

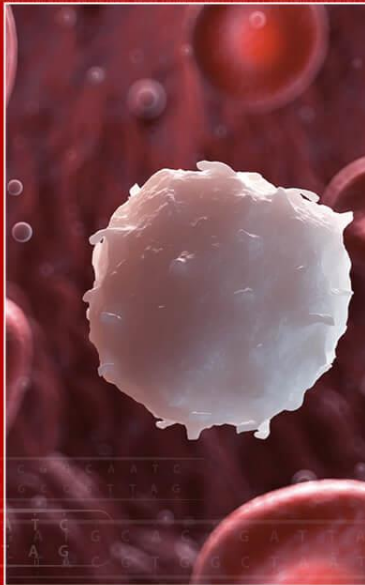
The Evidence Base for Patient Navigation

Electra D. Paskett, Ph.D.
November 13, 2017

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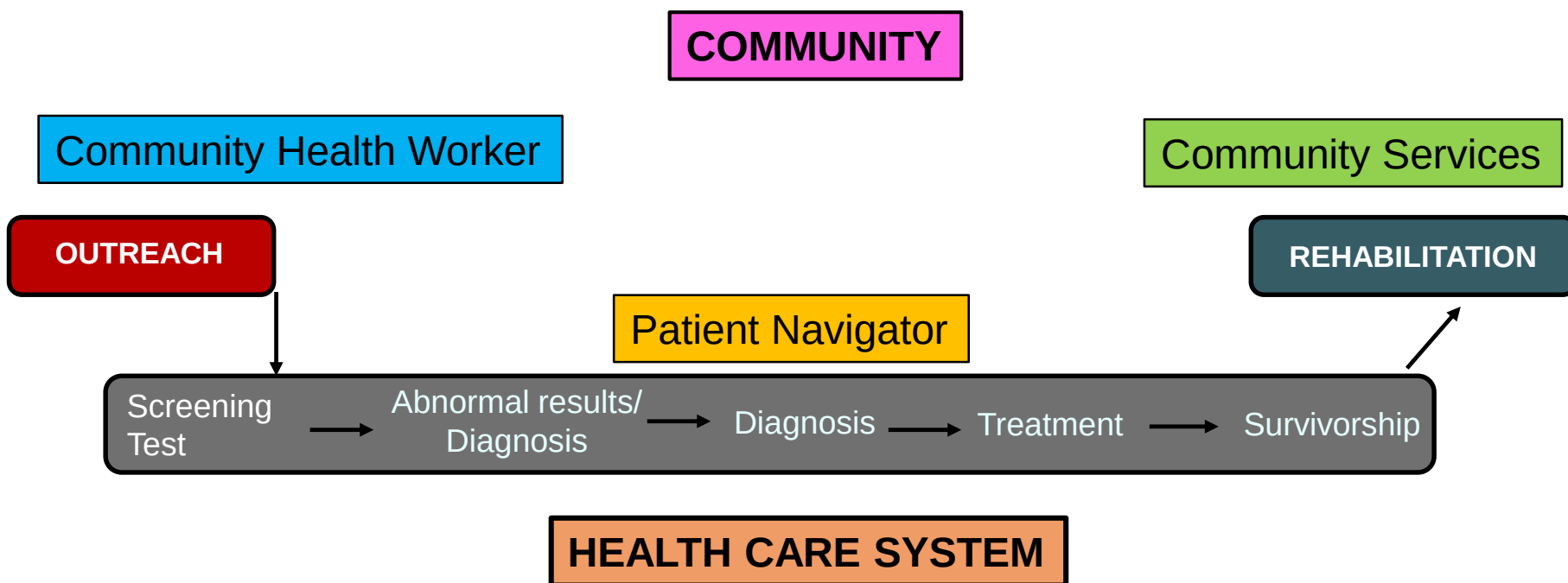


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Focus of Presentation

- Review the scientific basis for Patient Navigation (PN) across the cancer continuum
- Explore the opportunities to generate additional evidence about PN programs



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Case Presentation

- Mrs. Jones: 33 yo Black woman with cervical abnormality (HGSIL) on routine Pap test. OB/GYN recommended colposcopy within 6 weeks. No other health issues. Has 5yo twins. College education; working.
- Mr. Smith: 51 yo Black man, presented with rectal bleeding and pain. PCP recommended colonoscopy ASAP. Hx of mental health issues, no transportation, difficulty understanding instructions. Lives alone.

Who returned for follow-up?

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Case Presentation

- Mr. Smith: 51 yo Black man, presented with rectal bleeding and pain. PCP recommended colonoscopy ASAP. Hx of mental health issues, no transportation, difficulty understanding instructions. Lives alone.
- Because he had a Navigator:
 - Coaching to take prep as instructed
 - Went to the hospital to accompany the patient home
 - Phone calls to his doctor's office, scheduling and transportation at OSU East
 - 5cm polyp removed on successful colonoscopy
 - Encouraged to be his own navigator

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Does the Interval Between Confirmed Diagnosis of Breast Cancer and Treatment Initiation for Breast Cancer Impact Outcome Among Low-Income Women?

Policy Impact Among Underserved Populations



A. Ferketich



E. Paskett



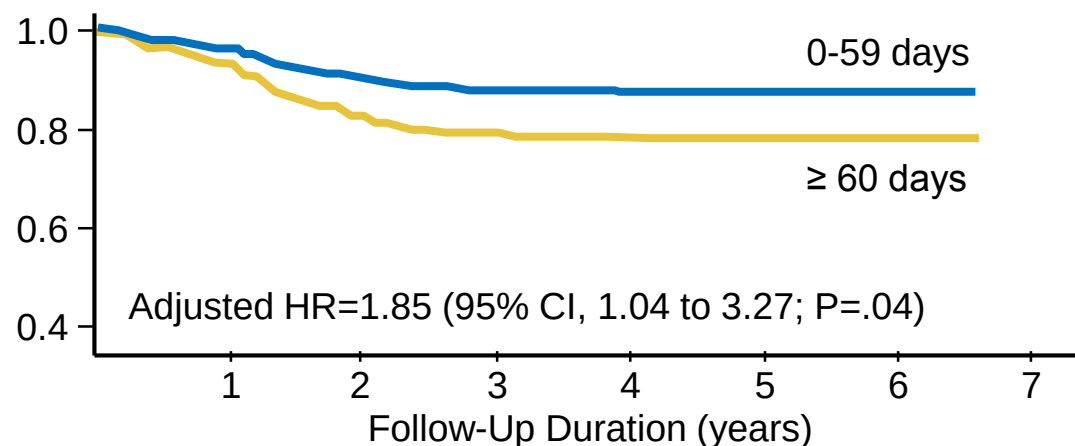
E. Seiber



Waiting 60 days to initiate treatment was associated with a significant (66% and 85%) increased risk of overall and breast cancer–related death, respectively, among late-stage, low income patients.

JCO 2012

Breast Cancer-Specific Adjusted Survival (probability)



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Underlying Premise of PN

- PN will get patients into the health care system (ever or faster)
- Abnormalities will be resolved or cancers will be treated earlier
- Address barriers to care:
 - System-level
 - Provider-level
 - Patient-level – including the Social Determinants of Health
- Resulting in better outcomes:
 - Morbidity and mortality (*McLaughlin et al, JCO, 2012*)
 - Quality of care/satisfaction
 - Costs

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Why Do We Need a Scientific Base for PN?

- Evidence-based interventions are needed
 - For implementation into clinics
- To assure reimbursement for services
 - Affordable Health Care Act
 - ACOS Accreditation
 - Insurance
- Sources
 - Before Patient Navigation Research Program (PNRP)
 - PNRP
 - After PNRP

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Does Navigation Make a Difference? Before PNRP

- Data from randomized clinical trials sparse
- Observational data supported navigation
- Navigation studied along some points of the cancer continuum and not others
- Certain cancer sites did not receive attention
- Much of the work had been qualitative

Paskett, Harrop, Wells, CA J Clin, 2011

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The Patient Navigation Research Program (PNRP)



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PNRP Grantee Map

Victoria Warren-Mears
Northwest Portland Area
Indian Health Board

Steven T. Rosen
Northwestern University
Elizabeth Calhoun
University of Illinois at Chicago

Electra Paskett
Ohio State University

Kevin Fiscella
University of Rochester
Medical Center

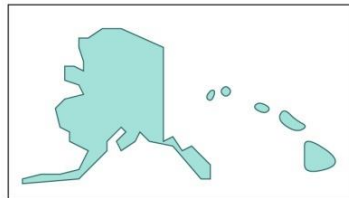
Peter Raich
Denver Health
and Hospitals
Authority

Karen Freund
Boston University

Steven R. Patierno
The George Washington
University Cancer Institute

Donald Dudley
University of Texas,
Health Science Center
at San Antonio

Richard Roetzheim
H. Lee Moffitt Cancer
Center and Research Institute



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Continuum of Navigation in PNRP

Prevention

Abnormal Screen → Diagnosis (T1)

Cancer Diagnosis → Treatment Start (T2)

Throughout Treatment

Survivorship

Palliative Care

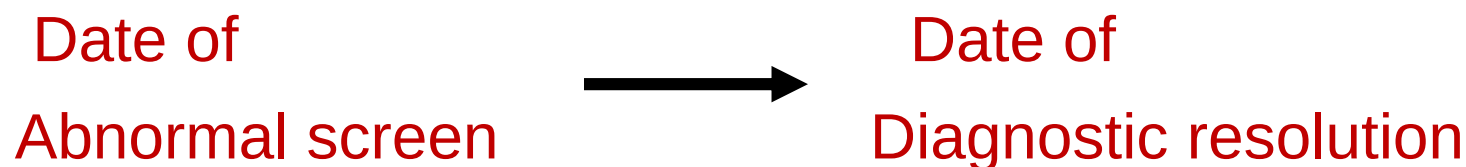
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Methods

- Time to diagnostic resolution defined:



- Different study designs across PNRP sites
- Prospective Meta-analysis
- Outcomes:
 - Time to resolution (TTR)
 - 0-90 days and 91-365 days

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Sample Size by Screening Abnormality

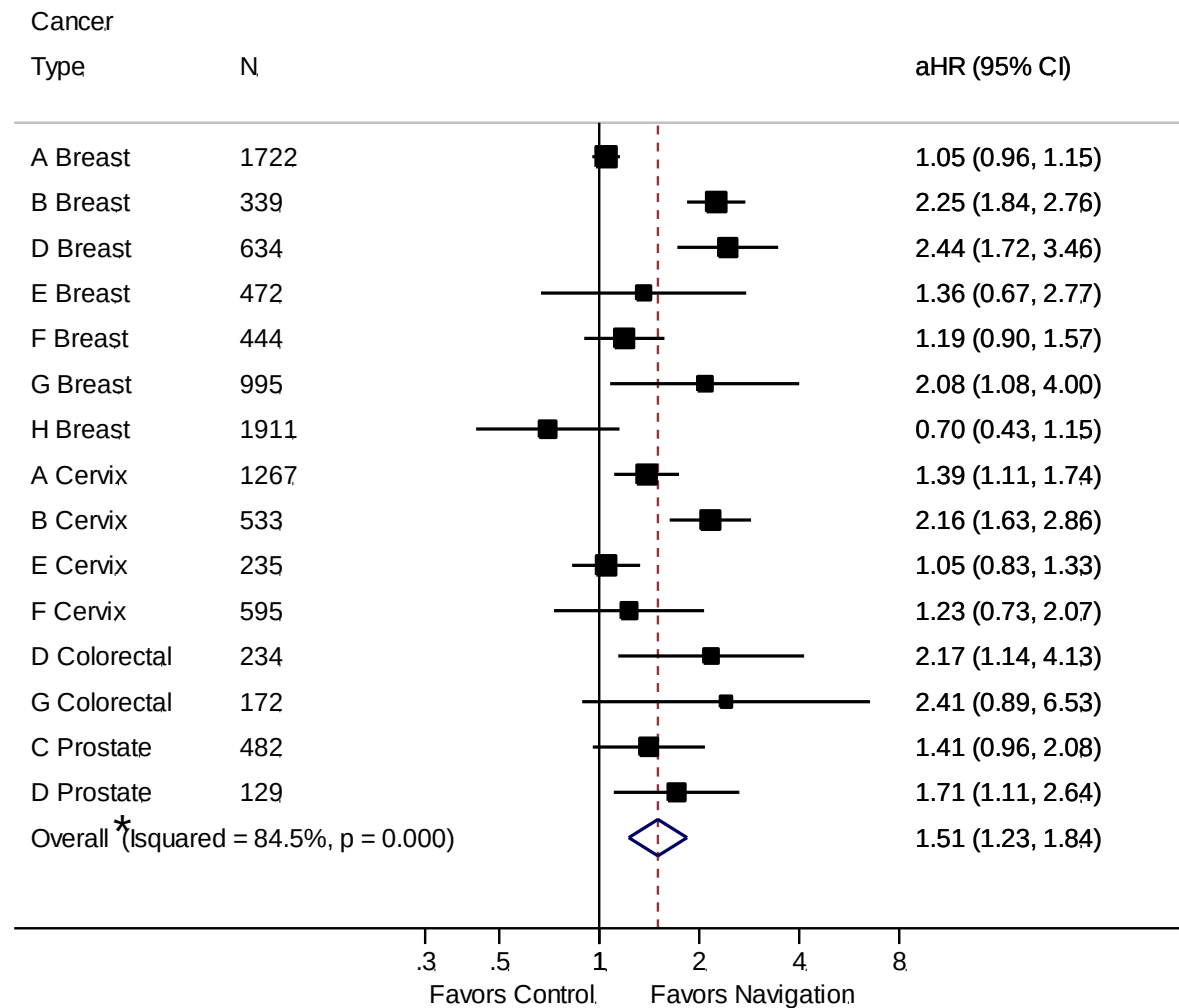
Abnormal Screen	Intervention Arm N	Control Arm N	Total N (%)
Breast	3,075	3,643	6,718 (64)
Cervical	1,455	1,226	2,681 (26)
Colorectal	192	244	436 (4)
Prostate	306	311	617 (6)
Total	5028	5424	10,452

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Demographic Covariates

Variable	Value	Outcome 1 Diagnostic Evaluation (N=10,521)			
		Intervention		Control	
		N	(%)	N	(%)
Race /Ethnicity	White	1,224	24%	1,370	25%
	African American	1,487	29%	1,843	34%
	Hispanic	2,142	42%	1,964	36%
	Other	207	4%	185	3%
Insurance	Private	1,202	24%	1,599	29%
	Public	1,969	39%	2,290	42%
	Uninsured	1,837	36%	1,548	28%
Gender	Female	4,665	92%	5,006	92%
Marital	Married	1,772	35%	1,588	29%
Age (yrs)	Mean $\pm$ SD	43.6 $\pm$ 14.8		47.2 $\pm$ 14.9	
Cancer Type	Breast	3,083	61%	3,643	67%
	Cervical	1,455	29%	1,226	22%
	Colorectal	219	4%	278	5%
	Prostate	306	6%	311	6%
Freund et al, JNCI 2014					

Meta-analysis of Impact of PN on Diagnostic Resolution after Cancer Screening Abnormality from 91 - 365 Days



Freund et al, JNCI 2014

*I squared addresses the heterogeneity of the model, and is not the overall effect of the intervention

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Continuum of Navigation in PNRP

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Abnormal Screen → Diagnosis (T1)

Cancer Diagnosis → Treatment Start (T2)

Throughout Treatment

Survivorship

Palliative Care

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Impact of Navigation during Diagnostic and Treatment Phases

Time to Start of Treatment

	Days 0 – 90 Adjusted HR (95% CI)	Days 91-365 Adjusted HR (95% CI)
Diagnostic phase	1.1 (0.96 – 1.3)	1.5 (1.2 – 1.8)
Treatment phase	0.85 (0.7 – 1.01)	1.4 (1.1 – 1.9)

Freund et al, JNCI 2014

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Who Benefits from Patient Navigation?



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How to Decide Who needs PN?

- Who is at risk of delay/loss to follow-up?
- Who has barriers?
- Who is helped most by navigation?

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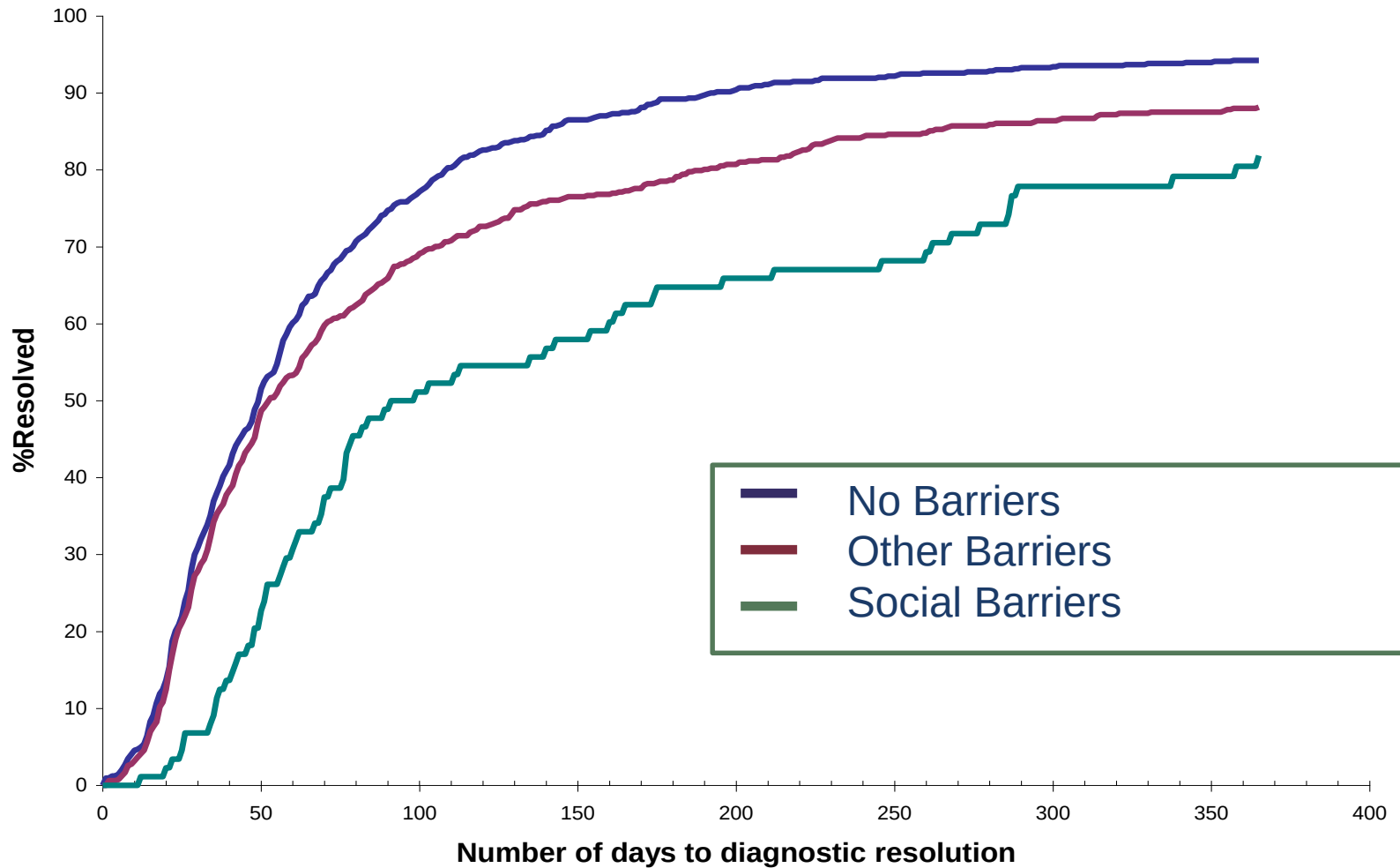
Delay/loss to Follow-up

- Who is at risk of delay/loss to follow-up?
 - More co-morbidities
 - **Barriers to care**
 - Incomes <\$10,000
 - Unemployed
 - Less education
 - Renters vs homeowners
 - Non-married
 - 2+ dependents

Katz et al, WHI 2014

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Types of Barriers to Care and Delay in Time to Diagnostic Resolution



Primeau et al, J Gen Med 2014

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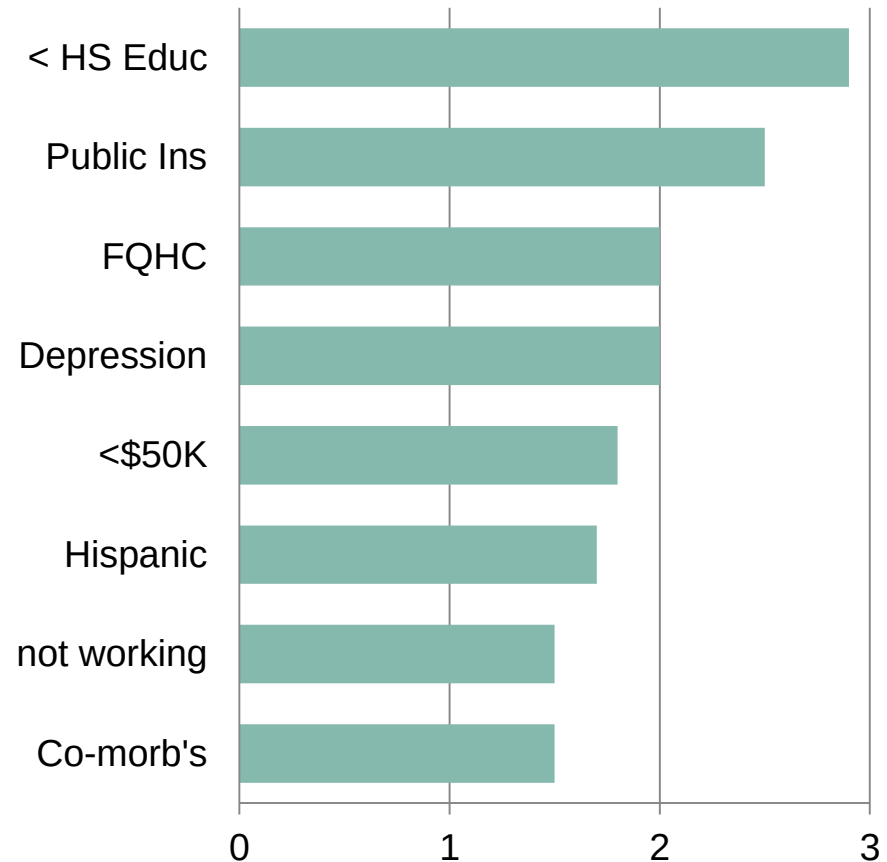
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Who Reports a Barrier?

Using data from Ohio PNRP those who are more likely to report barriers include:

- Non-white, lower educated, unemployed/retired, income <\$50K
- Uninsured, comorbidities

Odds of Reporting a Barrier to Care



Krok et al, Cancer 2015

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Who Does PN Help the Most?



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Navigation Eliminated Disparities by Income

Household Income	Adjusted HR for Control Arm (95% C.I.)	Adjusted HR for Navigation Arm (95% C.I.)
< \$10,000	0.81 (0.64, 1.02)	0.96 (0.76, 1.21)
\$10,000 – \$19,999	0.90 (0.71, 1.16)	1.06 (0.83, 1.34)
\$20,000 - \$49,999	0.87 (0.68, 1.10)	1.09 (0.87, 1.36)
\$50,000 +	Ref.	0.95 (0.75, 1.19)

Rodday et al, Cancer 2015

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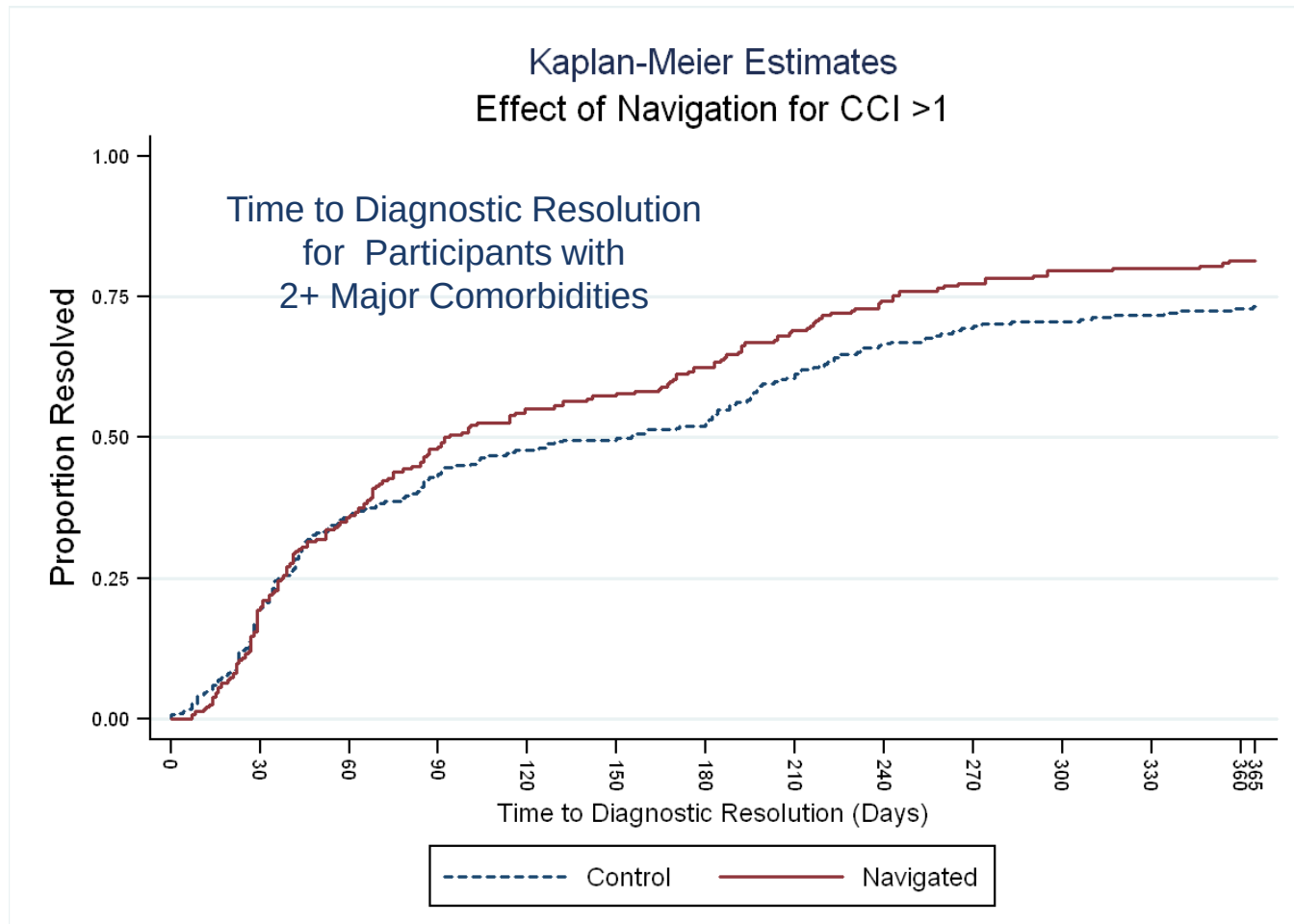
Navigation Eliminated Disparities by Employment

Employment	Adjusted HR for Control Arm (95% C.I.)	Adjusted HR for Navigation Arm (95% C.I.)
Full time	Ref.	1.15 (1.00, 1.34)
Part time	1.00 (0.82, 1.23)	1.32 (1.11, 1.57)
Unemployed	0.85 (0.74, 0.98)	1.12 (0.98, 1.29)

Rodday et al, Cancer 2015

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Impact of Navigation for Patients with Other Comorbidities



Whitley et al, Cancer 2017

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Conclusions of PNRP

- PNRP demonstrated in a large, diverse population that PN can:
 - Reduce delays to receiving follow-up care for cancer abnormalities
 - Reduce delays to starting cancer treatment
 - Reduce those lost to follow-up
 - PN “found” 18-20% who would have been “lost”
 - Help those at most need
- Those who need PN are:
 - At most risk for loss/delay
 - Poorer, sicker, and have more barriers to care

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Evidence Since PNRP: A Review

- Evidence from 2010 through 2015 in women's cancers:
 - 29 articles that met inclusion criteria
 - 5 included other cancers and men (5 colorectal cancer; 1 lung)
 - Areas include:
 - Screening for breast and cervical cancer
 - Diagnostic resolution
 - After diagnosis
 - Various study designs, however, few were RCT
 - Overwhelming focus on breast
 - Majority demonstrated PN to be effective:
 - Screening, time to diagnosis/treatment, adherence to care, quality of life, receipt of quality care, improved knowledge and communication

Krok-Schoen, Oliveri and Paskett, Front. Oncol, 2016

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Most Recent Evidence

- Colorectal cancer screening: Increased screening with decision aid in vulnerable population - RCT (*Reuland et al., 2017, JAMA Oncol*)
- Costs and health care use in Medicaid population with cancer: Costs, ED visits, hospitalizations and ICU stays declined in navigated vs non-navigated controls – Observational study (*Rocque et al, JAMA Oncol, 2017*)

“Saved over \$19 million in health care costs....”

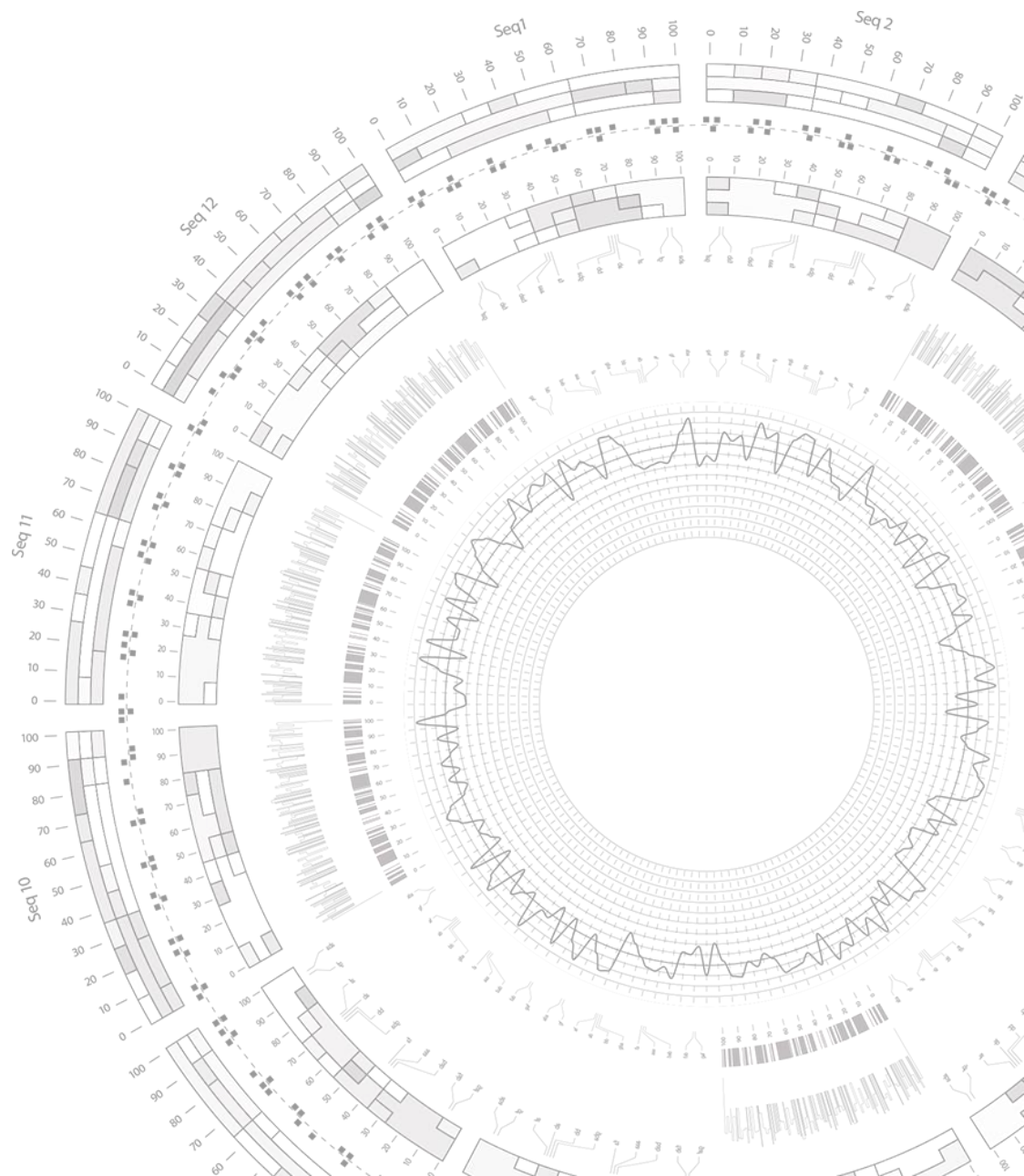
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Opportunities to Generate Additional Evidence

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Gaps in Evidence

- More comprehensive patient population
 - Cancer continuum
 - Post-treatment setting – few studies
 - Wider spectrum of cancers
 - Overwhelming focus on breast cancer
- Innovative study designs
 - RCT are limited due to funding and duration
 - Implementation science studies may offer solutions
 - Metrics need to expand: missed appointments; satisfaction with care; mortality; costs/ROI
- Ways to sustain PN need to be examined
 - Using different models
 - Payment structures

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Way Finder Program: PN Program



- Komen grant funded PN at Breast Center
 - Focused on Medicaid and minority patients from abnormal screen through treatment
- Upper Payment Limit Grant funded by OSU Wexner Medical Center
 - Four clinics – Family Practice, GI, GYN, Breast
- Goals:
 1. To reduce the “no show” and cancellation rates by 40% in participating clinics
 2. To increase adherence to recommended preventative tests in Medicaid patients seen in participating clinics by at least 40%
 3. To assess cost savings of the program

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Goal 1: To reduce the “no show” rates by 40% in participating clinics

No Show Rates

Clinic	*Baseline	Navigated N/S Rate	Percent Change	Current Overall Rate
Care Point East	21%	10.1 %	52%	23%
Rardin	22%	10.1 %	54%	22.8%
Colposcopy	45%	26.8 %	40.5%	34.0%
Endoscopy	32%	6.1 %	80%	22.9%

(First 6 months of data)

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Goal 2: To increase adherence to recommended preventative tests for Medicaid patients seen in participating clinics by at least 40%

Overdue for Pap/Cervical Cancer Screening

Clinic	Baseline	Current	Percent Change
CPE	55%	45%	18.2%
Rardin	56%	41%	26.8%

Overdue for Mammogram

Clinic	Baseline	Current	Percent Change
CPE	50%	27.28%	45%
Rardin	50%	24.24%	52%

Overdue for CRC Screening

Clinic	Baseline	Current	Percent Change
CPE	40%	28.33%	29%
Rardin	40%	25.95%	35%

(First 6 months of data)

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Novel Opportunity

- Do we have enough evidence that PN works?
 - Yes, in most of the cancer continuum, in many populations, and several outcomes
- What do we need now?
 - Innovative study designs in real world settings
 - Expand the populations – cancers and settings
 - Use additional metrics - cost and ROI information
 - Focus on sustainability – make the business case
 - Policy regarding PN and reimbursement

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Thank You

To learn more about Ohio State's cancer program, please visit **cancer.osu.edu** or follow us in social media:



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