

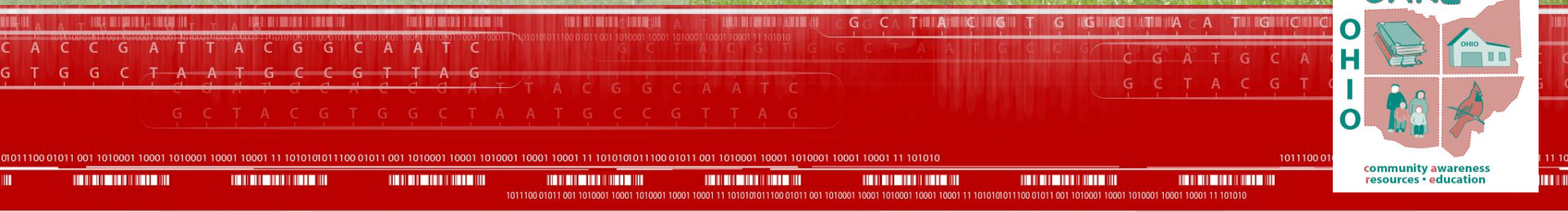
A Multi-Level Model to Address Cervical Cancer Disparities in Appalachia

Electra D. Paskett, Ph.D.
for the OSU CPHHD

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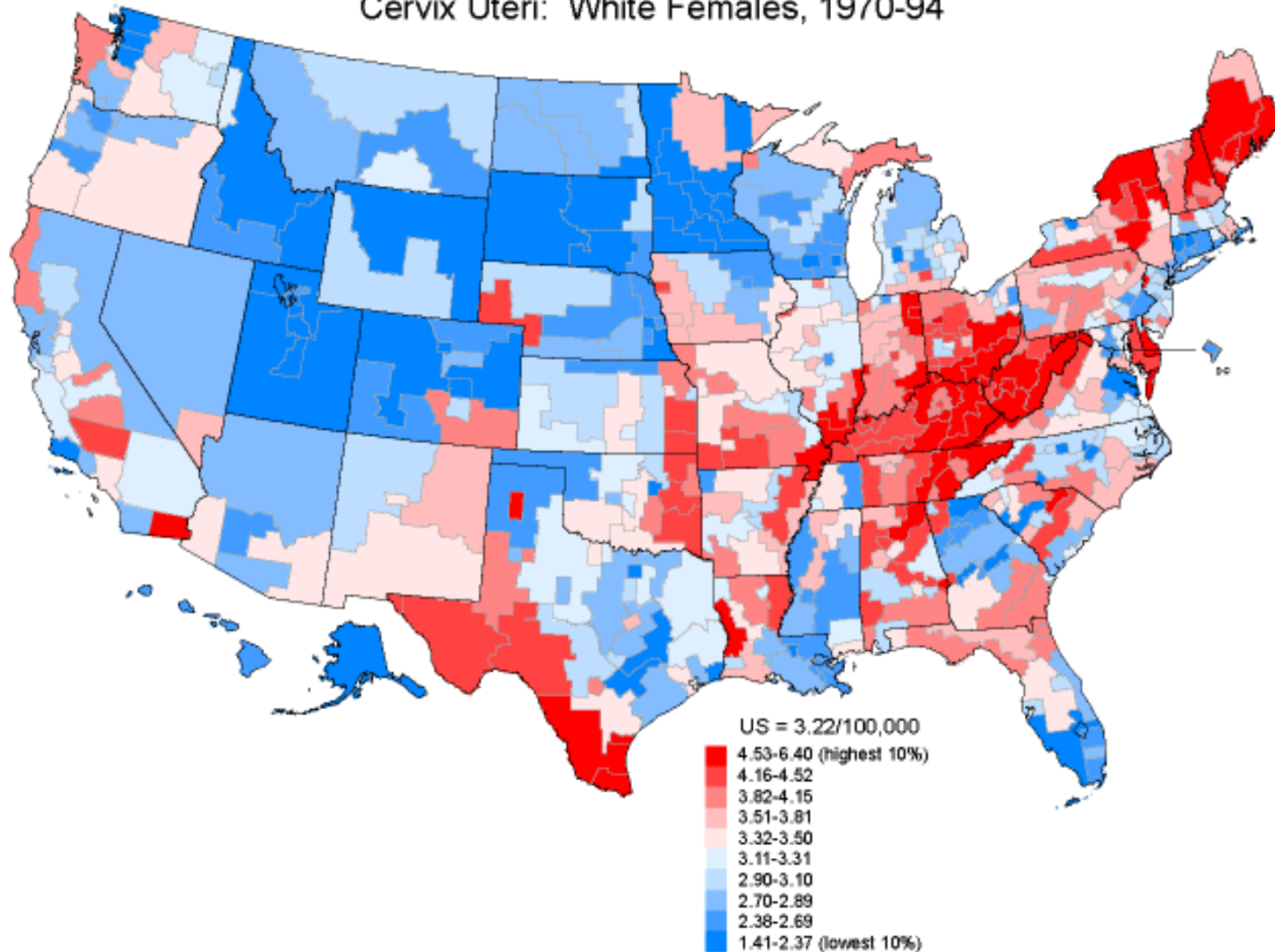
Disclosures

- Grant funding to the Institution:
 - Pfizer
 - Merck Foundation
 - Breast Cancer Research Foundation
 - FoxConn Technology Group
 - Genentech
 - Guardant Health
- Advisory Board Member: GSK
- Appointments:
 - Member, National Cancer Advisory Board, NCI
 - Chair, Ohio Commission on Minority Health
 - Member, NCCN Survivorship Guidelines Panel
- The research I will discuss was/is funded by:
 - The NIH, National Cancer Institute
 - Merck (past studies)



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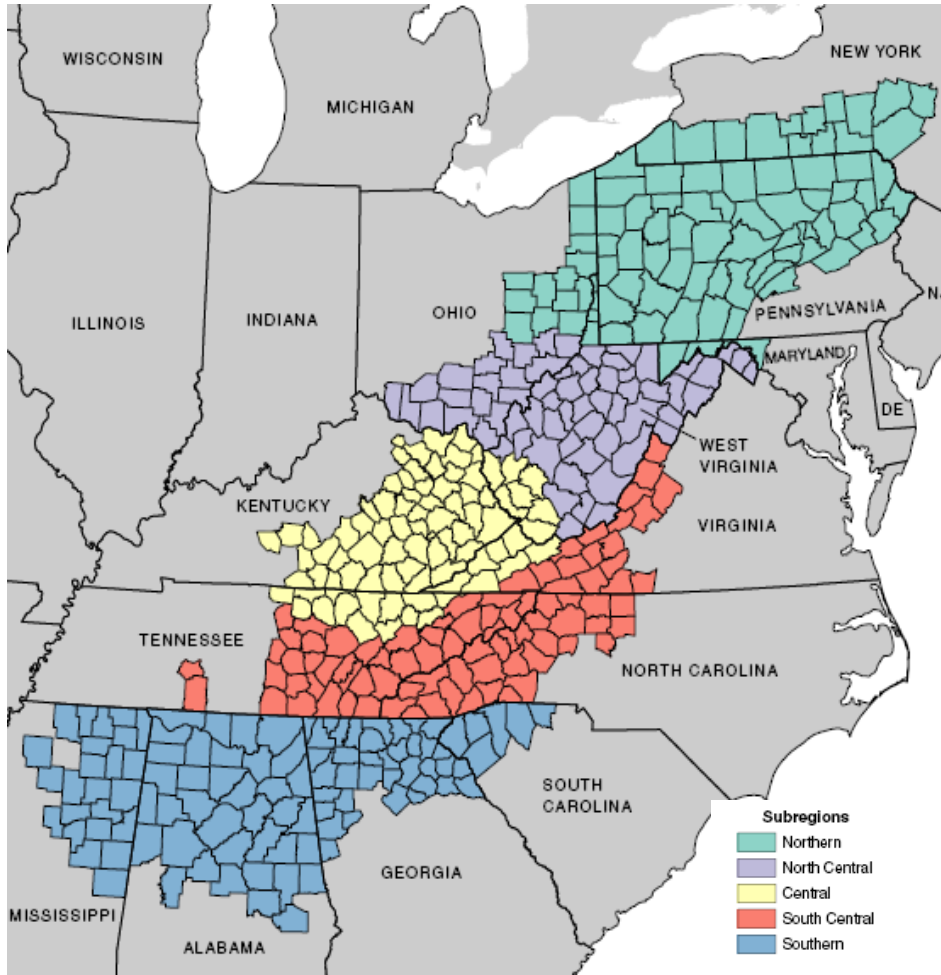
Cancer Mortality Rates by State Economic Area (Age-adjusted 1970 US Population) Cervix Uteri: White Females, 1970-94



(National Cancer Institute, 2001)

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Appalachia



(Appalachian Regional Commission, 2009)

- Appalachia consists of 420 counties in 13 states
- 5 regions: Northern, North Central, Central, South Central and Southern
- Appalachian Regional Commission defined in 1965 in response to region's deficits
- 24.8 million residents (about 8% of total U.S. population)

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Characteristics Of Appalachia

- Both urban and rural areas
- Less racial diversity
 - 12% minorities in Appalachia, 31% in U.S.
- Higher rates of poverty
 - Poverty rate: 16.6% in Appalachia, 12.3% in U.S.
 - 78 Appalachian counties are considered “distressed”
- Lower education
 - High school diploma: 77% in Appalachia, 81% in U.S.
 - Bachelor’s degree: 18% in Appalachia, 25% in U.S.

(**All figures from Census 2000 data**)

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Health In Appalachia

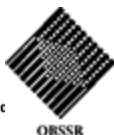
- Appalachia is a traditionally underserved area in terms of the health care system
- Excess mortality exists in Appalachia with cancer and heart disease being leading causes of death
- Cancer is the leading cause of death
- Factors contributing to health disparities in region
 - Lower SES
 - Lack of medical care facilities and health care providers
 - Poor health behaviors
 - Poor communication with health care providers

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Cells to Society: Overcoming Health Disparities

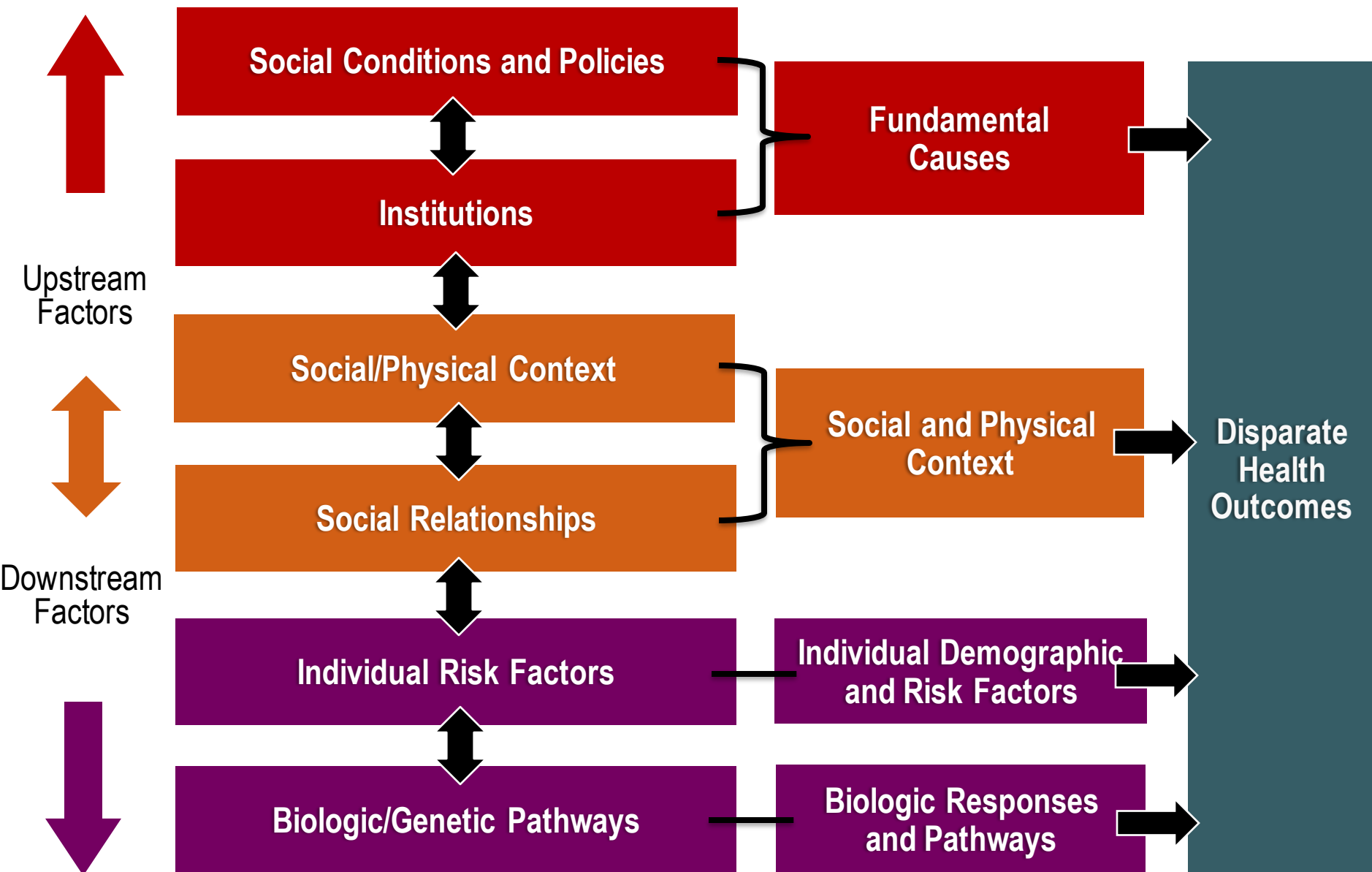
<http://cancercontrol.cancer.gov/populationhealthcenters/cphhd/index.html>



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Model for Analysis of Population Health and Health Disparities



(Warnecke et al., AJP 2008)

Model Levels

Risk Factor Levels

Intervention Levels

Social Conditions and Policies

States with no mammography, genetic testing or treatment quality/access assurance acts

Enact legislation to assure access to genetic testing, quality treatment and follow-up

Institutions

Poor quality mammography/follow-up, no coverage of genetic testing

Navigators to assist with follow-up/genetic testing; Enforce/enact coverage

Social/Physical Context

No mammography, treatment, or genetic testing facilities located nearby

Mobile mammography; transportation to treatment; telemedicine for genetic counseling and genetic testing

Social Relationships

No positive role models for early detection or genetic testing

Group-based education programs; peer-navigation

Individual Risk Factors

Lower rates of mammography and other preventive options and genetic testing uptake

Increase mammography; acceptance of genetic testing

Biologic/Genetic Pathways

Genetic susceptibility BC/Triple negative disease

Genetic counseling and testing with recommending surveillance

OSU Center for Population Health And Health Disparities (CPHHD)



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Goal

To understand why Appalachian Ohio women have high incidence and mortality rates for cervical cancer

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CARE-I *aka the First 5 Years*

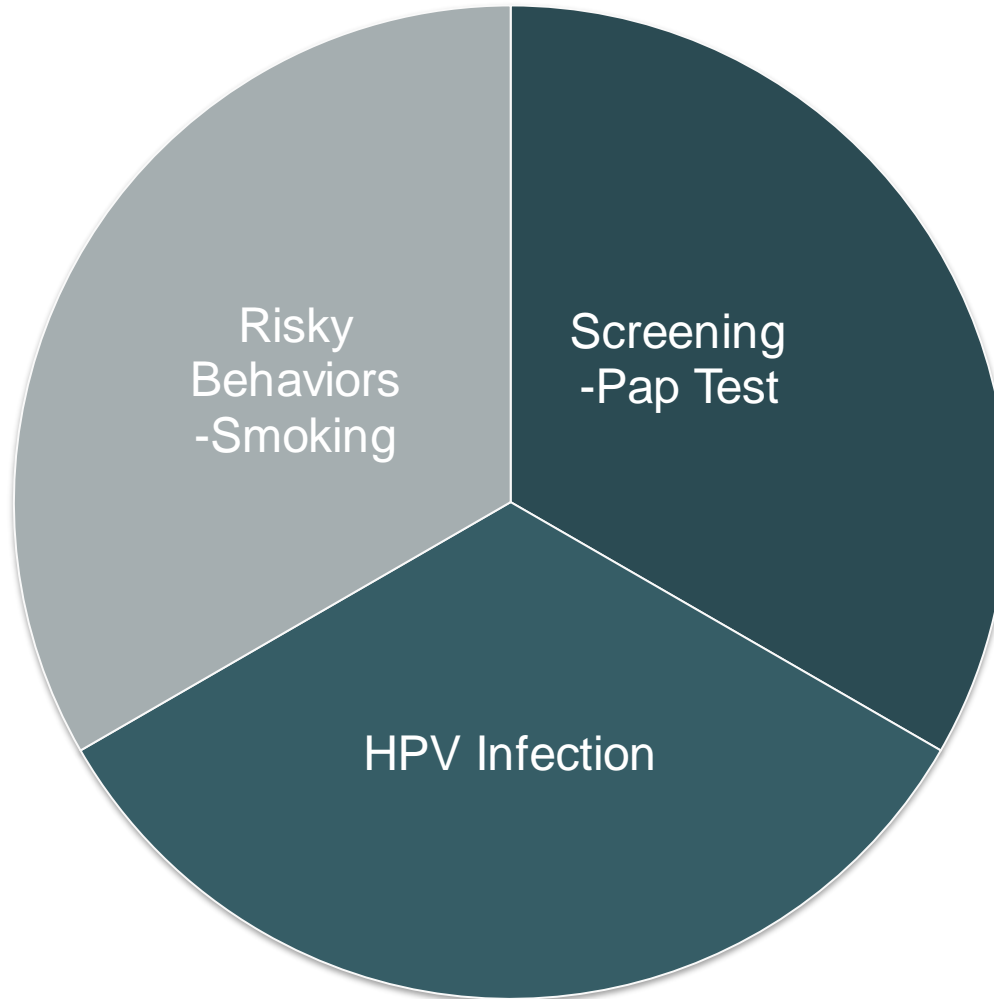


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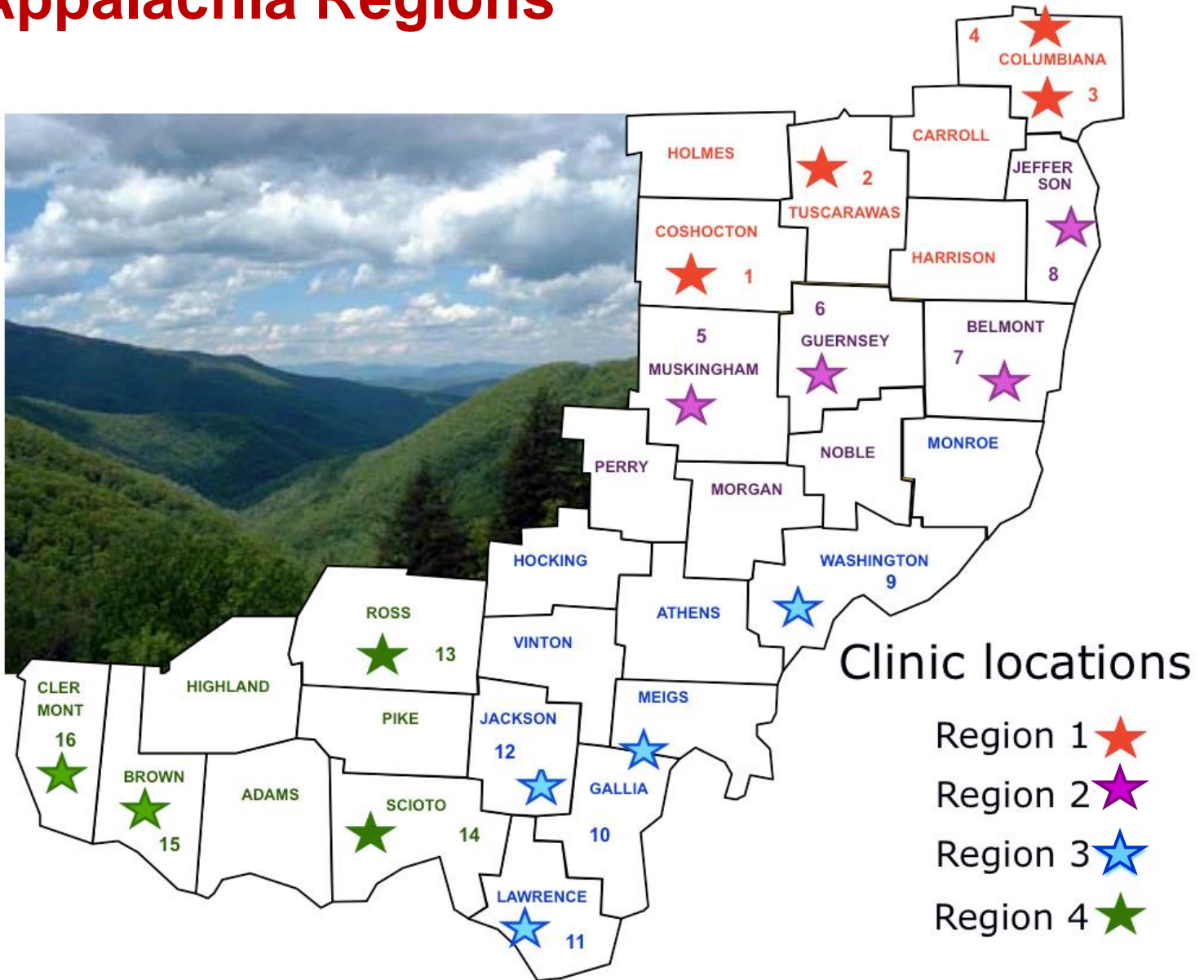
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Cervical Cancer: 2002



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Ohio Appalachia Regions



Lay Health Advisor Intervention to Improve Pap Smear Utilization among Ohio Appalachian Women

Project Leader: *Electra D. Paskett, PhD*
Mira Katz, PhD
Paul Reiter, PhD
Jill M. Oliveri, MPH, DrPH
Amy Lehman, MS
Stan Lemeshow, PhD
Douglas Post, PhD
Mack Ruffin, MD



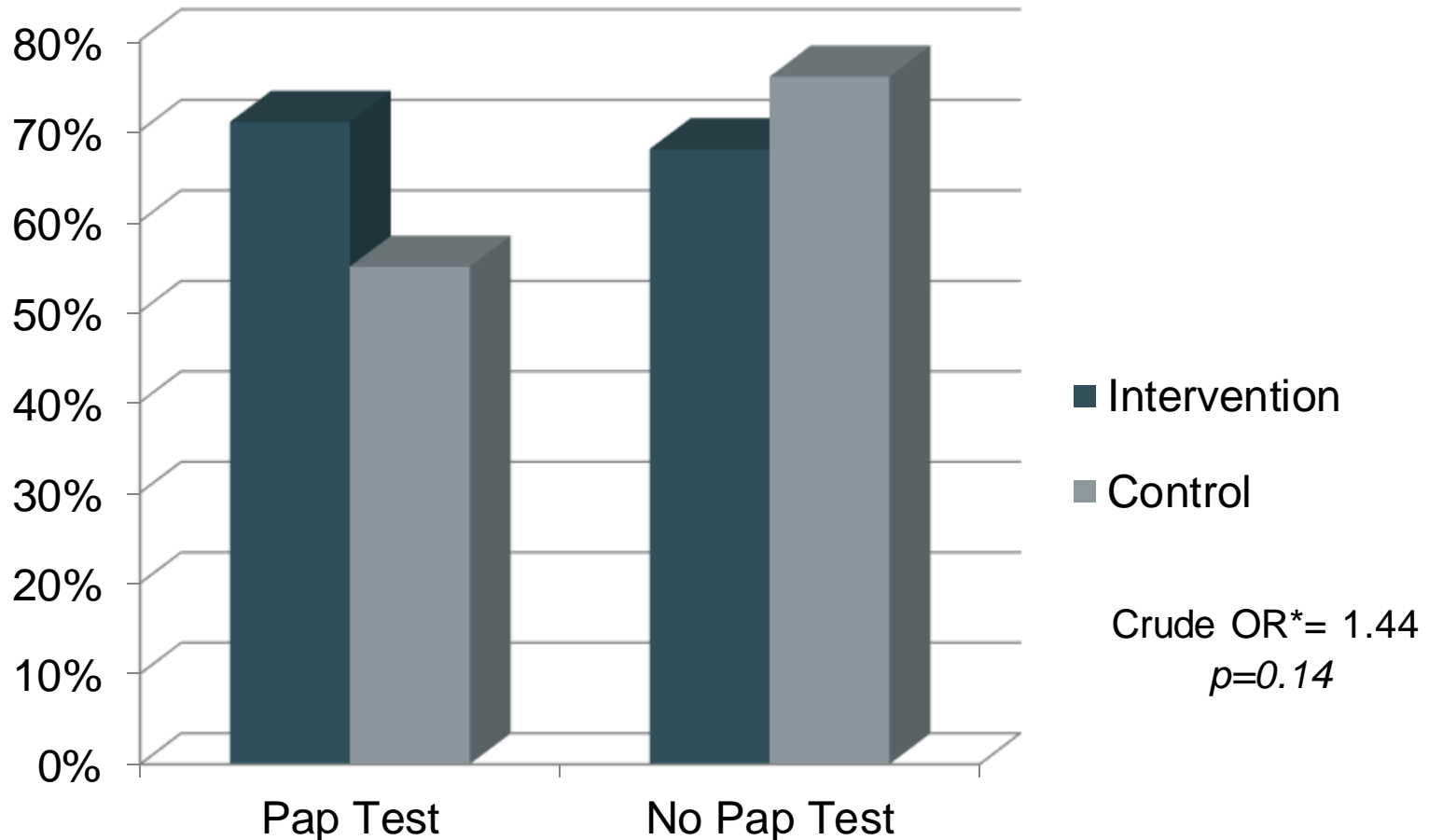
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Components of the Intervention

- Two in-person visits by a LHA
- Mailed materials based on Stages of Change
- Phone calls
- LHA assessed cervical cancer risk, addressed barriers to receiving a Pap test, and provided educational materials
- Usual care received a letter from their doctor and brochure about Pap tests
- Women were in program for 10 months

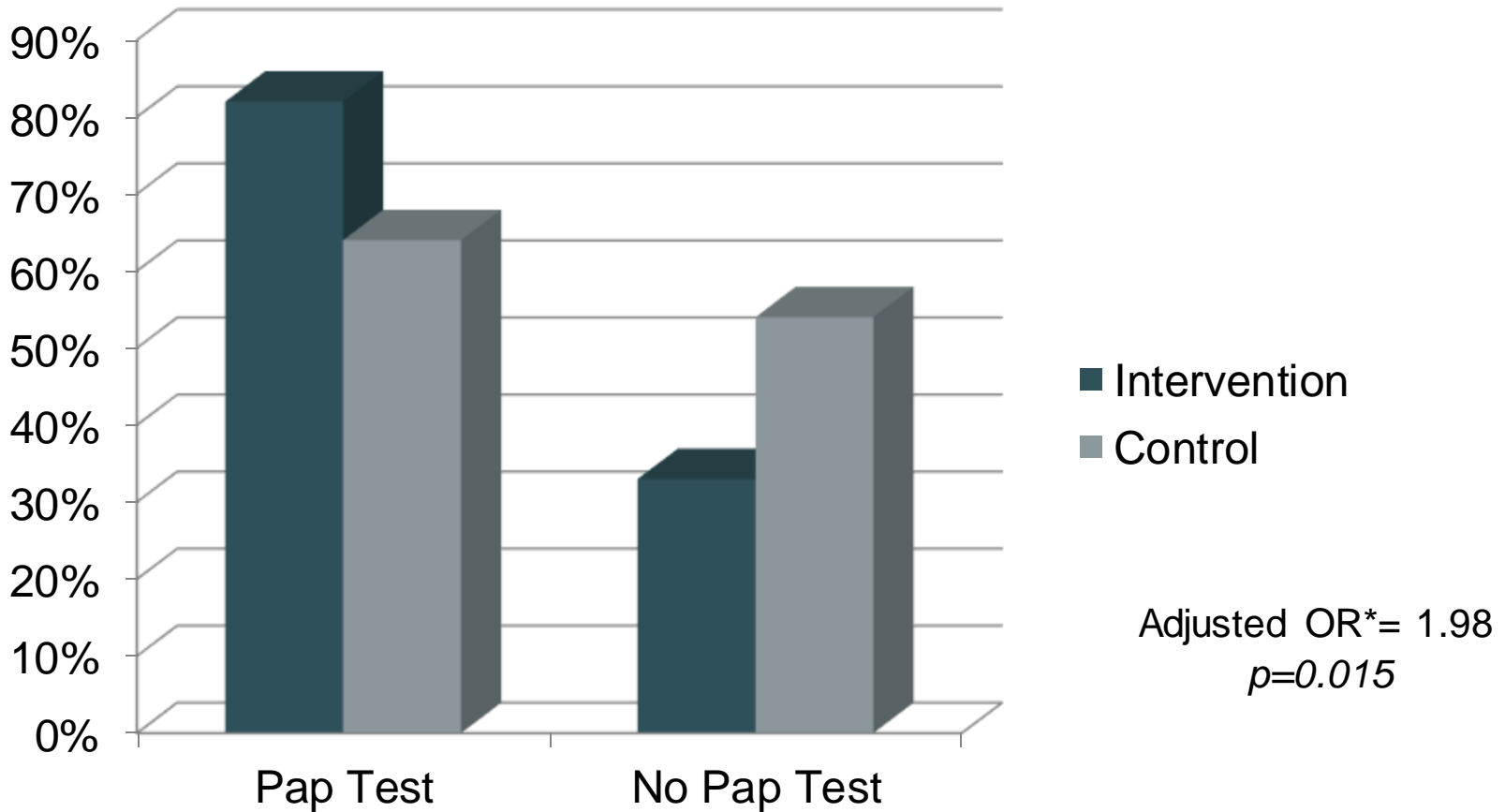
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Summary of MRR Pap Status (N=270)



* Clinic included as a random effect

Summary of Self-Reported Pap Status (N=235)



**Adjusted for age, race, education, employment status, SES, marital status, health insurance, and previous abnormal Pap. Clinic included as a random effect in models.*

Evaluation of a Lay Advisor Cessation Intervention in Ohio Appalachian Women

Project Leader: *Mary Ellen Wewers, PhD*
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Amy Ferketich, PhD
Karen Ahijevych, PhD
Bryan Ball, MS
Electra Paskett, PhD
Stanley Lemeshow, PhD



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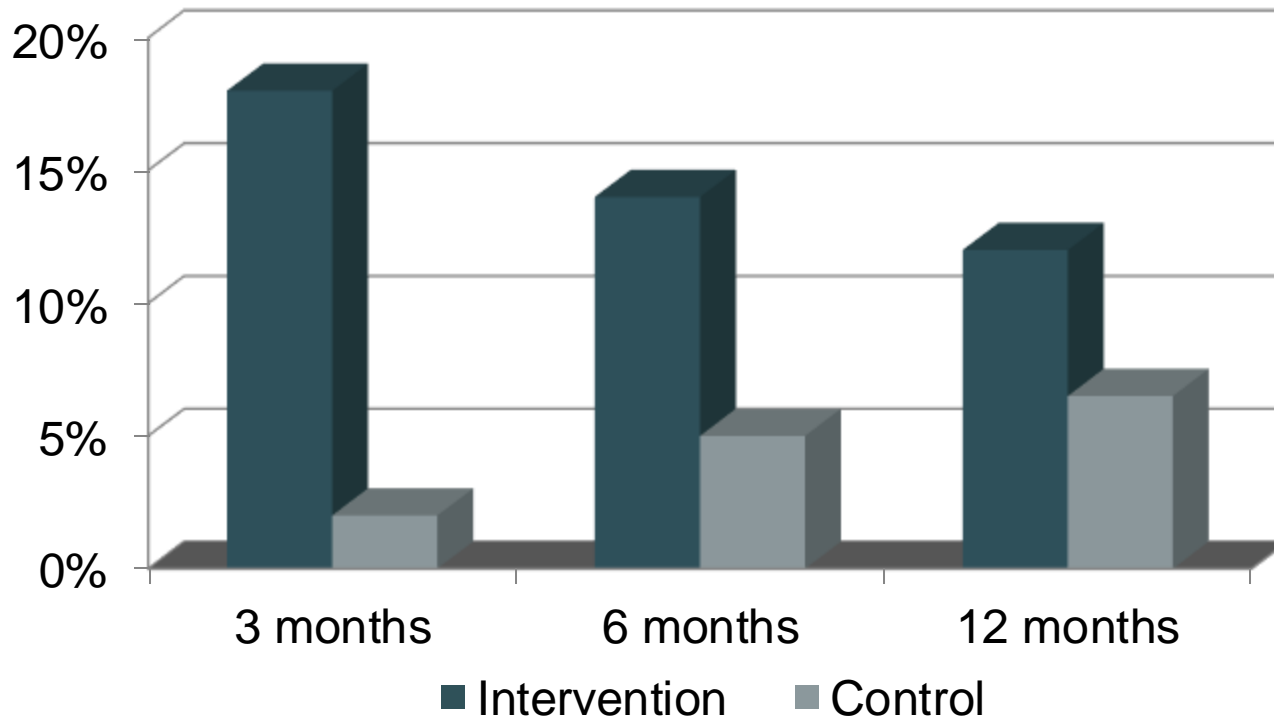
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Components of the Intervention

- Cessation protocol delivered by trained LHA
 - Behavioral counseling
 - Nicotine replacement therapy (NRT)
 - 10-week period
- Control arm
 - Signed letter from provider advising they quit
 - Print information on how to quit and use of NRT
 - Make an appointment to discuss treatment options

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Cotinine-Validated Cessation Rates



All p-values are <0.02 except for 12 month ($p=0.09$)

(Wewers et al, CEBP, 2009)

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Predictors of Abnormal Cervical Cytology

Project Leader: *Mack T. Ruffin, MD*

Electra D. Paskett, PhD

Ron Glaser, PhD

Janice Kiecolt-Glaser, PhD

Mary Ellen Wewers, PhD

Elizabeth Unger, MD, PhD

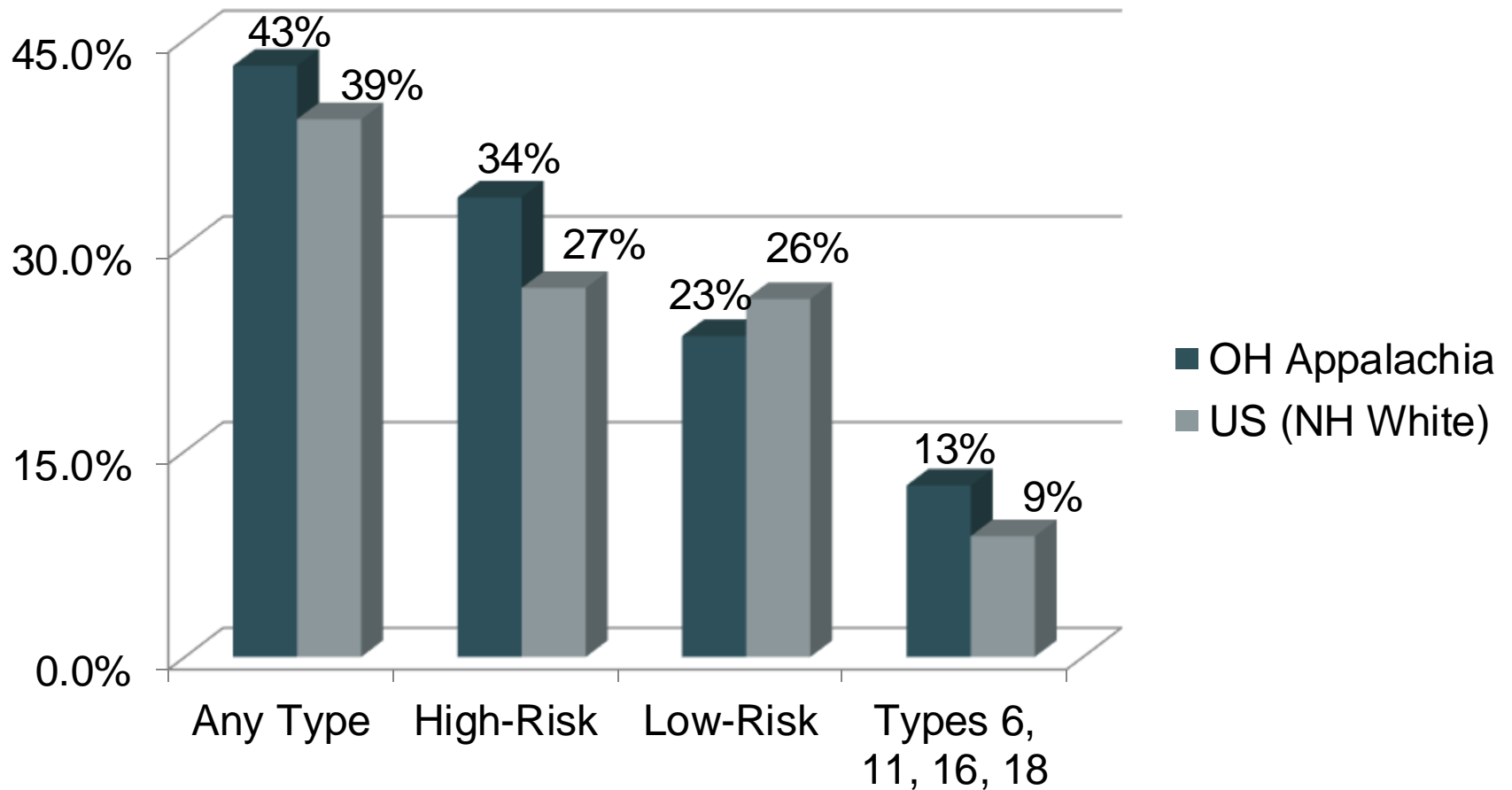


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HPV Prevalence By Type



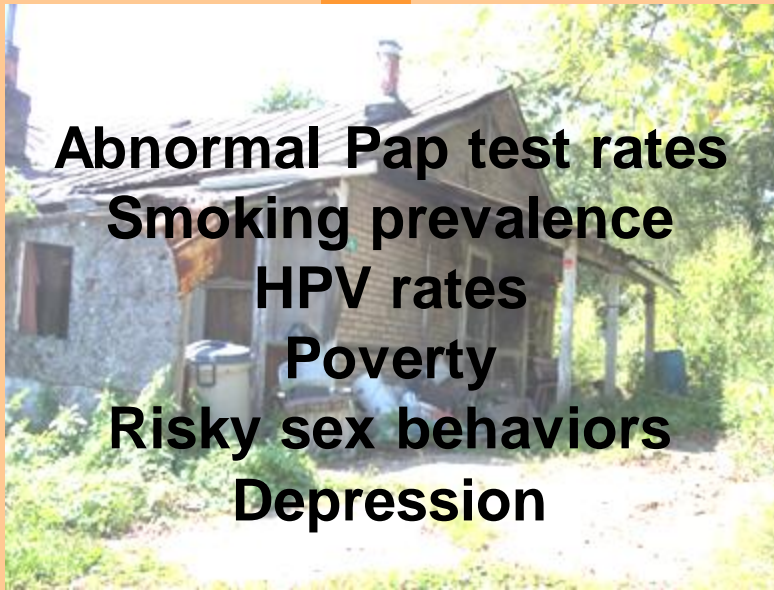
Correlates of Infection with High-Risk HPV Type (n=1116)

	OR (95% CI)
Age 18-26	3.2 (1.9-5.7)**
Current smoker	1.5 (1.0-2.3)*
Prior abnormal Pap test	1.5 (1.0-2.2)*
5+ lifetime partners	2.6 (1.7-3.9)**
2+ partners in last year	1.7 (1.1-2.7)*

* $p < 0.05$, ** $p < 0.001$

Cervical Cancer

Appalachian Culture



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OSU CPHHD: CARE-II



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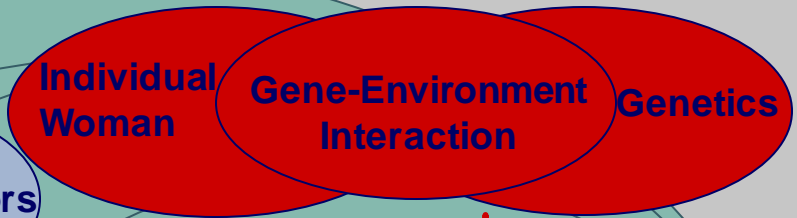
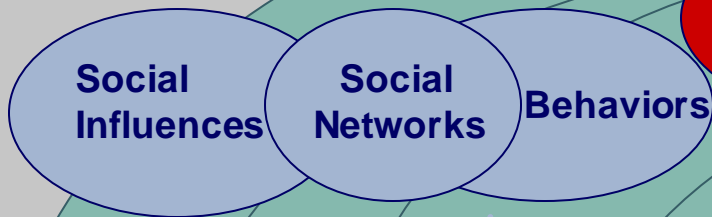


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CARE II: A SDH Model For Addressing Cervical Cancer Disparities In Appalachia

Project 2

Project 1



Social Conditions and Policies

Institutions

Social/Physical Context

Social Relationships

Individual Risk Factors

Biologic/Genetic Pathways

- Culture
- Health policy

- Health care systems

- Neighborhoods
- Access to health care

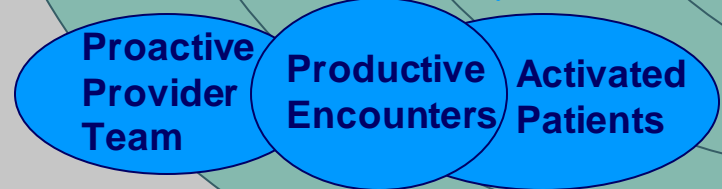
- Social Networks

- SES
- Tobacco use
- Sexual behaviors
- HPV Vaccine

- Genetics
- Immune system
- HPV



Cervical Cancer



Project 4

Project 3

Inherited and Somatic Alterations of the TGF- β Ligand and Receptor Complex in Cervical Cancer

Project Leader: *Chris Weghorst, PhD*
David Cohn, MD
Gerard Nuovo, MD
Thomas J. Knobloch, PhD
Mack T. Ruffin IV, MD, MPH



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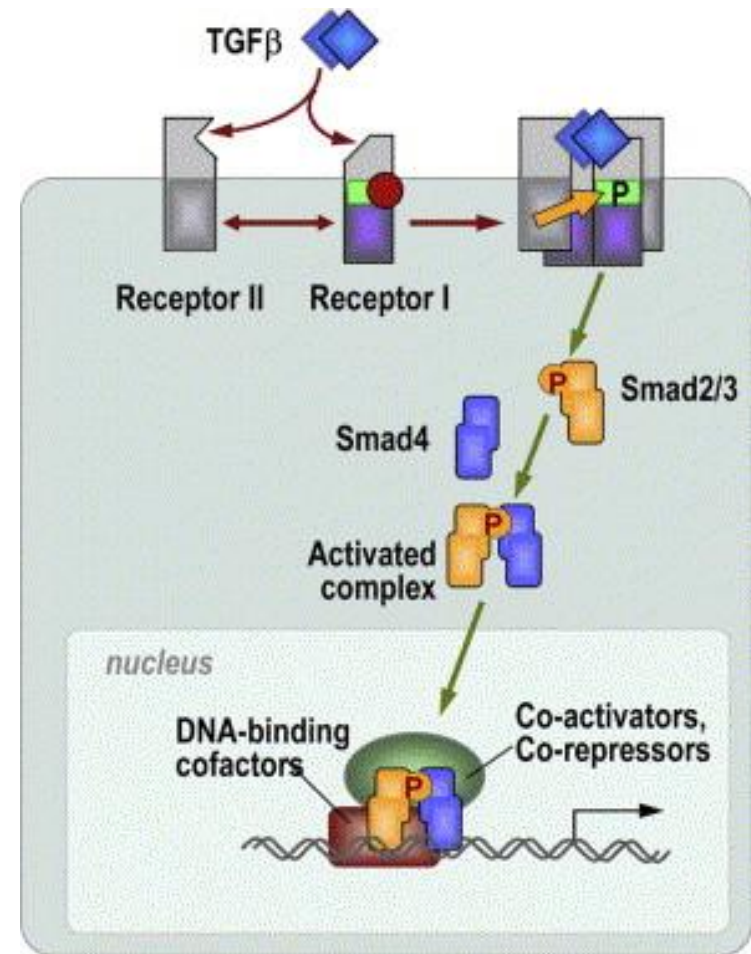
Overall Goal

Determine the role of heritable and somatically acquired **genetic alterations** in relation to key components of the Transforming Growth Factor β (**TGF- β**) receptor complex, whose variant forms are established cancer susceptibility alleles, or associated with cancer development.

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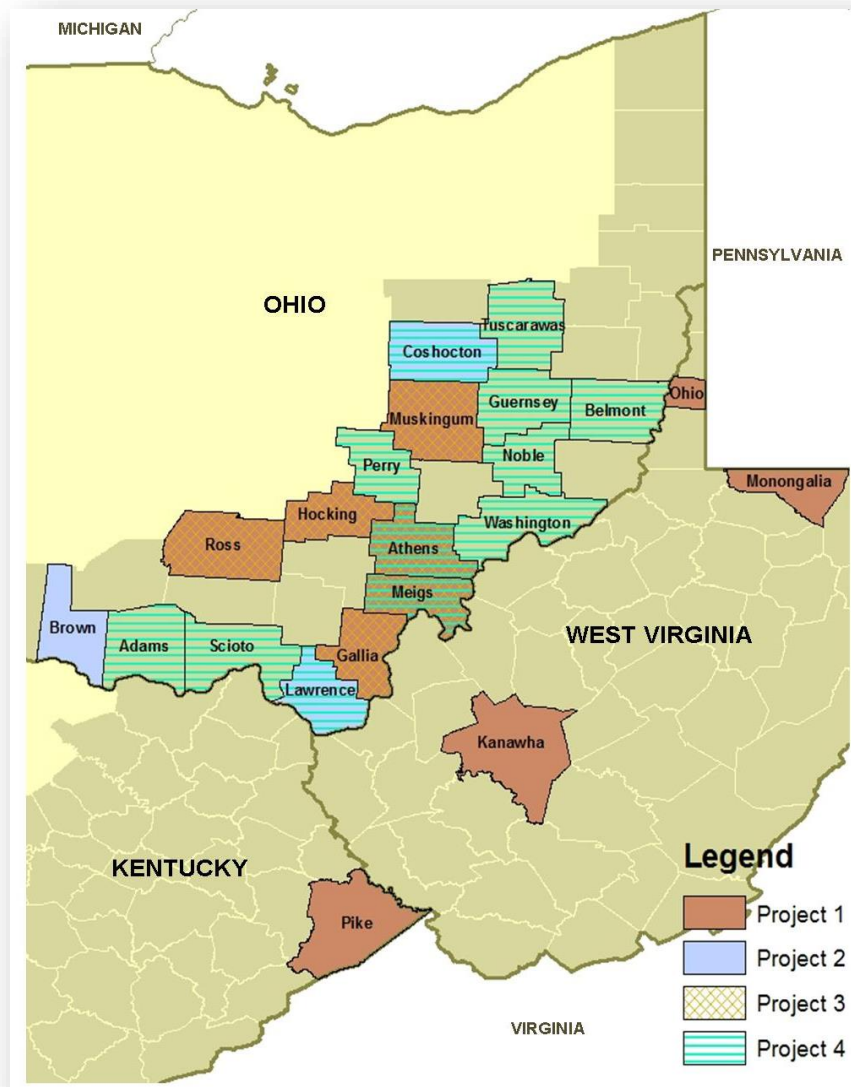
Transforming Growth Factor – β Receptor Pathway

- Frequently altered in human cancers
 - Somatic deletions, insertions and mutations
 - Deregulation of gene and protein expression
 - Polymorphic variants
 - SNPs
 - TGFBR1*6A
- Examine association between genotypes and cancer status



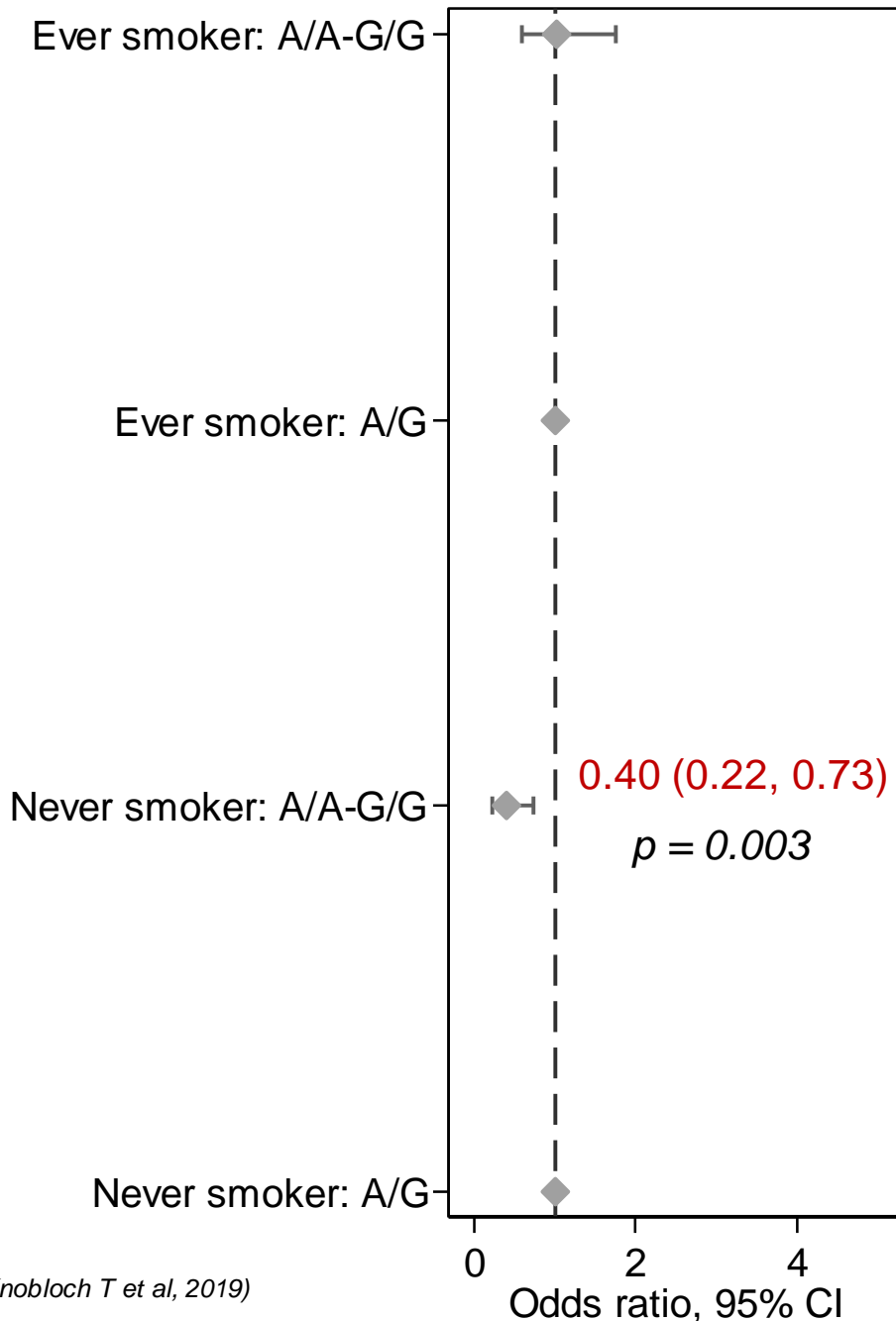
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Catchment Area and Enrollment



- CARE-II
 - Cervical Ca Cases = 173
 - Healthy Controls = 113
 - Blood, buccal swab, HPV
 - Questionnaires
- CARE-I
 - Healthy Controls = 729
 - Blood, HPV
 - Questionnaires

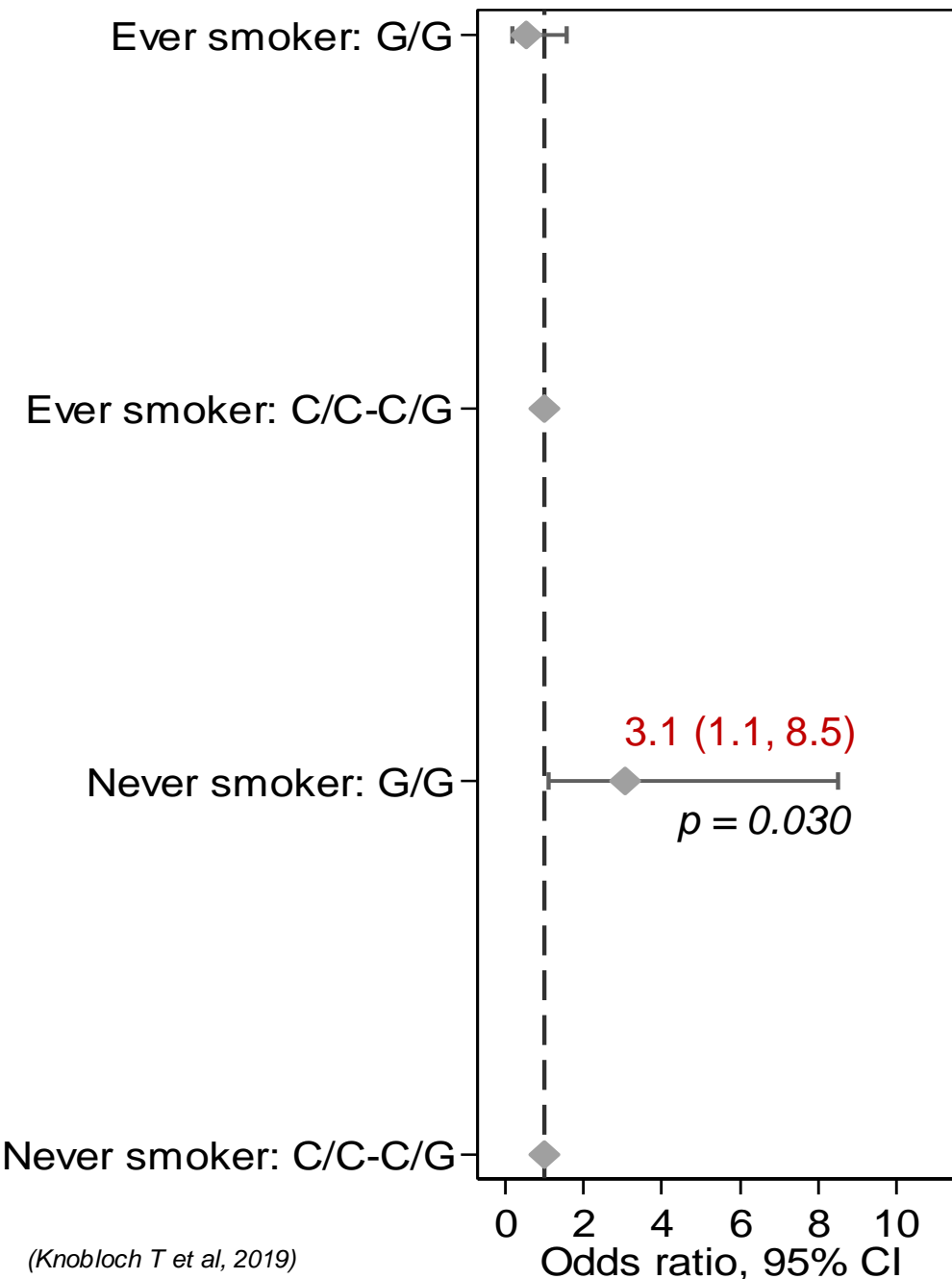
Overdominant



- **TGFB1: rs1800469**
- Ligand for the pathway
- SNP in promoter region
- Interaction of smoking status by genotype:
 - ($p = 0.02$)
 - Homozygous never smokers, protective effect

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Dominant



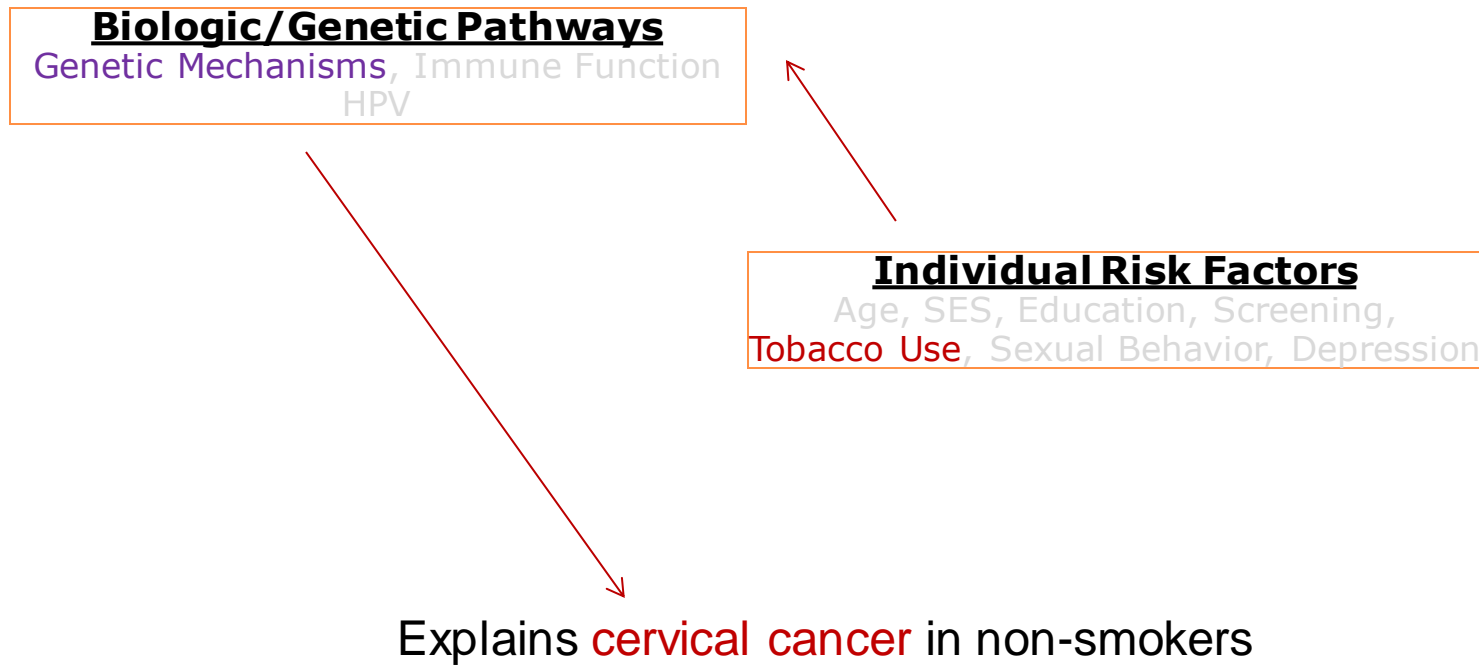
(Knobloch T et al, 2019)

- **TP53: rs1042522**
- Apoptosis and cell cycle in cervical cancer
- Interaction of smoking status by genotype
 - ($p = 0.02$)
 - G/G never smokers have higher risk

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Multi-Level Causes and Interactions

Project 1: What is the prevalence of a genetic polymorphism in Appalachian population with cervical cancer vs control women?



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Social Networks and Tobacco Use among Ohio Appalachian Women

Project Leader: *Mary Ellen Wewers, Ph.D.*
Amy Ferketich, Ph.D.
Valdis Krebs, Ph.D.
Christopher Browning Ph.D.
Doug Post, Ph.D.



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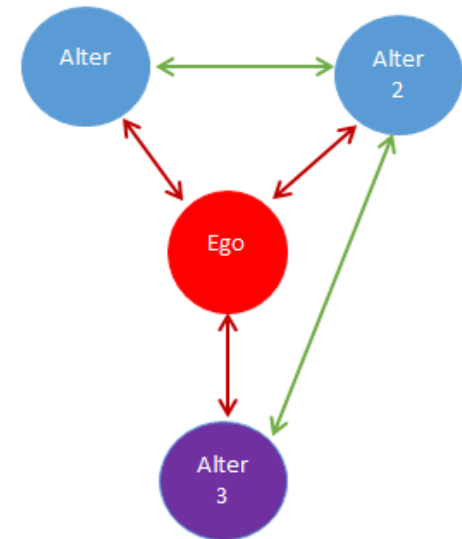
Social Networks and Smoking Patterns

PROBLEM:

- Tobacco use is a putative risk factor for cervical cancer
- Smoking prevalence in Ohio among women = 24%
- Smoking prevalence among Ohio Appalachian women = 32%

Project 2:

- Goal: Characterize social networks by smoking status
 - never, former and current smokers
- Determine the association between individual, interpersonal, workplace and community characteristics and social networks



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Research Design

- Cross-sectional survey:
 - Administered by trained OSU interviewer who resided in Appalachian County
 - Face-to-face interview lasting approximately one hour
 - Data captured on REDCap platform and sent electronically to OSU server
 - Respondent reimbursed with \$50 gift card for time and effort
 - Most interviews conducted in participant's home or a county agency

(Thomson TL et al, 2018)

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Sample Characteristics

N=408	Mean	Percent	Median
Age	51.7 Range 18 - 95		
Health insurance coverage		88.7 %	
High CES-D score		17.6%	
Current Smoker		20.1%	
Former Smoker		22.5%	
Full-time/Part-time Employment		48.0%	
Bachelor or Higher Education		24.0%	
Household Income (\$)			40,000-49,999

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Multinomial logistic regression model for differences by smoking status

(N=383; 74 current smokers, 87 former smokers, 222 never smokers)

Variable	Unit	OR former vs. current	OR never vs. current	p-value
Individual level factor				
Age	One unit increase	1.07 (1.03 – 1.11)	1.06 (1.02 – 1.09)	0.0008
CES-D score	One unit increase	0.95 (0.91 – 0.999)	0.93 (0.88 – 0.98)	0.0157
Intrapersonal level factor				
Social influence-injunctive norm	One unit increase	0.77 (0.63 – 0.94)	0.70 (0.58 – 0.85)	0.0010
Social participation	One unit increase	1.17 (0.95 – 1.45)	1.36 (1.10 – 1.67)	0.0047
% ties who smoke in advice network	10% increase	0.76 (0.62 – 0.92)	0.72 (0.59 – 0.87)	0.0032
E/I index in time network	0.1 unit increase	0.80 (0.71 – 0.90)	0.76 (0.67 – 0.86)	<.0001
E/I index in advice network	0.1 unit increase	0.82 (0.74 – 0.92)	0.80 (0.72 – 0.90)	0.0003
Neighborhood level factor				
Neighborhood cohesion	One unit increase	0.88 (0.78 – 0.997)	0.86 (0.76 – 0.97)	0.0406

(Nemeth JM, et al., 2018)

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Multi-level Causes and Interactions

Project 2: Can the social networks of Appalachian female smokers assist in smoking cessation?

Social/Physical Context

Collective Efficacy, Social Capital,
Access to Resources, **Social Cohesion**,
Segregation, Neighborhood Disadvantage

Social Relationships

Social Networks, Social Support
Social Influences

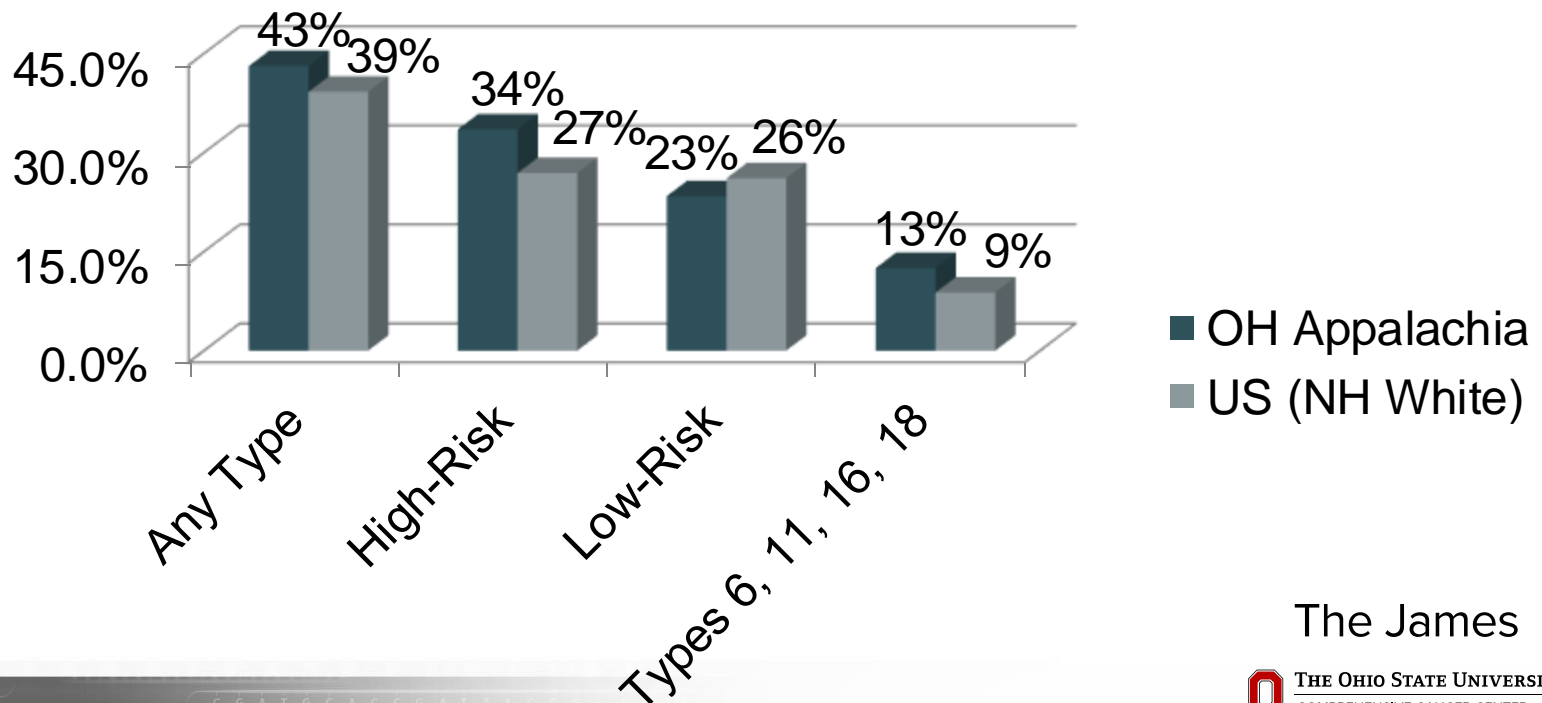
Individual Risk Factors

Age, SES, Education, Screening,
Tobacco Use, Sexual Behavior, **Depression**

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Perfect Storm for Cervical Cancer?

- Tobacco Use - *Carcinogen*
- Genetics among non-smokers
- Infection with HPV? HPV Vaccine uptake? Efficacy of HPV vaccine?



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HPV Immunization Response and Stress

Project Leader: *Mack Ruffin, MD*

*Erinn Hade, Pat Fahey, Liza
Christian, Cecilia DeGraffinreid, Lori
Hill, Mary Chambers, Megan Cleland*

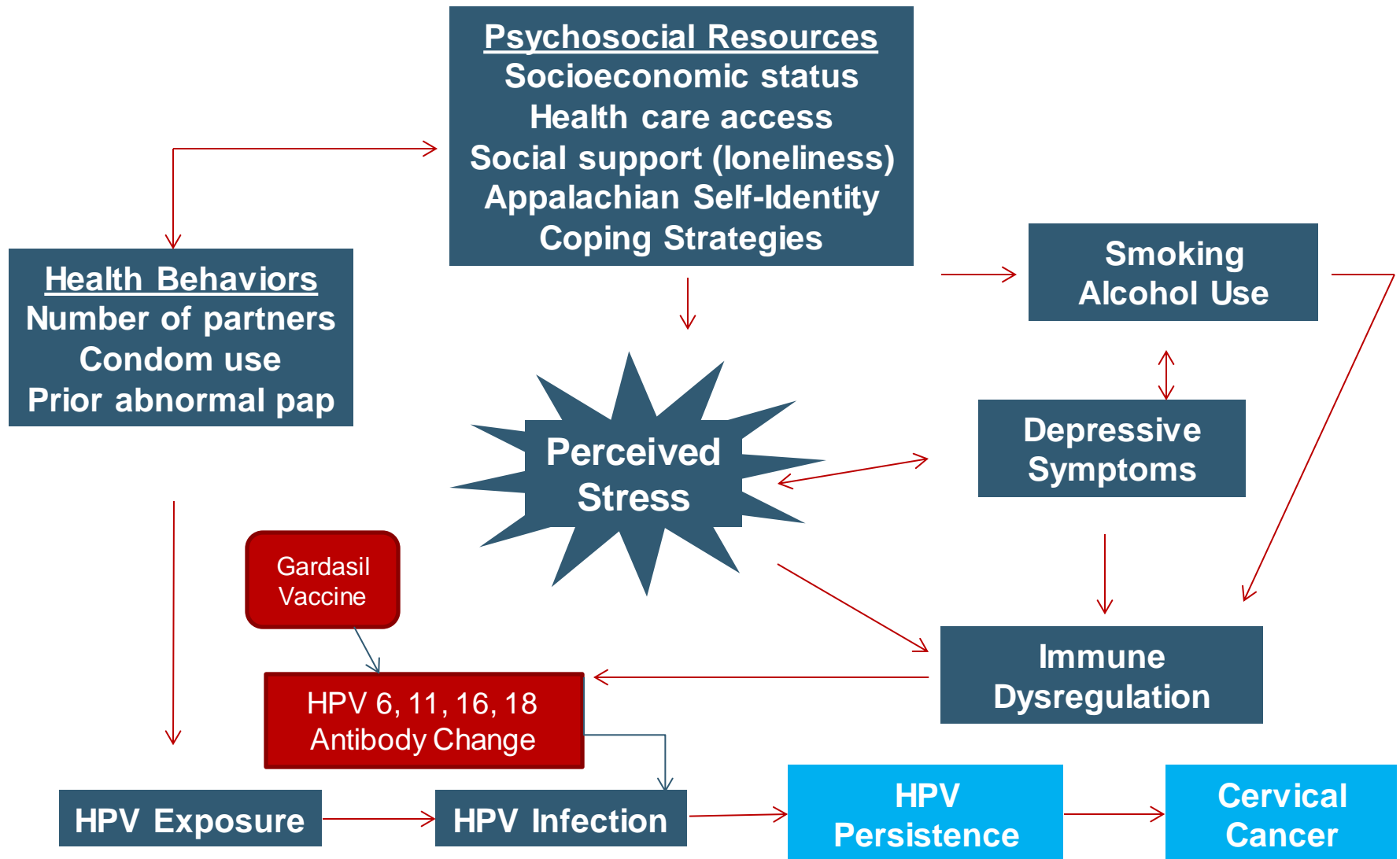


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Model of Stress and HPV Infection



Study Demographics (n=185)

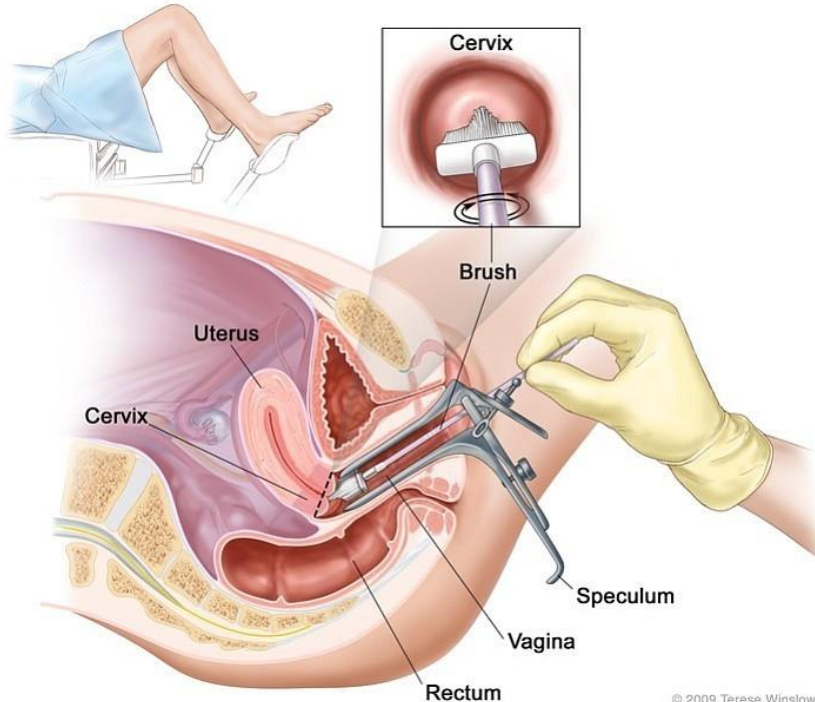
- Age
 - Mean=22.8 years (2.4)
- Race
 - White (85.4%)
- Marital Status
 - Single 138 (70.4%)
- Income Ladder
 - Community=5.9 (1.8)
 - Nation=5.7 (1.9)
- Neighborhood Cohesion
 - 17.6 (4.0)
- Self-Id as Appalachian
 - 72 (38.9%)
- Never had sex
 - 8 (4.3%)
- Sexual Partners
 - 6.5 (3.4%)
- Age First Intercourse
 - 16.6 years (2.3)
- Smoking
 - Current 48 (26%)
- Drink Alcohol
 - Yes 134 (72.4%)
 - Binge in last month
 - 66 (49% of Drinkers)
- Drug Use 40 (22%)
- BMI Mean 27.5 (8.0)
 - Overweight/obese (51%)
- Prior Abnormal pap
 - 43 (30%)
- Perceived Stress Scale
 - Mean PSS= 23.5 (8.1 sd)
- **CES-D Score**
 - Median 9
 - ≥ 16 51 (28%)

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Baseline Biological Measures

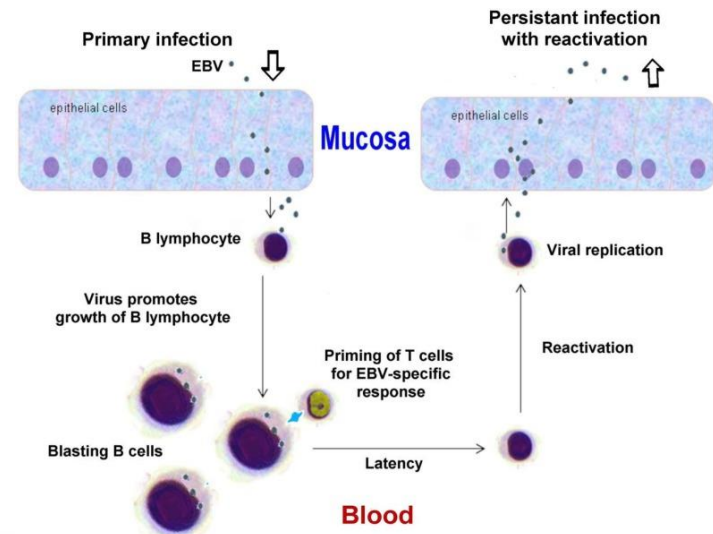
Cervical HPV DNA

- Negative = 85 (50%)
- HPV 16 = 15 (8 %)
- HPV 18 = 5 (3 %)



Serology

- HPV Serology +
 - HPV 16 = 43 (23 %)
 - HPV 18 = 26 (14%)
- EBV Titers
 - Negative = 16 (9%)
 - Low = 40 (22%)
 - Medium = 116 (63%)
 - High = 13 (7%)



Does Stress Impact Immune Response to HPV Vaccine?

- Impact on HPV 18 Titer Change
 - Perceived Stress Scale
 - 10 unit increase resulted in a 22% decrease in titer change
 - Not clinically significant difference
- Impact on HPV 16 Titer Change
 - Number of Lifetime Sexual Partners
 - ≥ 4 than 60% higher titer change
- No other variables impacted titers

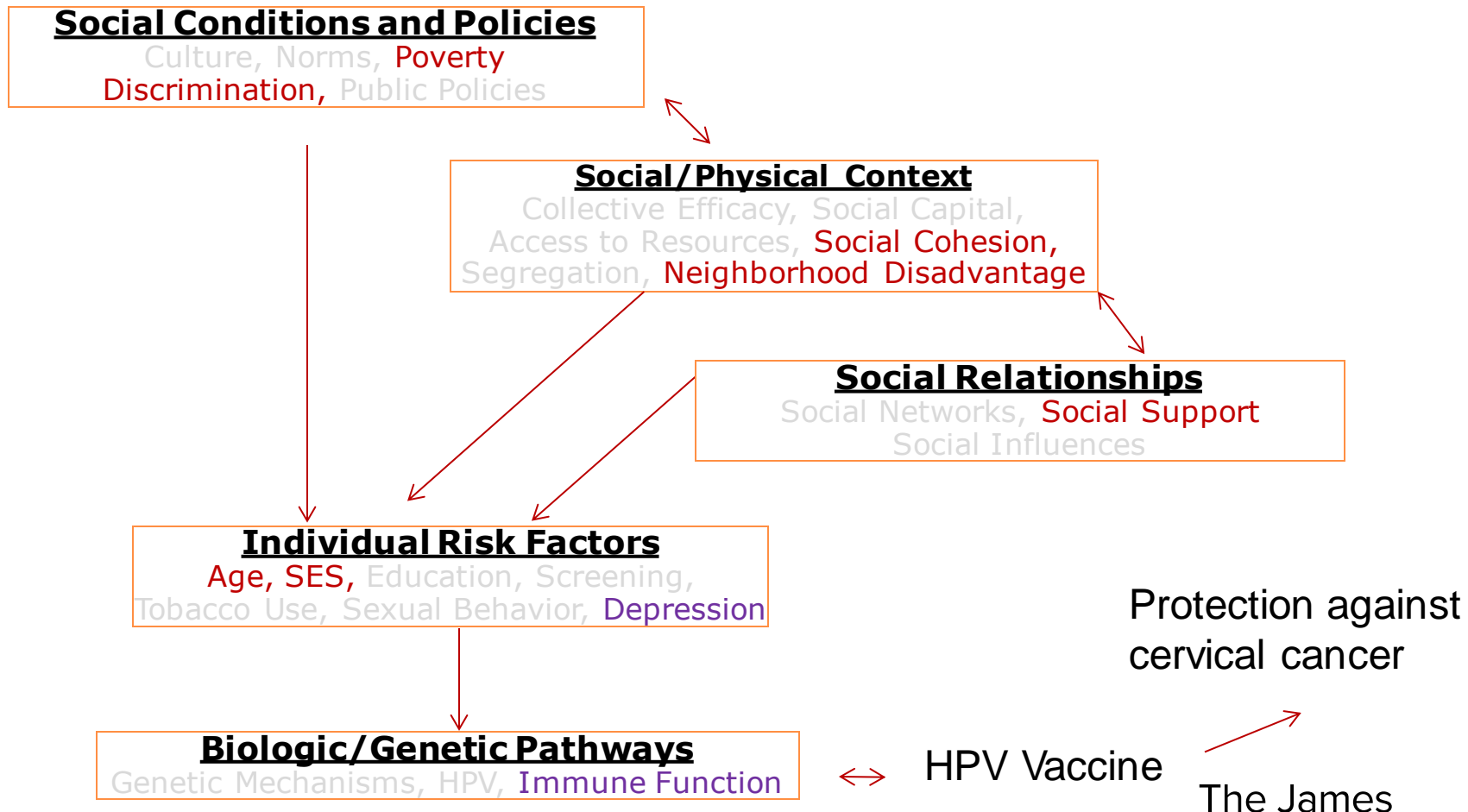
HPV vaccine will have an effect on the immune system of Appalachian women

(Paskett et al., 2020)

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Multi-Level Causes and Interactions

Project 3: Do Appalachian women who are “stressed” develop immunity to HPV after receiving the vaccine?



The PARENT (Parents in Appalachia Receive Education Needed for Teens) Project

Project Leader: *Electra Paskett, PhD*

Cathy Tatum, MA

Mike Pennell, PhD

Morgan Richardson

Mira Katz, PhD

Paul Reiter, PhD

Janice Raup-Krieger, PhD

David Cohn, MD



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Primary Aims

- To develop and **evaluate** a multi-level HPV **vaccine intervention** to increase HPV vaccination rates among young girls and adolescent females (9-17) living in Ohio Appalachia
- Levels:
 - **Parents** of female adolescents who live in Ohio Appalachia (Level 1)
 - **Health care providers** who practice at health departments and provider offices (Level 2)
 - **Health departments and provider offices** in Ohio Appalachia (Level 3)
- Intervention tested in 6 Ohio Appalachia counties (intervention) vs 6 usual care Ohio Appalachia counties (control)
 - **Control** counties receive education on the **flu and the flu vaccine**

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HPV Vaccine Uptake: Group Randomized Trial

First Shot within Three Months

Received Shot	Control Arm	HPV Arm	p-value
Yes	4 (3%)	10 (8%)	0.045
No	120 (97%)	120 (92%)	

First Shot within Six Months (Ever)

Received Shot	Control Arm	HPV Arm	p-value
Yes	8 (7%)	17 (13%)	0.003
No	116 (94%)	113 (87%)	

Results: Secondary Outcome

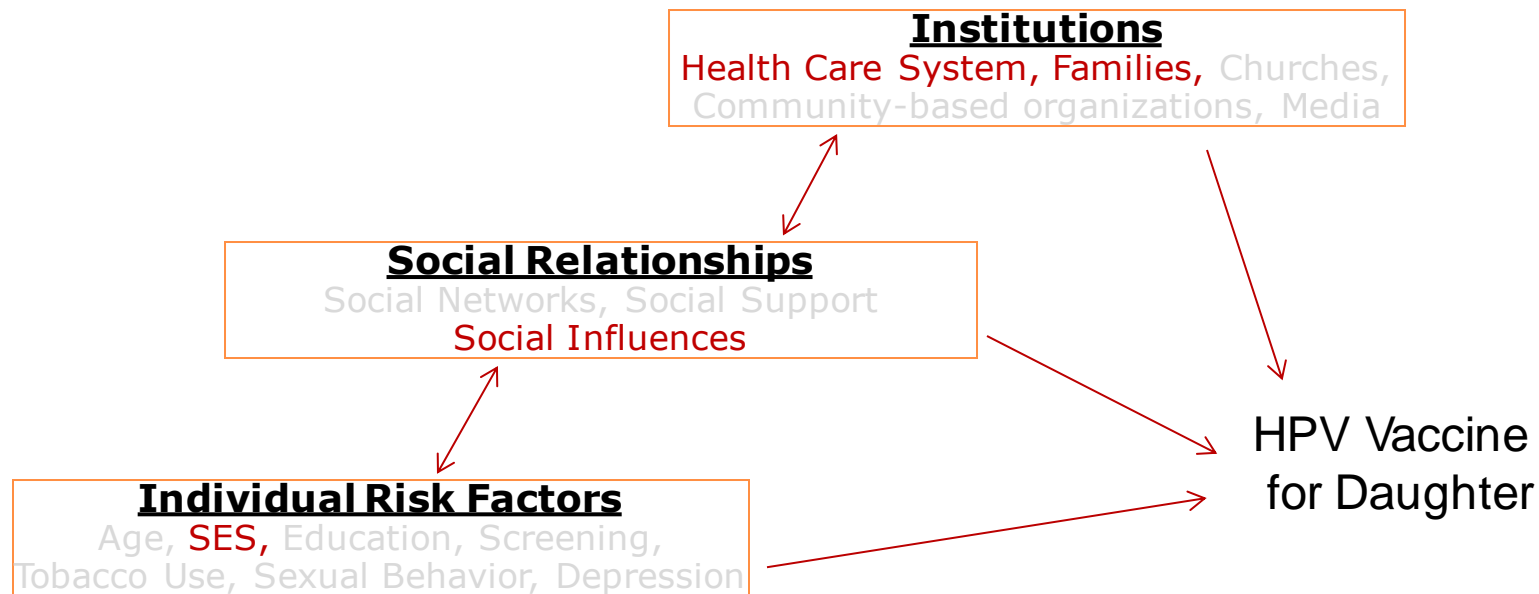
Predictors of Shot within Three Months

Variable	Received Shot	Didn't Receive Shot	OR (95% CI)	p-value
<i>Parents' age (yrs)</i>	47.9 ± 7.7	43.4 ± 6.5	1.10 (1.02, 1.19)	0.016
<i>Employment status</i>				
Full Time	10 (9%)	100 (91%)	3.50 (1.07, 11.48)	0.029
< Full Time	4 (3%)	140 (97%)	ref	

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Multi-Level Interactions and Interventions

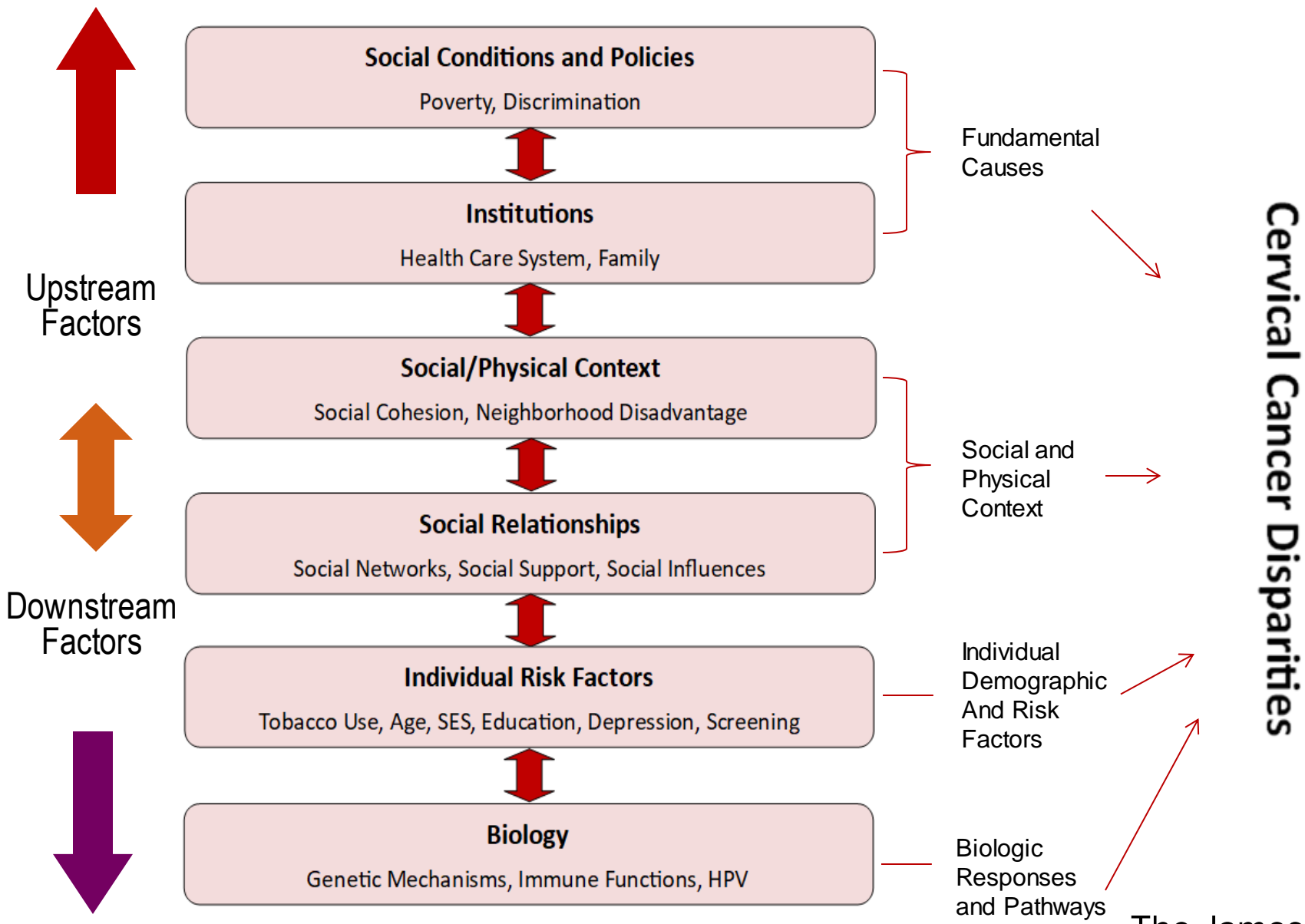
Project 4: Can a multi-level intervention improve HPV vaccination rates among young girls?



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Can we now create
a multi-level model to
explain
cervical cancer
disparities
in Appalachia?

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Paskett et al, *Cancer Prev Res*, 2020

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Acknowledgements

INVESTIGATORS:

Electra Paskett	Susan Geyer
Mira Katz	Kathi Kemper
Mike Pennell	Bo Lu
Paul Reiter	Christopher Weghorst
Janice Raup-Krieger	Maura Gillison
David Cohn	Thomas Knobloch
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Stanley Lemeshow	Valdis Krebs
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Megan Behney	

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What's Next?

Improving Uptake of Cervical Cancer Prevention Services in Appalachia

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WEST VIRGINIA UNIVERSITY

A CANCER FREE WORLD STARTS HERE



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Goal

- To address the burden of cervical cancer in Appalachia through the delivery of a clinic-based integrated prevention program that focuses on:
 - Tobacco smoking
 - Human Papillomavirus (HPV) vaccination
 - Lack of cervical cancer screening
- Designed to target individual, social and community, health system and broader contextual-level barriers related to the burden of cervical cancer.
- Across 4 Appalachian states, in FQHC's with 4 partner universities



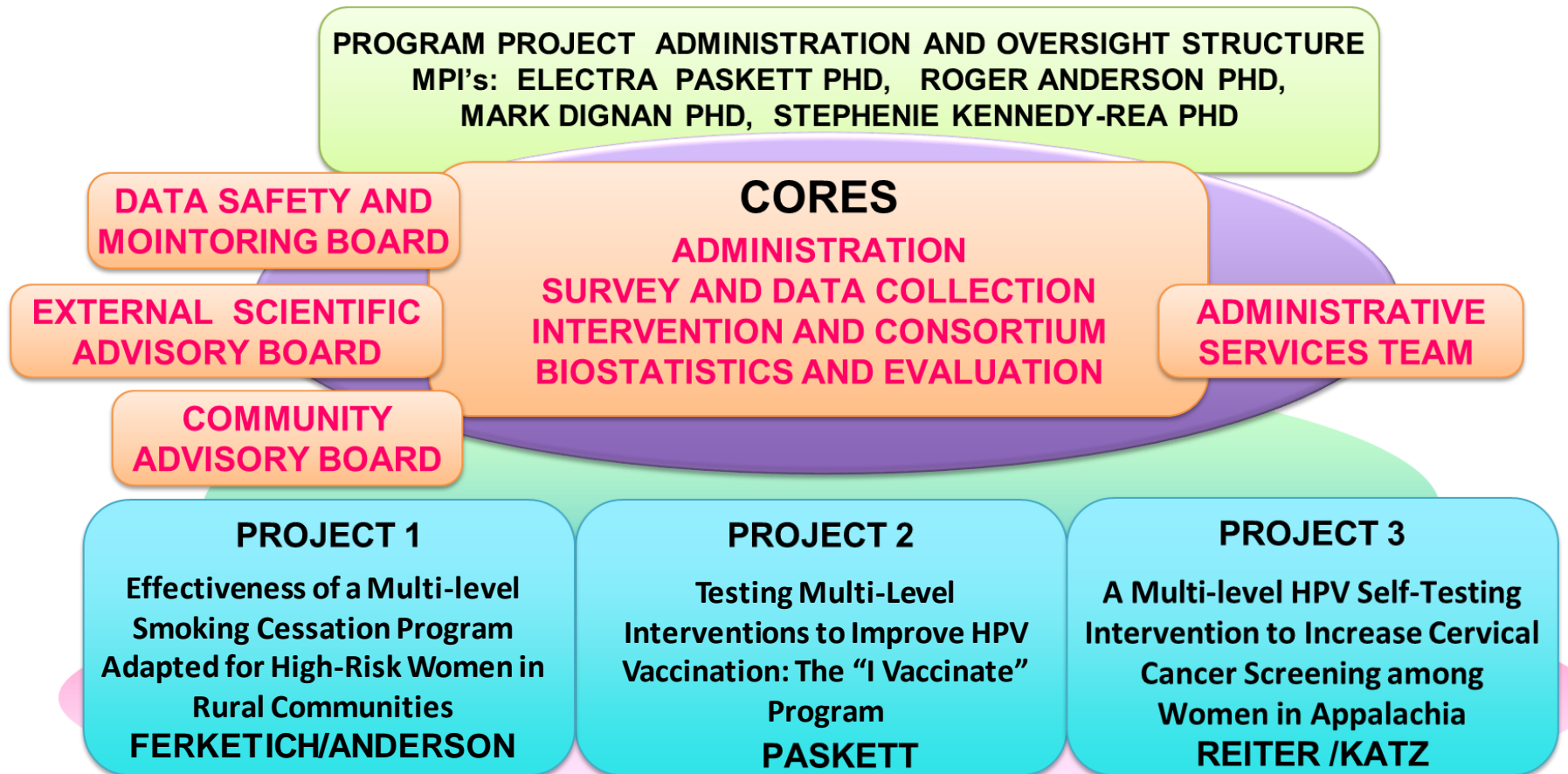
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Overall Aims

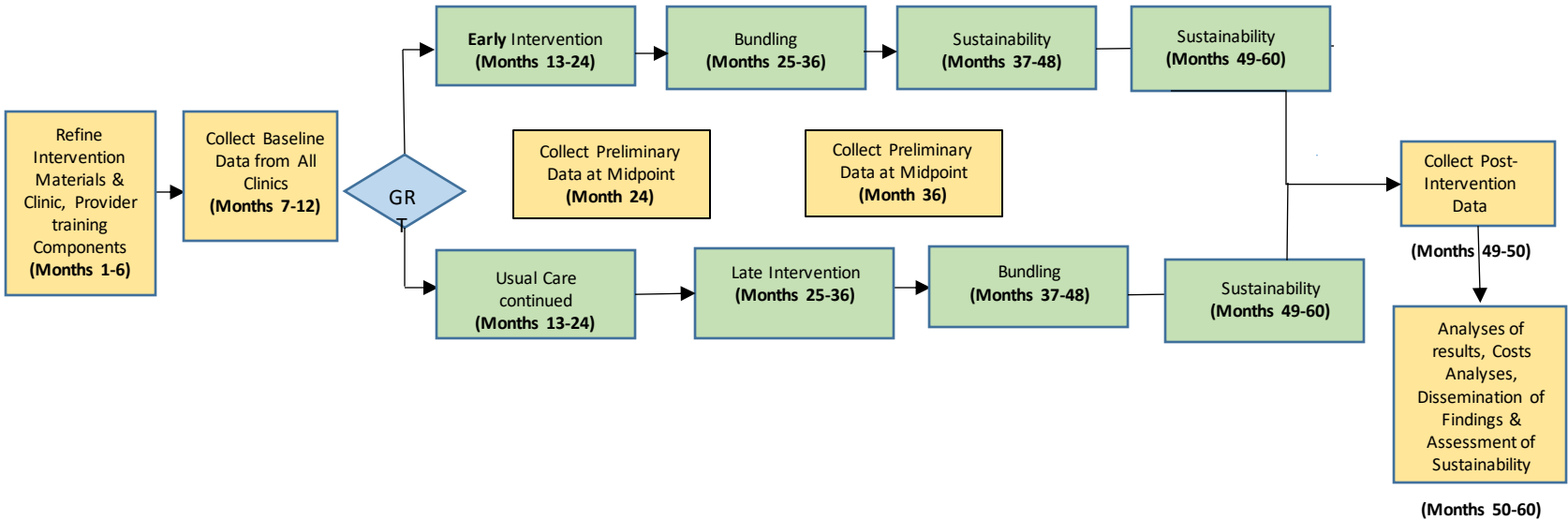
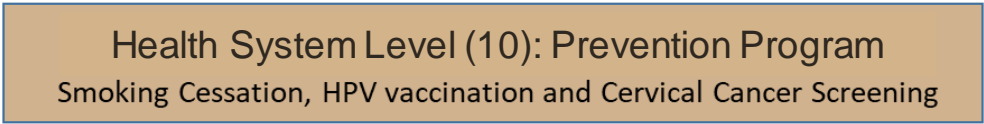
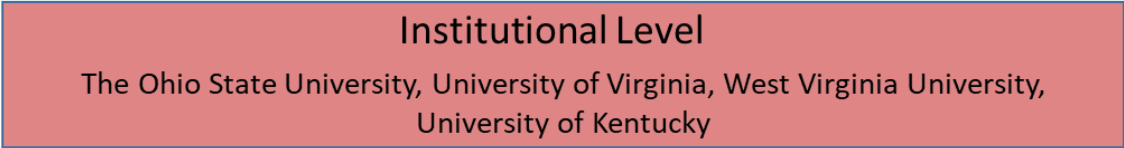
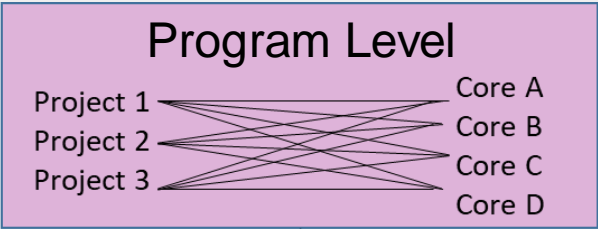
- Test the effectiveness of an integrated cervical cancer prevention program designed to address three causes of cervical cancer
- Evaluate the impact of the cervical cancer prevention program at the clinics, including:
 - Implementation
 - Acceptability
 - Short term impact
 - Long term impact
 - Bundling
 - Sustainability
- New wrinkle: COVID-19
 - Delay in starting Phase 2
 - In person vs telehealth vs putting off visits/appointments
 - Clinic viability/staffing

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Program Project Organization and Leadership



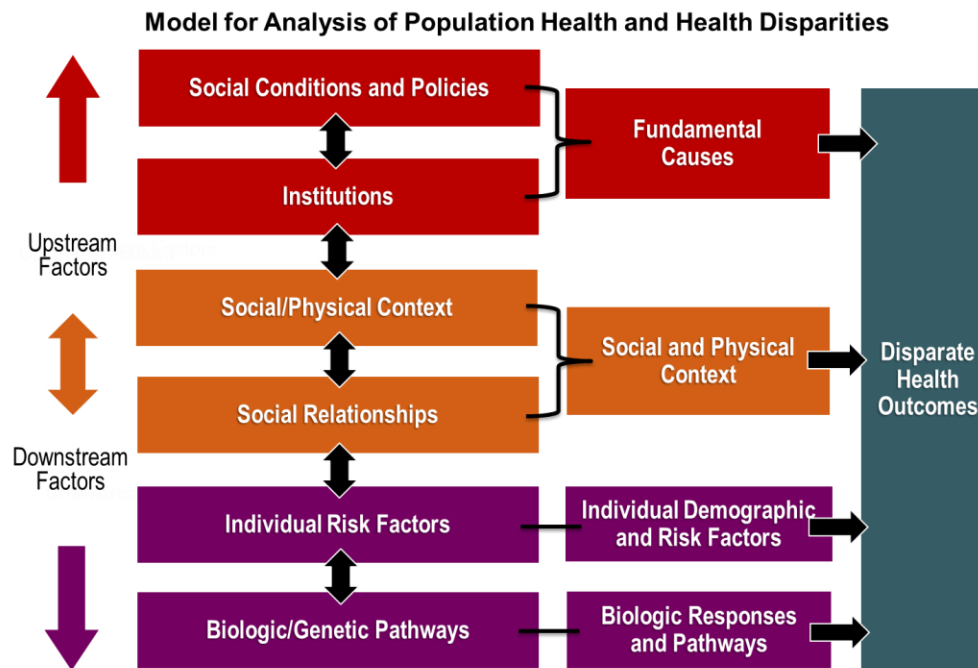
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Synergy

- All projects and cores focus on:
 - Reducing risk of Cervical Cancer throughout generations in families
 - Multi-level Framework for Addressing Disparities
 - Implementation Science



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***Break Free: Effectiveness of a Multi-level
Smoking Cessation Program Adapted for High-
risk Women in Rural Communities
The “Break Free” Program***

Project 1

Project Leaders: Roger Anderson, PHD & Amy Ferketich, PHD

Jessica Burris, PHD, Co-Investigator

Robert Kleges, PHD, Co-Investigator

Amie Ashcraft, PHD, Co-Investigator

Goal: to embed an evidence-based smoking cessation program –
Break Free – within a larger, multifaceted, integrated cervical cancer
prevention program

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Project Aims



- **Aim 1:** Test the effectiveness of a physician-level intervention based on a Theory of Planned Behavior framework.
 - Compare changes in knowledge and attitudes of providers via educational session pre-post surveys; and
 - Identify changes in clinic practices that occur as a result of the program in terms of role responsibilities for cessation.
- **Aim 2:** Test a patient-level community-health worker smoking cessation intervention to reduce cervical cancer risk in rural women aged 18 to 65 years.
- **Aim 3:** Test the efficacy of a novel intervention sub-component that delays smoking cessation based on readiness to quit by promoting smoking reduction phased to smoking cessation.

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Testing Multi-Level Interventions to Improve HPV Vaccination: The “I Vaccinate” Program

Project 2

Project Leader: Electra Paskett, PhD

Pamela Murray, MD, MHP, Co-Investigator

Jessica Malpass, PHD, Co-Investigator

Mira Katz, PHD, Co-Investigator

Mark Dignan, PHD, Co-Investigator

- **Goal:** Increase adherence to HPV vaccination recommendations by testing a multi-level intervention at health system levels of clinic, provider, parent and patient

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Project Aims



- Test the effectiveness of a multi-level intervention (MLI) directed at clinics, provider, and patients to improve HPV vaccine initiation and completion in health systems in 4 Appalachian states (KY, OH, WV, and VA) among:
 - Children aged 11-12; and
 - Those aged 13-45 for catch-up vaccination.

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A Multi-level HPV Self-Testing Intervention to Increase Cervical Cancer Screening among Women in Appalachia

Project 3

Project Leaders: Paul Reiter, PHD & Mira Katz, PHD

Emma Mitchell, PHD, Co-Investigator

Amie Ashcraft, PHD, Co-Investigator

Mark Dignan, PHD, Co-Investigator

Mack Ruffin, MD (Consultant)

Goal: to determine the effectiveness and implementation of a multilevel cervical cancer screening intervention that features a mail-based HPV self-testing program for unscreened and underscreened women in Appalachia

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Project Aims



The HOME Initiative

Educating Women. Improving Health.

- Aim 1: Determine the efficacy of the multilevel intervention
- Aim 2: Identify predictors of HPV self-test return and receipt of follow-up among high-risk HPV-positive women
- Aim 3: Determine the prevalence of high-risk HPV infection among self-test returners and cervical abnormalities among women found to be positive for high-risk HPV

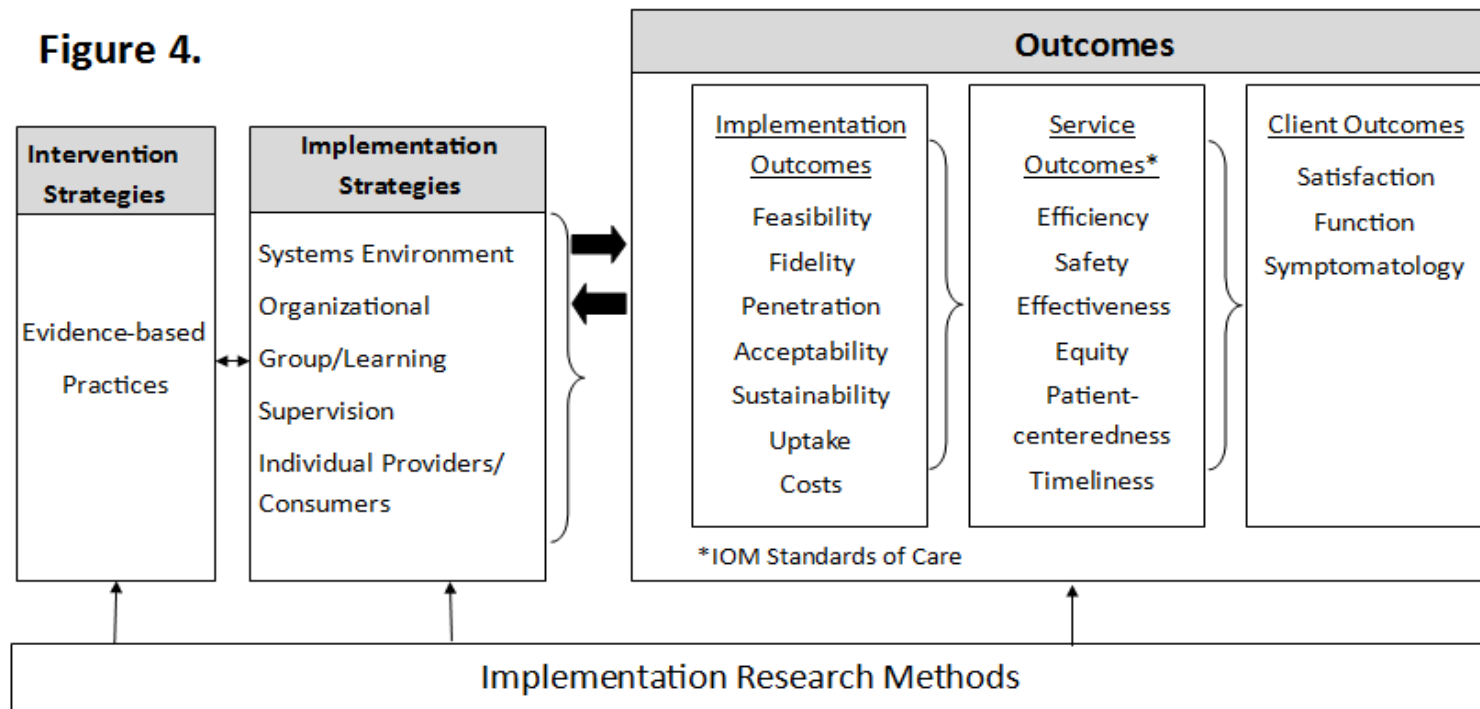
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Bundling – Clinic Level

- Woman in office visit:
 - Smokes
 - Needs Pap
 - Has children who need HPV vaccine
 - Is under age 45
- Provider can address all aspects of the program
 - Introduce each intervention to providers one at a time
 - HPV vaccine
 - Smoking
 - Pap Testing
- Over first 9 months of Active Intervention Period
 - Last 3 months teach how to bundle
 - Sustainability phase will test this further

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Evaluation Framework



(Proctor et al., 2009)

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Evaluation

■ Program-level Analyses

- Examine contributions of individual, community, primary care practice, and intervention effects on uptake of recommended cervical cancer prevention services in the participating clinics

■ Individual-level Variables

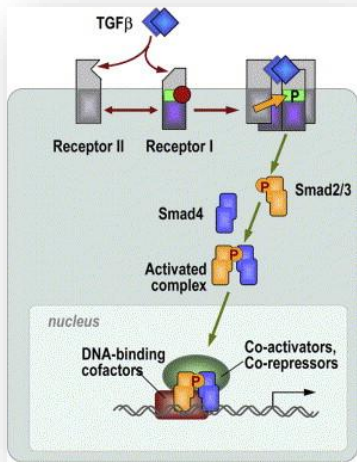
- Variables collected directly through surveys, ecological level data
- Core variables - demographics, residence location, and provider(s) seen
- Create unique variables to address project-specific objectives

■ Contextual Variables

- Indicators of population characteristics, health care supply, and location of health care resources

■ Cost-effectiveness

- Analyses for each project as well as an analysis for the entire program
- Cost identification analysis combined with outcome measures to establish the cost per desirable outcome
- Exploratory cost-benefit or cost-effectiveness analyses to assess sustainability



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community awareness
resources • education



Questions?



IS THE HPV VACCINE FOR MY DAUGHTER?

TALK TO YOUR NURSE OR DOCTOR.

You have hopes for your daughter and they do not include cervical cancer. Protect your daughter against HPV by having her vaccinated now.