

# Utilization of OncoType DX Test for Breast Cancer in the Community Setting

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# Background

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- Chemotherapy is recommended for many women with early-stage breast cancer, but the benefit of chemotherapy varies.
- Identifying women who are most likely to benefit from chemotherapy may help with more individualized treatment.
- OncoType DX test evaluates the activity of 21 genes from a tissue sample of LN-, HR+, and HER2- breast cancer to determine the risk of recurrence based on the recurrence score ranging from 0 to 100.

# Background

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- OncoType DX test was added to the 2008 NCCN breast cancer treatment guidelines as an option for the management of women newly diagnosed with LN-, HR+, and HER2- breast cancer.
- For women with a low recurrence score (<18), hormone therapy may be the only adjuvant therapy needed.
- Women with a high recurrence score (>30) may be candidates for chemotherapy in addition to hormone therapy.

# Background

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- Studies on the utilization of OncoType DX test by socioeconomic status (SES) are limited due to incomplete test information in population-based cancer registry data.
- One study using 2008-2010 California Cancer Registry data found that low census-tract SES, black race, and Medicaid insurance were associated with a lower use of OncoType DX test (Cress RD, 2016).
- Carolina Breast Cancer Study III, including cases diagnosed in 2008-2014, found black patients were less likely than white patients to receive the test (Roberts MC, 2016).

# Background

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- To supplement the SEER dataset with more complete and accurate OncoType DX data, NCI linked 2004-2012 SEER data with the test data from Genomic Health Inc. (GHI) in 2015; GHI is the only lab performing the test for the study period.
- The linkage significantly improved the completeness of the test data in SEER data (Dr. Petkov).
  - 41.7% of the tests obtained from the linkage were not captured by SEER registries
  - 57.2% increase in receipt of the test from the baseline SEER data

# Objectives

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- Assess the utilization of OncoType DX test by socioeconomic status (SES) and clinical factors.
- Examine the association of SES and clinical factors with recurrence risk.
- Evaluate the impact of OncoType DX results on use of adjuvant chemotherapy.

# Methods

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- Data sources:
  - SEER-GHI linkage
  - CDC-funded Comparative Effective Research Project
- Eligibility criteria:
  - LN-, HR+, HER2- breast cancers diagnosed in Louisiana in 2010-2012
  - 2011 diagnosed cases only for chemotherapy
- Univariate analysis and multivariable logistic models were employed.

## Use of OncoType DX Test: LN-, HR+, HER2- Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

Variables	OncoType DX (Yes)		OncoType DX (No)		P-value
	Count	%	Count	%	
Total	1,453	38.8	2,296	61.2	
Race					0.0003
White	1,159	40.5	1,700	59.5	
Black	283	32.9	576	67.1	
Other/Unknown	11	35.5	20	64.5	
Age at diagnosis, years					<0.0001
<50	258	47.4	286	52.6	
50 - <60	408	50.2	405	49.8	
60 - <70	504	47.0	569	53.0	
70 - <80	255	30.0	594	70.0	
80+	28	6.0	442	94.0	



## Use of OncoType DX Test: LN-/HR+/HER2-Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

Variables	OncoType DX (Yes)		OncoType DX (No)		P-value
	Count	%	Count	%	
Insurance					<0.0001
No insurance	24	35.8	43	64.2	
Private	798	47.8	871	52.2	
Medicaid	117	24.4	363	75.6	
Medicare and Other Public	370	30.3	850	69.7	
Unknown	144	46.0	169	54.0	
Poverty (census tract level)					<0.0001
0% - <5%	159	46.4	184	53.6	
5% - <10%	356	42.7	477	57.3	
10% - <20%	547	40.0	820	60.0	
20% - 100%	391	32.4	815	67.6	

## Use of OncoType DX Test: LN-/HR+/HER2- Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

Variables	OncoType DX (Yes)		OncoType DX (No)		P-value
	Count	%	Count	%	
<b>Tumor Size (cm)</b>					<0.0001
< 1.0	298	26.7	818	73.3	
1.0 - < 2.0	774	49.1	802	50.9	
2.0 - < 3.0	241	42.7	324	57.3	
≥ 3.0	110	28.4	278	71.6	
Unknown	30	28.8	74	71.2	
<b>Grade</b>					<0.0001
Well differentiated	391	34.9	730	65.1	
Moderately differentiated	733	42.4	997	57.6	
Poorly/Undifferentiated	256	39.9	386	60.1	
Unknown	73	28.5	183	71.5	

## Odds of Not Having OncoType DX Test: LN-/HR+/HER2- Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

Variables	Case count	Crude Odds Ratio and 95% CI	Adjusted Odds Ratio and 95% CI
<b>Race</b>			
White	2859	reference	reference
Black	859	1.39 (1.18 - 1.63)	1.30 (1.08 - 1.57)
Other/Unknown	31	1.24 (0.59 - 2.60)	1.10 (0.48 - 2.53)
<b>Age at diagnosis, years</b>			
<50	544	reference	reference
50 - <60	813	0.90 (0.72 - 1.11)	0.90 (0.72 - 1.14)
60 - <70	1073	1.02 (0.83 - 1.25)	1.07 (0.85 - 1.34)
70 - <80	849	2.10 (1.68 - 2.63)	2.33 (1.80 - 3.02)
80+	470	14.2 (9.38 - 21.6)	16.4 (10.6 - 25.5)

Adjusted logistic regression model included SES (race, age, insurance, and census-tract poverty,) tumor size, and tumor grade).

## Odds of Not Having OncoType DX Test: LN-/HR+/HER2- Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

Variables	Case count	Crude Odds Ratio and 95% CI	Adjusted Odds Ratio and 95% CI
<b>Insurance</b>			
Private	67	reference	reference
No insurance	1669	1.64 (0.99 - 2.73)	1.85 (1.08 - 3.14)
Medicaid	480	2.84 (2.26 - 3.58)	2.55 (2.00 - 3.27)
Medicare and Other Public	1220	2.11 (1.80 - 2.46)	1.17 (0.97 - 1.42)
Unknown	313	1.08 (0.84 - 1.37)	1.17 (0.91 - 1.52)
<b>Poverty (census tract level)</b>			
0% - <5%	343	reference	reference
5% - <10%	833	1.16 (0.90 - 1.49)	1.06 (0.81 - 1.40)
10% - <20%	1367	1.30 (1.02 - 1.64)	1.20 (0.92 - 1.55)
20% - 100%	1206	1.80 (1.41 - 2.30)	1.38 (1.04 - 1.81)

Adjusted logistic regression model included SES (race, age, insurance, census-tract poverty), tumor size, and tumor grade).

## Odds of Not Having OncoType DX Test: LN-, HR+, HER2- Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

Variables	Case count	Crude Odds Ratio and 95% CI	Adjusted Odds Ratio and 95% CI
<b>Tumor Size</b>			
< 1.0cm	1116	reference	reference
1.0 - < 2.0 cm	1576	0.38 (0.32 - 0.45)	0.33 (0.28 - 0.40)
2.0 - < 3.0 cm	565	0.49 (0.40 - 0.61)	0.40 (0.32 - 0.51)
3.0cm +	388	0.92 (0.71 - 1.19)	0.76 (0.57 - 1.00)
Unknown	104	0.90 (0.58 - 1.40)	0.90 (0.56 - 1.45)
<b>Grade</b>			
Well differentiated	1121	reference	reference
Moderately differentiated	1730	0.73 (0.62 - 0.85)	0.78 (0.66 - 0.93)
Poorly/Undifferentiated	642	0.81 (0.66 - 0.99)	0.93 (0.74 - 1.16)
Unknown	256	1.34 (1.00 - 1.81)	1.26 (0.91 - 1.75)

Adjusted logistic regression model included SES (race, age, insurance, and census-tract poverty), tumor size, and tumor grade).

## Distribution of Recurrence Risk based on Recurrence Score (RS) <sup>1</sup>: LN-, HR+, HER2- Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

	Low RS<18	Intermediate RS 18-30	High RS>30	P-value
<b>Total</b>	57.0	35.8	7.2	
<b>Race</b>				0.0387
White	56.6	36.8	6.6	
Black	57.9	32.8	9.3	
Other/Unknown	81.8	0.0	18.2	
<b>Age at diagnosis, years</b>				0.3605
<50	58.2	36.8	5.0	
50 - <60	54.5	38.4	7.1	
60 - <70	55.8	36.0	8.1	
70 - <80	60.9	31.9	7.2	
80+	70.4	18.5	11.1	

RS was from OncoType DX test

## Distribution of Recurrence Risk based on Recurrence Score (RS)<sup>1</sup>: LN-, HR+, HER2- Breast Cancer Cases Diagnosed in 2010-2012, Louisiana

	Low RS<18	Intermediate RS 18-30	High RS>30	P-value
<b>Insurance</b>				0.2708
No insurance	37.5	50.0	12.5	
Private	57.2	35.7	7.1	
Medicaid	59.5	28.8	11.7	
Medicare and Other Public	57.4	36.2	6.4	
Unknown	56.7	38.1	5.2	
<b>Poverty (census tract level)</b>				0.9913
0% - <5%	60.0	33.8	6.2	
5% - <10%	56.3	36.2	7.5	
10% - <20%	56.6	35.8	7.5	
20% - 100%	57.1	36.0	6.9	

RS was from OncoType DX test.

Distribution of Recurrence Risk based on Recurrence Score (RS) <sup>1</sup>  
LN-, HR+, HER2- Breast Cancer Cases Diagnosed  
in 2010-2012, Louisiana

	Low RS<18	Intermediate RS 18-30	High RS>30	P-value
<b>Tumor Size (cm)</b>				0.108
< 1.0	55.1	40.3	4.6	
1.0 - < 2.0	59.1	34.1	6.8	
2.0 - < 3.0	53.0	35.8	11.2	
≥ 3.0	54.0	37.0	9.0	
Unknown	65.5	31.0	3.4	
<b>Grade</b>				<0.0001
Well differentiated	66.9	31.4	1.6	
Moderately differentiated	59.9	34.5	5.6	
Poorly/Undifferentiated	32.6	45.4	22.0	
Unknown	51.6	41.9	6.5	

RS was from OncoType DX test



## Odds of Receiving Chemotherapy by Recurrence Risk (RS)<sup>1</sup> among LN-, HR+, HER2- Breast Cancer Cases Diagnosed in 2011, Louisiana

Recurrence Risk	Case count	Crude OR (95% CI)	Adj OR <sup>2</sup> (95% CI)
No OncoType DX test	794	Reference	Reference
Low (RS<18)	275	0.17 (0.09-0.33)	0.08 (0.04-0.16)
Intermediate (RS 18-30)	168	2.90 (2.03-4.13)	2.04 (1.31-3.17)
High (RS>30)	42	20.8 (9.06-47.7)	20.0 (6.95-57.7)

1. Recurrence risk was based on the recurrence score from OncoType DX test

2. Adjusted logistic regression model included SES (race, age, insurance, census poverty, tumor size, and tumor grade).

# Summary/Discussions

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- Use of OncoType DX test varied by SES. Black race, old ages ( $\geq 70$  years), no insurance or Medicaid, high census tract poverty ( $\geq 20\%$ ) are significantly associated with lower use of OncoType DX test after adjustment.
- Recurrence risk varied among those receiving OncoType DX test. Black race, no insurance or Medicaid, and large tumor size ( $\geq 2$  cm), poorly/undifferentiated grade are more likely to have a high recurrence risk (RS  $> 30$ ).
- Results of OncoType DX test appear to guide the use of chemotherapy. The odds of receiving chemotherapy is significantly higher among those with intermediate (RS:18-30) and high recurrence (RS $>30$ ) scores, as compared with those with low recurrence score (RS $<18$ ) or without test.

## Summary/Discussions

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- Our findings are consistent with prior reports in regards of the association of lower SES with lower use of OncoType DX.
- One possible explanation/reason for no OncoType DX test could be that some oncologists consider the test is not necessary because chemotherapy use or not use is determined based on tumor characteristics.
- However, tumor characteristics such as tumor size and grade may not adequately reflect the recurrence risk. OncoType DX test provides additional information to help individual decision-making regarding chemotherapy use.

## Limitations

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- 2.4% of the OncoType DX test had no results due to various reasons such as failed test, cancelled tests, etc.
- Only be able to assess the impact of OncoType DX results on use of adjuvant chemotherapy for 2011 diagnosed cases.
- Did not include facility type in analysis.

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## Receipt of Chemo by Recurrence Risk (RS)<sup>1</sup>: LN-/HR+/HER2- Breast Cancer Cases Diagnosed in 2011, Louisiana

	No	Low (RS<18)	Intermediate (RS 18-30)	High (RS>30)
<b>Total</b>	19.4	4.0	41.1	83.3
<b>Tumor Size (cm)</b>				
< 1.0	4.9	5.5	48.6	50.0
1.0 - < 2.0	17.3	1.9	36.1	87.0
2.0 - < 3.0	37.7	10.9	39.3	80.0
≥ 3.0	50.0	0.0	50.0	100.0
Unknown	0.0	0.0	50.0	0.0
<b>Grade</b>				
Well differentiated	6.6	2.2	36.1	50.0
Moderately differentiated	18.2	4.6	42.9	84.2
Poorly differentiated	45.0	5.0	47.2	89.5
Unknown	23.0	11.1	25.0	50.0

RS was from OncoType DX test