.00
Yes	326 (16.99)	211 (11.38)		100 (30.96)		128 (16.10)	1.00
Molecular Type							
ER+HER2+	768 (40.65)	417 (22.16)	0.50	116 (35.73)	0.11	301 (41.21)	1.00
ER+HER2-	140 (7.52)	80 (4.26)		24 (7.41)		61 (8.36)	1.00
ER-HER2+	54 (2.90)	30 (1.60)		14 (4.32)		16 (2.18)	1.00
Triple Negative	84 (4.51)	80 (4.26)	0.03	21 (6.48)	0.001	59 (8.10)	1.00
Histology type							
Ductal	1566 (79.65)	792 (42.62)	1.00	232 (72.05)	1.00	660 (77.35)	1.00
Lobular	227 (11.55)	137 (7.28)		42 (12.94)		99 (13.45)	1.00
Ductal + Lobular	14 (0.71)	15 (0.80)		7 (2.17)		9 (1.24)	1.00
Others							

Interval breast cancers diagnosed <1 year had significantly larger tumor size, more LN involvement, higher clinical stage and more lobular histology

New Analysis Submitted/Unpublished Yet



Inflammatory Diet and Breast Cancer Development Hypothesis



Dietary Pattern

- The quantities, proportions, variety, or combination of different foods, drinks, and nutrients in diets, and the frequency with which they are **habitually consumed**.
- Empirical hypothesis-oriented patterns
 - Empirical Dietary Inflammatory Pattern (EDIP) score
 - Empirical Dietary Index for Hyperinsulinemia (EDIH) score
 - Empirical hypothesis-oriented dietary patterns combine advantages of a priori and a posteriori methods



Development of the Empirical Dietary Pattern (EDIP) Score

- Sample of 5,230 women in the NHS who donated blood sample in 1989/1990
- Intakes of 39 previously defined food groups as predictors of 3 inflammatory markers in the reduced rank regression model (Hu et al., JNutri 1999)
- Reduced rank regression (RRR) models to derive a dietary pattern predictive of 3 inflammation markers: CRP, IL6, and TNF α R2
- Stepwise linear regression applied to RRR pattern to identify important components
- Components weighted and summed to constitute the EDIP score for each individual

Tabung et al., JNutri (2016)



Food groups for Empirical Dietary Inflammatory Pattern (EDIP) score calculation

Food Groups	Specific Food Intakes
Pro-inflammatory	
Processed meat	Sausages, salami
Red meat	Beef, lamb, hamburger patty
Organ meat	Beef / chicken liver, other organ meats of lamb and beef
Other fish	Canned tuna, fish other than dark-meat fish
Other vegetables	Celery, mushroom, green pepper, corn, eggplant, zucchini, cucumber
Refined grains	White bread, muffin, bagel or roll breads, white rice, pasta, biscuits, noodle
High energy beverages	Soft drinks, other carbonated beverages with sugar or fruit punch drinks
Tomatoes	Fresh Tomato, tomato sauce
Anti-inflammatory	
Tea	Dark tea
Beer	Beer
Wine	Wine
Coffee	Coffee
Dark yellow vegetables	Carrots, winter squash
Leafy green vegetables	Spinach, lettuce, mixed vegetables
Snacks	Potato chips, corn chips, pufak (extruded corn snack), popcorn, cracker
Fruit Juice	Apple, orange, cantaloupe juices
Pizza	Pizza

Tabung et al., JNutri (2016)



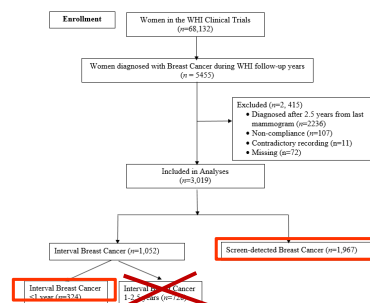
TABLE 1 Components of the EDIP and their correlations with plasma inflammatory markers in the Nurses' Health Study (n = 5230, 1986–1990)

	RRR dietary pattern ¹	EDIP ²	CRP	IL-6	TNF α R2	Weights
RRR dietary pattern ³	1.00	0.96	0.21	0.19	0.15	NA
EDIP ²		1.00	0.21	0.19	0.15	NA
EDIP components ³						
Positive associations						
Processed meat	0.24	0.24	0.08	0.09	-0.0001*	180.03
Red meat	0.22	0.23	0.07	0.08	-0.02	140.15
Organ meat	0.08	0.07	0.06	0.05	0.01*	144.61
Other fish	0.08	0.06	0.05	-0.02*	-0.04	232.45
Other vegetables	0.07	0.07	0.03	-0.002*	0.002*	138.14
Refined grains	0.28	0.28	0.08	0.08	0.02*	81.21
High-energy beverages	0.26	0.26	0.03	0.05	0.01*	156.95
Low-energy beverages	0.18	0.19	0.07	0.05	-0.01*	94.77
Tomatoes	0.15	0.16	0.05	0.02*	-0.002*	167.92
Inverse associations						
Beer	-0.19	-0.19	-0.08	-0.08	-0.12	-136.99
Wine	-0.38	-0.38	-0.12	-0.13	-0.15	-240.70
Tea	0.02*	0.02*	0.01*	-0.02	-0.01*	-42.25
Coffee	-0.46	-0.51	-0.11	-0.07	-0.10	-63.18
Dark yellow vegetables	-0.13	-0.14	-0.02*	-0.06	-0.02*	-166.37
Leafy green vegetables	-0.23	-0.24	-0.02*	-0.07	-0.08	-180.29
Snacks	-0.06	-0.06	-0.004*	-0.02*	0.04	-45.08
Fruit juice	-0.03	-0.04	-0.02*	-0.02*	-0.02*	-58.95
Pizza	-0.07	-0.08	-0.03	0.001*	-0.08	-1175.21

* P > 0.05, Tabung et al., JNutri (2016)



Overview of Case Selection Analyses



Statistical Considerations

- Demographic and clinical variables comparisons between interval breast cancer vs. screen-detected breast cancer using
 - T-test
 - Chi-square test
 - Logistic regression
- Covariates were selected for inclusion in logistic regression models based on univariate analyses as well as common risk factors for breast cancer.



Odds ratios (95% Confidence Intervals) of interval breast cancer associated with tertiles of dietary inflammatory potential (EDIP) and empirical dietary index for hyperinsulinemia (EDIH) scores

Variable	EDIP ¹			EDIH ²		
	Tertile 1 (least inflammatory)	Tertile 2	Tertile 3 (most inflammatory)	Tertile 1 (least insulinemic)	Tertile 2	Tertile 3 (most insulinemic)
Number of participants	748	748	748	748	748	748
Person-Years of Follow-up (Mean, SD)	17.19 (5.68)	17.08 (5.65)	16.38 (5.67)	17.14 (5.68)	16.93 (5.76)	16.58 (5.95)
Mean (SD)	-1.13 (0.76)	0.11 (0.23)	1.07 (0.55)	-0.92 (0.70)	0.15 (0.21)	1.23 (0.73)
Median	-0.93	0.12	0.92	-0.73	0.15	0.98
Min, Max	-7.52, -0.32	-0.32, 0.49	0.48, 5.28	-6.84, -0.22	-0.22, 0.52	0.52, 5.05
Unadjusted OR	1.00 (Reference)	0.90 (0.67, 1.21)	0.99 (0.74, 1.32)	1.00 (Reference)	0.96 (0.72, 1.27)	0.82 (0.61, 1.10)
Adjusted OR Model ³	1.00 (Reference)	0.97 (0.71, 1.32)	1.07 (0.78, 1.48)	1.00 (Reference)	1.00 (0.74, 1.34)	0.92 (0.67, 1.26)

- EDIP scores were adjusted for total energy intake using the residual method 27. Higher (more positive) EDIP scores indicate a more inflammatory diet while lower scores indicate less inflammatory diets.
- EDIH scores were adjusted for total energy intake using the residual method 27. Higher (more positive) scores indicate more highly insulinemic diet (hyperinsulinemia or insulin resistance) while lower (more negative) scores indicate less insulinemic or insulin sensitive diets.
- Adjusted for age at enrollment, race/ethnicity, total energy intake, the Gail risk score, BMI, waist-to-hip ratio, comorbidity, total number of mammograms before diagnosis, income, education, smoking status, and alcohol intake.



Risk Factor Comparisons

Variable	Interval Breast Cancer (N=324)	Breast cancer detected by screening (N=1,969)	P- value
Demographic characteristics			
Age at enrollment, mean (SD), y	63.07 (7.15)	63.24 (6.79)	0.68
BMI (kg/m ²) at enrollment, mean (SD)	28.08 (5.35)	29.46 (5.74)	<0.001
continuous variable			
BMI (kg/m ²) at enrollment, categorical variable			<0.001
Underweight	2 (0.62)	8 (0.41)	
Normal weight	95 (29.32)	439 (22.30)	
Overweight	126 (38.89)	675 (34.28)	
Obese	101 (31.17)	847 (43.02)	
Waist-to-hip ratio at enrollment, mean (SD)	0.81 (0.07)	0.82 (0.08)	0.03
Height (cm)	161.8 (6.48)	162.2 (6.49)	0.25
Gall 5-yr risk score	2.00 (1.22)	1.86 (1.08)	0.03
Family history of breast cancer, No. (%)			0.22
Yes	80 (25.9)	423 (22.7)	
No	229 (74.1)	1441 (77.3)	
Missing	15	105	
Ever full-term birth, No. (%)			0.54
Yes	273 (96.5)	1732 (97.1)	
No	10 (3.5)	51 (2.9)	

Interval breast cancers have lower BMI and Waist-to-hip ratio



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	Odds Ratio				
	Model 1	Model 2	Model 3	Model 4	Model 5
BMI Categories					
Underweight (BMI <18.5)	1.16 (0.24, 5.53)	1.14 (0.24, 5.44)	1.14 (0.24, 5.46)	1.12 (0.23, 5.39)	0.97 (0.20, 4.77)
Normal weight (BMI:18.5-24.9)	1.00 (Ref)	1.00 (Ref)	1.00 (Ref)	1.00 (Ref)	1.00 (Ref)
Overweight (BMI: >24.9-29.9)	0.86 (0.64, 1.16)	0.88 (0.65, 1.18)	0.88 (0.65, 1.19)	0.89 (0.66, 1.20)	0.93 (0.68, 1.26)
Obese (BMI > 29.9)	0.55 (0.41, 0.75)	0.57 (0.41, 0.80)	0.58 (0.42, 0.81)	0.60 (0.43, 0.83)	0.64 (0.45, 0.91)
BMI Continuous Variables					
Per 1 unite increase	0.96 (0.94, 0.98)	0.96 (0.94, 0.98)	0.96 (0.94, 0.98)	0.96 (0.94, 0.99)	0.96 (0.94, 0.99)
WHR					
Per 1 unite increase		0.58 (0.10, 3.32)	0.55 (0.09, 3.18)	0.54 (0.09, 3.13)	0.53 (0.09, 3.14)
Gall 5-year risk					
Per 1 unite increase			1.10 (1.00, 1.22)	1.11 (1.00, 1.22)	1.11 (1.00, 1.22)

1. This table reports a series of sequential multivariate models where a new variable is added to each model. Numbers in cells represent the Odds Ratios and 95% confidence intervals computed from the Logistic Regression model.

- Model 1: Unadjusted model
- Model 2: Model 1 + WHR
- Model 3: Model 2 + Gall 5-year risk score
- Model 4: Model 3 + total dietary energy intake and total energy expended from recreational physical activity
- Model 5: Model 4 + for hormone replacement therapy clinical trial arm and dietary modification trial arm, smoking status, alcohol intake, breast feeding, number of pregnancies, # live births, education and comorbidity



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Multivariate Logistic Regression for Insufficient (>2yr) Mammogram Screening among women 50-75 years old among Probability Sample



The Understanding Cancer in Oregon project aims to understand the cancer-related needs of Oregonians.

<https://www.ohsu.edu/knight-cancer-institute/understanding-cancer-oregon>

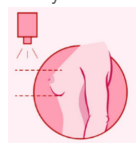
Participant Characteristics	OR (95% CI)	p
Urban-Rural Status		0.99
Urban	1.00 (ref)	
Rural	1.01 (0.48, 2.10)	
Race/Ethnicity		0.12
Non-Hispanic White	1.00 (ref)	
Non-White	2.19 (0.82, 5.84)	
Education		0.90
College graduate	1.00 (ref)	
Not college graduate	1.00 (0.48, 2.12)	
Marital Status		0.51
Married/Living as married	1.00 (ref)	
Divorced/widowed/separated	1.76 (0.44, 4.45)	
Never Married	1.02 (0.42, 2.49)	
Occupation Status		0.85
Employed	1.00 (ref)	
Unemployed/Retired	1.01 (0.45, 2.25)	
BMI		0.01
Under/Healthy weight	1.00 (ref)	
Overweight	1.11 (0.44, 4.45)	
Obese	3.74 (1.46, 9.64)	
Ever Had Cancer		0.98
Yes	1.00 (ref)	
No	0.99 (0.46, 2.10)	
Health Insurance		0.001
Yes	1.00 (ref)	
No	14.04 (2.79, 70.50)	
Smoking		0.72
Never smokers	1.00 (ref)	
Past or current smokers	0.98 (0.56, 1.54)	
Knowledge of Mammogram Screening		0.83
Correct	1.00 (ref)	
Incorrect	1.11 (0.44, 2.80)	
Age (1-year old increase)		0.47
Cancer Risk score (1-point increase)	1.02 (0.56, 1.88)	
	1.00 (0.44, 1.75)	0.97



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Summary of Risk Factors and Interval Breast Cancer Risk

- Inflammatory Dietary Pattern or Hyperglycemic Index Dietary Pattern are not associated with interval breast cancer risk
- Obesity is associated with lower breast cancer risk
- Gail risk score are positively associated with breast cancer risk



Unique Biology

Interval Breast Cancer



Diet, Microbiome and Interval Breast Cancer (DMIBC) Study-----Ongoing



Diet, Microbiome and Interval Breast Cancer (DMIBC) Study: Case-Control Study

Flyer for Cases

Have you... Recently Had a Breast Cancer Diagnosis?

Your diagnosis may be due to self-detection or screening. However, some breast cancer is not found until it has grown large enough to be detected. Within 2 years of your last normal mammogram screening, you may have had a breast cancer diagnosis. You may be eligible for a breast screening mammogram if you are detected with breast cancer.

You may be eligible to join the Diet, Microbiome and Interval Breast Cancer Study

Who May Participate?

- Female
- Age 20-69 years old
- Recent diagnosis of breast cancer (within 2 years of your last normal mammogram)
- No prior cancer history (not including non-melanoma skin cancer)

What is Involved?

- Self-administered questionnaire
- Self-collected stool samples
- Phone call from study team



Flyer for Controls

Have you... Had a normal mammogram within the last two years?

We are looking for healthy, control subjects to participate in a research study at OHSU.

Diet, Microbiome and Interval Breast Cancer Study

Who May Participate?

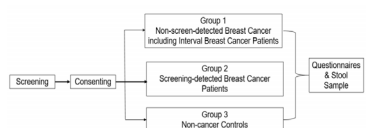
- Female
- Age 20-69 years old
- For 40-69 years old, has had a normal mammogram within 2 years after last normal mammogram
- No prior cancer history (not including non-melanoma skin cancer)
- No prior cancer history (not including non-melanoma skin cancer)

What is Involved?

- Self-administered questionnaire
- Self-collected stool samples
- Email and/or Phone call from study team



DMIBC Study Data Collection



Currently enroll all
newly diagnosed
Breast Cancer
Patients before
Treatment

Questionnaire Components	Administration Mode	Time
Demographic and Lifestyle	REDCap or Paper	~10 mins
Dietary History Questionnaire III	https://epi.grants.cancer.gov/dhq3/ Each participant will have a unique DHQIII Link or Paper	~Up to 30 mins
Arizona Food Frequency Questionnaire	REDCap or Paper	~5 mins
Stool Sample Collection Questionnaire	Paper	~Up to 5 mins
Total		~50 mins



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DMIBC Study Enrollment Status

	Cases (N=53)	Controls (N=43)
Stool Sample Status		
Complete	38 (72%)	42 (98%)
Waiting	6 (11%)	1 (2%)
Not complete due to noncompliance and death	9 (17%)	0 (0%)
Age category		
≤ 50 years old	18 (34%)	9 (21%)
> 50 years old	35 (66%)	34 (79%)
Race/ethnicity		
White	46 (87%)	40 (93%)
Other	7 (13%)	3 (7%)
Education		
Below college graduate	15 (31%)	4 (5%)
College graduate and above	34 (69%)	39 (95%)



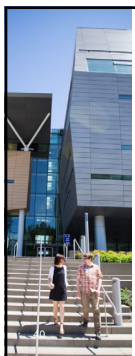
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Breast Cancer Patients Characteristics

Breast Cancer Group	N (Total=53)
General categorization	
Interval Breast Cancer	11 (21%)
Screen-detected Breast Cancer	30 (57%)
Non-screen-detected breast cancer other than Interval breast cancer	9 (19%)
Young screen breast cancer 20-49 years old	3 (6%)
Invasive/in situ	
Invasive	42 (79%)
In situ	11 (21%)
ER status	
ER+	47 (89%)
ER-	5 (9%)
Waiting to be abstracted	1 (2%)
PR status	
PR+	42 (79%)
PR-	9 (17%)
Not documented	1 (2%)
Waiting to be abstracted	1 (2%)
HER2 status	
HER2+	29 (55%)
HER2-	13 (25%)
Not documented/test not domaining	11 (21%)



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Next Steps

- Examine gut microbiome in association with interval breast cancer risk (new recruitment)
- Examine tissue immune profiles in association with interval breast cancer risk (new recruitment)



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Thank You