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Public Health Applications of Genomics

Colleen M. McBride, Ph.D.
Grace Crum Rollins Professor & Chair
Behavioral Sciences and Health Education Dept.
Emory Rollins School of Public Health
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Today's talk

- Importance of research to shape translation of genomics for Public Health
- Overview of social and behavioral research approaches
- Principles of public health
- Examples of translation research in priority areas
- Take home messages

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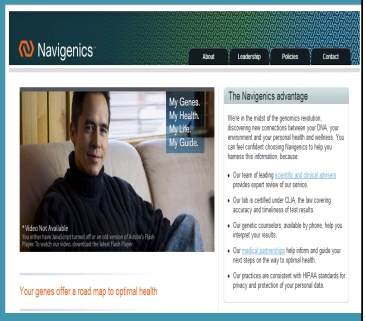
Genomic Translation: research agenda

Optimal application

Lost in translation

Premature translation



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PATHWAY GENOMICS™
YOUR FUTURE. Only Better!
activate
contact
user login
physician login
HOME
HOW IT WORKS
MORE INFO
PRODUCTS
PARTNERS
ABOUT US
Your Personal DNA Report
"Our DNA results provided us peace-of-mind. We've already taken action to reduce our risks"
The Washington Post
Walgreens won't sell genetic test over FDA objections
BY ROB STEIN
The nation's largest drugstore chain backed out Wednesday of plans to sell a saliva test that promised to scan a customer's DNA to assess his or her risk for breast cancer, heart attacks and a host of other diseases.
Walgreens had planned to offer the Pathway Genomics test at more than 6,000 of its 7,500 stores nationwide beginning Friday, but it reversed course after the Food and Drug Administration questioned whether the test could be sold legally without the agency's authorization.
"In light of the FDA contacting Pathway Genomics about its genetic test kit and anticipated ongoing discussions between the two parties, we've elected not to move forward with offering the Pathway product to our customers until we have further clarity on this matter," said Jim Cohn, a Walgreens spokesman.
The Washington Post reported Tuesday about plans by Pathway and Walgreens to start selling the over-the-counter test. Pathway said its Insight test could evaluate a propensity for developing medical conditions such as Alzheimer's disease, diabetes and obesity; the likelihood of parenting a baby with cystic fibrosis, Tay-Sachs disease and other genetic disorders; and the possible reaction to caffeine, cholesterol-lowering drugs, blood thinners and other medications.
Other companies have been selling on the Internet tests that can analyze genes for a person's risk of some diseases, and genetic tests for paternity and ancestry have been widely available in stores. But the plan by Pathway Genomics of San Diego represented the boldest move yet to bring personalized genomic science to the mass market.
It was welcomed by those who hope that deciphering the genetic code will launch a new era in biomedical science. But it raised objections from those who worried that the average consumer would have problems interpreting the results, leading to dangerous complacency about some diseas-
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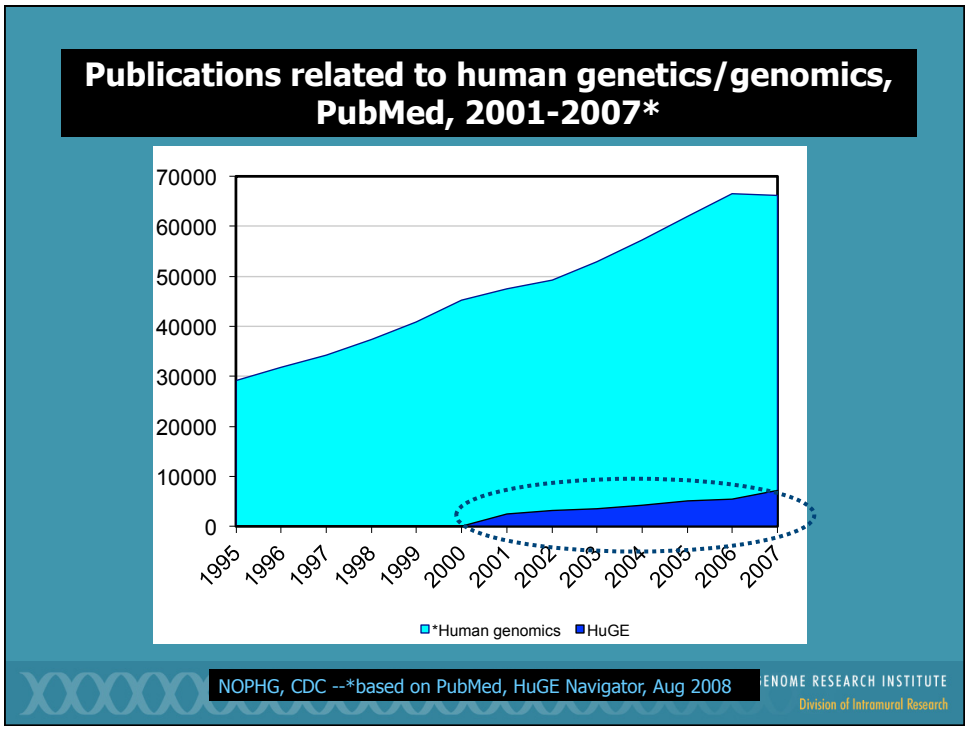
Publications related to human genetics/genomics, PubMed, 2001-2007*
70000
60000
50000
40000
30000
20000
10000
0
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
*Human genomics
HuGE
NOPHG, CDC --*based on PubMed, HuGE Navigator, Aug 2008
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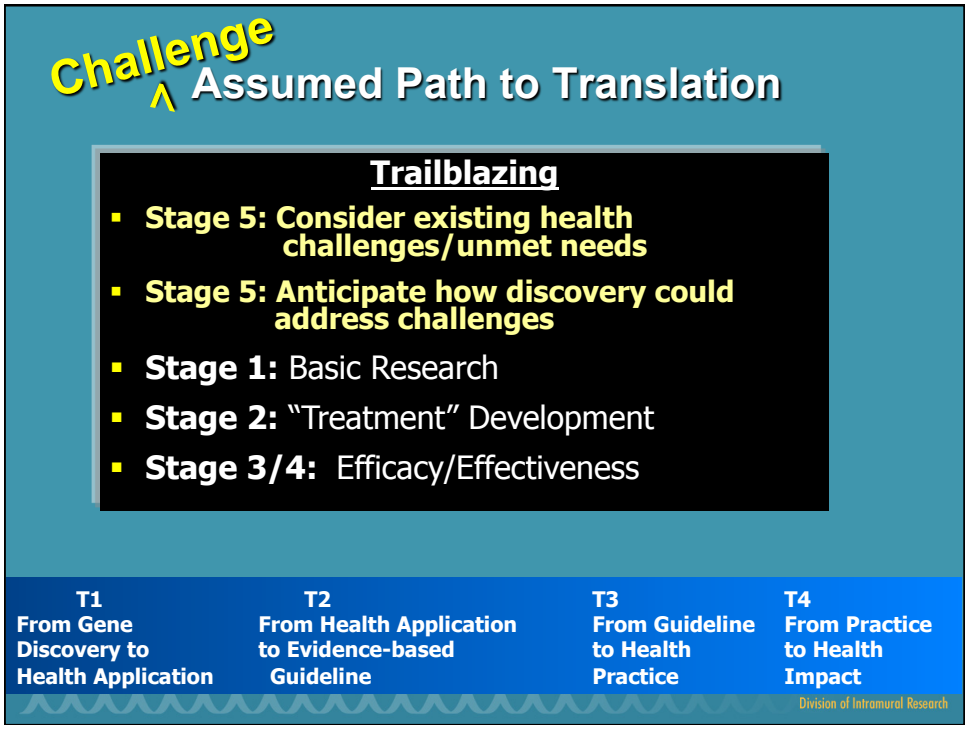
Challenge
Assumed Path to Translation
Trailblazing
Stage 5: Consider existing health challenges/unmet needs
Stage 5: Anticipate how discovery could address challenges
Stage 1: Basic Research
Stage 2: "Treatment" Development
Stage 3/4: Efficacy/Effectiveness
T1
From Gene Discovery to Health Application
T2
From Health Application to Evidence-based Guideline
T3
From Guideline to Health Practice
T4
From Practice to Health Impact
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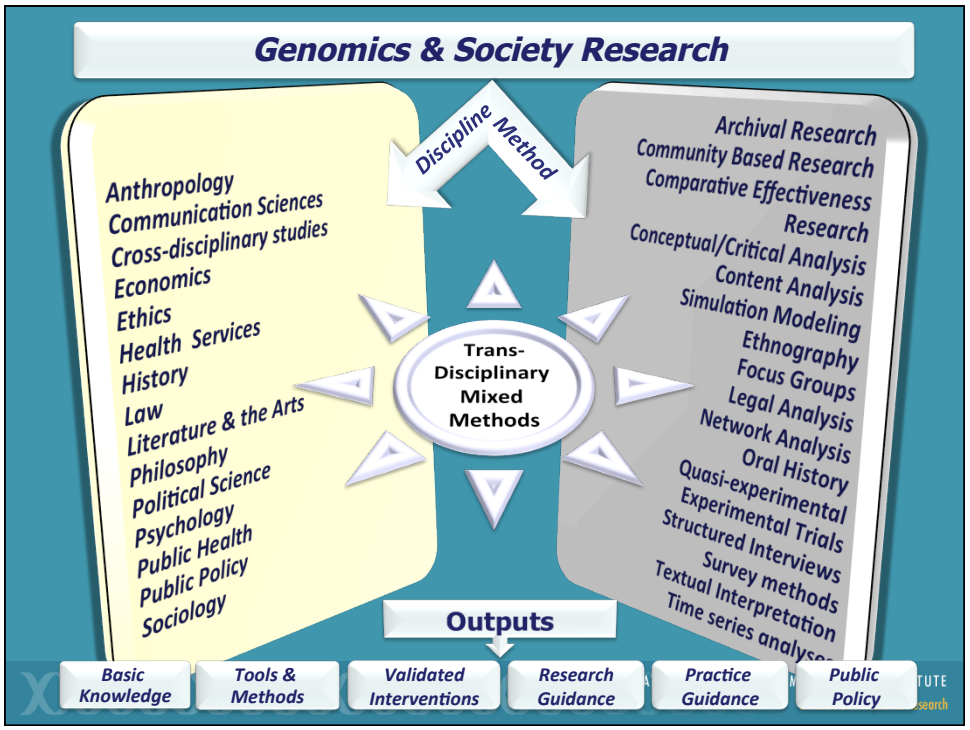

Genomics & Society Research
Discipline
Method
Anthropology
Communication Sciences
Cross-disciplinary studies
Economics
Ethics
Health Services
History
Law
Literature & the Arts
Philosophy
Political Science
Psychology
Public Health
Public Policy
Sociology
Trans-Disciplinary Mixed Methods
Archival Research
Community Based Research
Comparative Effectiveness Research
Conceptual/Critical Analysis
Content Analysis
Simulation Modeling
Ethnography
Focus Groups
Legal Analysis
Network Analysis
Oral History
Quasi-experimental
Experimental Trials
Structured Interviews
Survey methods
Textual Interpretation
Time series analys
Outputs
Basic Knowledge
Tools & Methods
Validated Interventions
Research Guidance
Practice Guidance
Public Policy

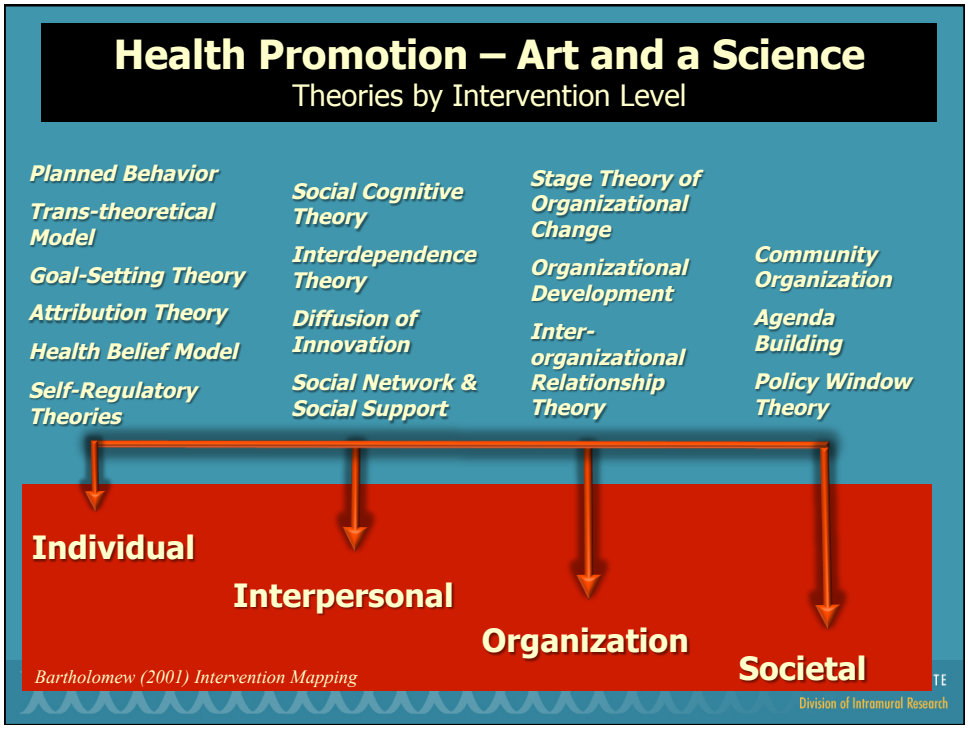
Social & Behavioral Research Approaches: What is an intervention?

Efforts directed at a target group to influence a desired outcome:

- Informed decision-making
- Individual or group behavior change
- Individual or group attitude change
- Public policy change

Intervention Objectives at the Intersection of Genomic Applications

Primary Prevention	***Healthy populations to prevent illness & injury***	***Susceptibility testing Tailored interventions***
Secondary Prevention	***Early detection, testing, hazard surveillance***	***Predictive testing of high risk groups, newborn screening***
Tertiary	***Those with disease conditions & injuries***	***Assisting those affected – e.g., living with rare conditions***


Health Promotion – Art and a Science
Theories by Intervention Level
Planned Behavior
Trans-theoretical Model
Goal-Setting Theory
Attribution Theory
Health Belief Model
Self-Regulatory Theories
Social Cognitive Theory
Interdependence Theory
Diffusion of Innovation
Social Network & Social Support
Stage Theory of Organizational Change
Organizational Development
Inter-organizational Relationship Theory
Community Organization
Agenda Building
Policy Window Theory
Individual
Interpersonal
Organization
Societal
Bartholomew (2001) Intervention Mapping
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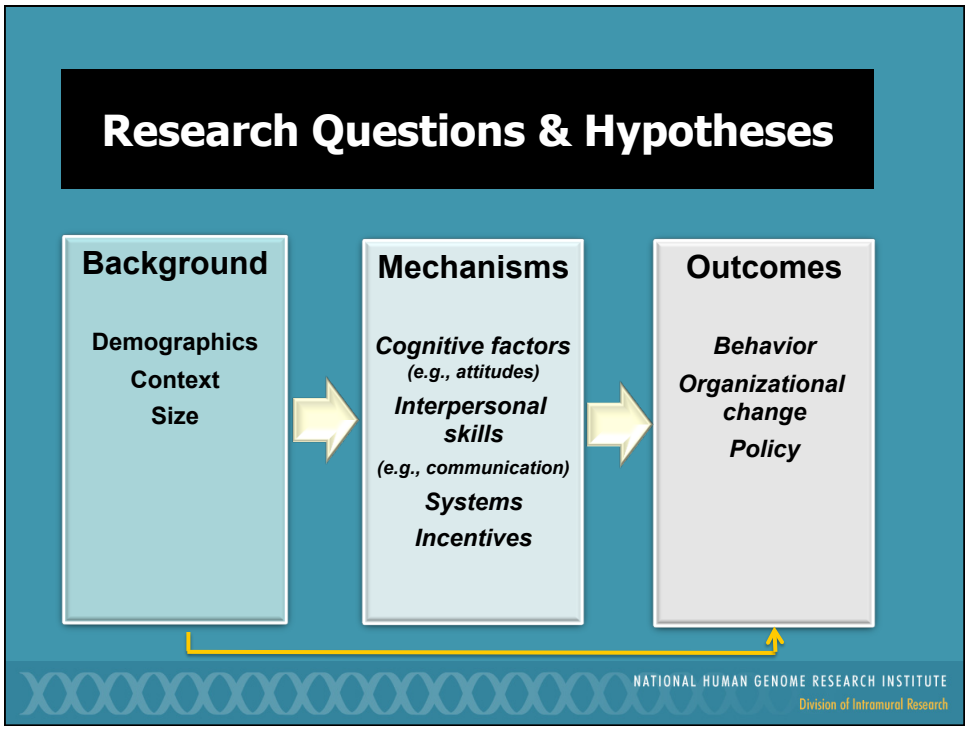
Research Questions & Hypotheses
Background
Demographics
Context
Size
Mechanisms
Cognitive factors
(e.g., attitudes)
Interpersonal skills
(e.g., communication)
Systems
Incentives
Outcomes
Behavior
Organizational change
Policy
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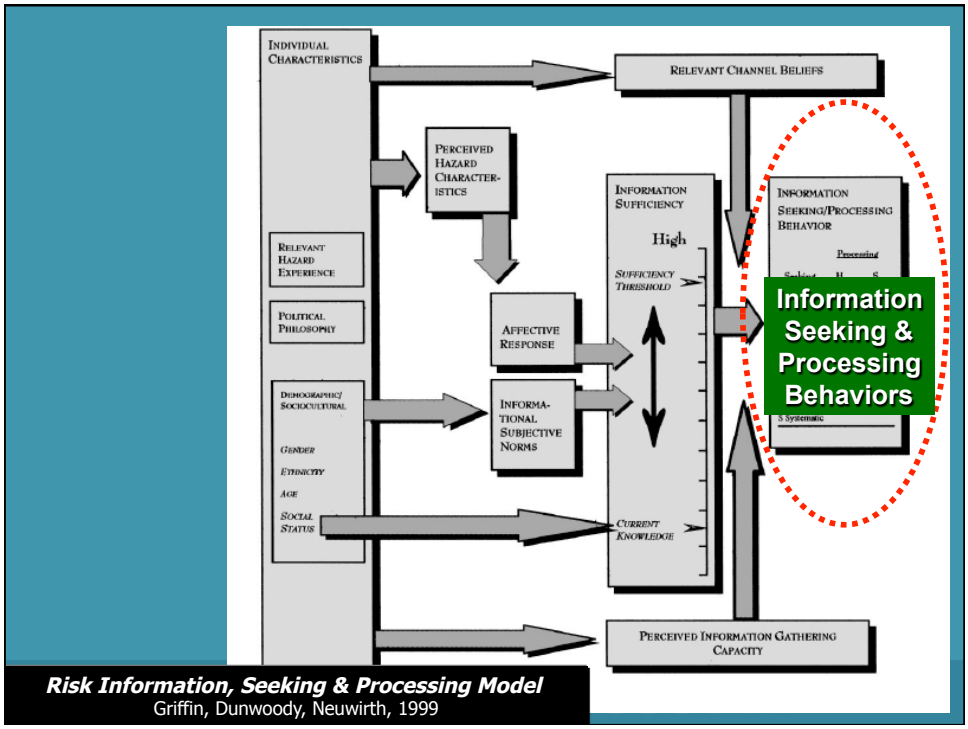
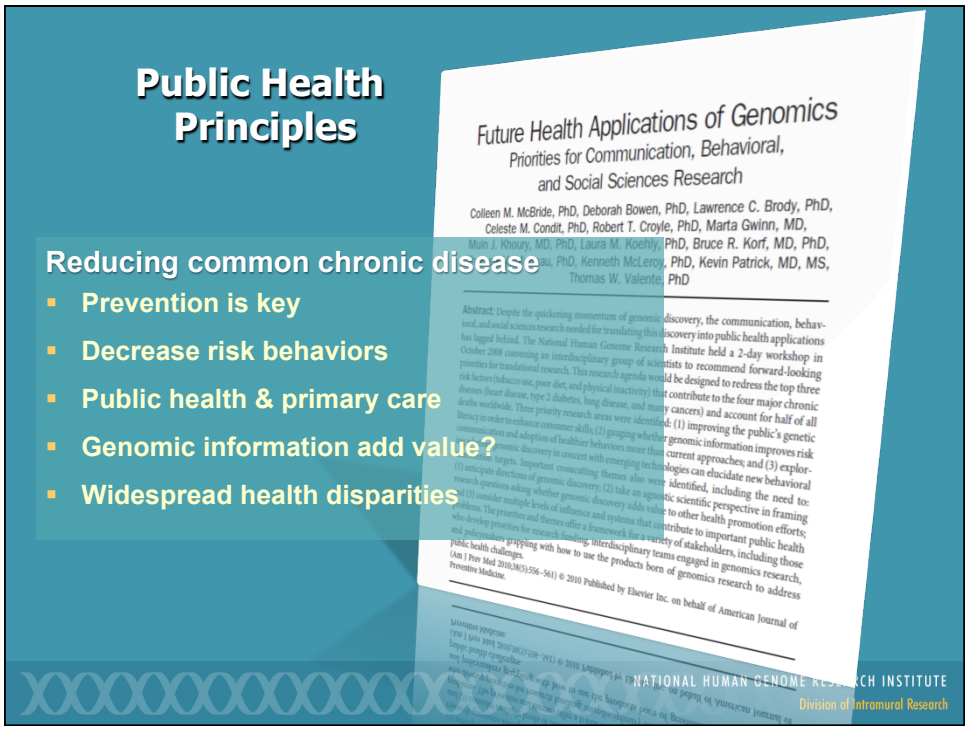

Individual Characteristics
Relevant Channel Beliefs
Perceived Hazard Characteristics
Information Sufficiency
High
Information Seeking/Processing Behavior
Relevant Hazard Experience
Sufficiency Threshold
Political Philosophy
Affective Response
Information Seeking & Processing Behaviors
Demographic/ Sociocultural
Informational Subjective Norms
Gender
Ethnicity
Age
Social Status
Current Knowledge
Perceived Information Gathering Capacity
Risk Information, Seeking & Processing Model
Griffin, Dunwoody, Neuwirth, 1999


Public Health Principles
Reducing common chronic disease
Prevention is key
Decrease risk behaviors
Public health & primary care
Genomic information add value?
Widespread health disparities
Future Health Applications of Genomics
Priorities for Communication, Behavioral, and Social Sciences Research
Colleen M. McBride, PhD, Deborah Bowen, PhD, Lawrence C. Brody, PhD, Celeste M. Condit, PhD, Robert T. Croyle, PhD, Marta Gwinn, MD, Muin J. Khoury, MD, PhD, Laura M. Koehly, PhD, Bruce R. Korf, MD, PhD, PhD, Kevin Patrick, MD, MS, Thomas W. Valente, PhD
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Public health interventions

Effectiveness

Efficacy

Reach

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Example: HNPCC Genetic counseling

Current approach

- High dose:
  - 2-3 hour sessions
- Resource intensive
  - Certified genetic counselor
  - Face to face sessions
- Demanding to sustain
  - Few genetic counselors
  - Reimbursement lacking
  - Expensive
- Highly efficacious
  - Low reach

Public Health approach

- Low dose:
  - < 1 hour
- Resource light
  - Implemented by clinic staff or health educators
  - Telephone, mail, internet
- Sustainable
  - Employ existing infrastructure
  - Inexpensive
- Effectiveness is the goal
  - Broad reach

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Clinical Genetic vs. Public Health Applications

Efficacy – Effectiveness Trade-off

Current approach

- Efficacy = .80
- Reach = .10
- .80 x .10
- Effectiveness = .08

Public Health model

- Efficacy = .20
- Reach = .50
- .20 x .50
- Effectiveness = .10

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Table 1. Areas of emphasis for genomic translational research

Priority research areas
Public understanding and use of genomic information
Potential for genomics to improve risk communication and health behavior change
Using genomics and other emerging technologies to identify new behavioral intervention targets and more sensitive intervention outcomes
Crosscutting themes
The need to anticipate directions of genomic discovery
The importance of framing research questions based on the assumption that genomics innovation may or may not add value to either individual or population-level health outcomes
The importance of systems thinking and ecologic or multilevel modeling, and transdisciplinary collaborations

McBride, Bowen, Brody, Condit et al., 2010

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Public Understanding of Genomics

Supp

- Public will be exagge common diseases/dc contributors
- Majority of individuals low probability susce
- Health care providers would be overwhelmed with patient follow-up
- Inappropriate health care use would increase

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Multiplex Prototype Test

8 health conditions & 15 genes

- **Diabetes**
  - ☑ KCNJ11
  - ☑ CAPN10
  - ☑ PPARg
  - ☑ TCF7L2
- **Heart Disease**
  - ☑ APOB
  - ☑ NOS3
  - ☑ CETP
- **High Cholesterol**
  - ☑ LIPC
- **Hypertension**
  - ☑ AGT
- **Lung cancer**
  - ☑ MPO
- **Colon Cancer**
  - ☑ MTHFR
- **Skin Cancer**
  - ☑ MC1R
- **Osteoporosis**
  - ☑ ESR1
  - ☑ IL6
  - ☑ COL1A1


Original Paper

Public Health Genomics

Considerations for Designing a Prototype Genetic Test for Use in Translational Research

C.H. Wade[a, b] C.M. McBride[b] S.L.R. Kardia[c] L.C. Brody[a]

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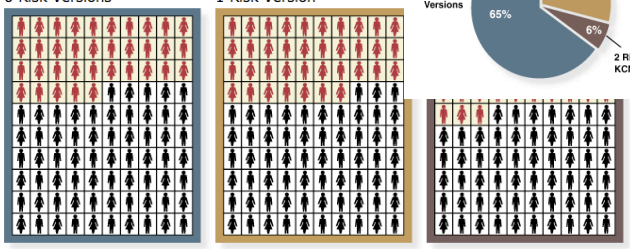
Information About Genes

What is someone's chance of getting diabetes in th KCNJ11 risk versions?

- People who have **no risk versions** of KCNJ11 will h chance of getting diabetes.
- People who have **1 risk version** of KCNJ11 will hav chance of getting diabetes.
- People who have **2 risk versions** of KCNJ11 will ha chance of getting diabetes.

Chance of getting diabetes based on the number of (Out of 100 people. People with diabetes are shown in re

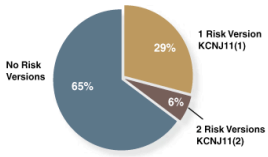
0 Risk Versions | 1 Risk Version



How common are the risk versions of KCNJ11?

- About 65% of people in the general public have **0 risk versions**.
- About 29% of people in the general public have **1 risk version**.
- About 6% of people in the general public have **2 risk versions**.

Percentage of People With 0, 1, or 2 Risk Versions of KCNJ11 in the General Public



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Study Design

- **NCI-funded Cancer Research Network**
  - Henry Ford Health System clinical recruitment site
    - Group Health Cooperative Survey coordination
- **Sample: Healthy adults**
  - Ages 25-40
  - Without diseases on test battery

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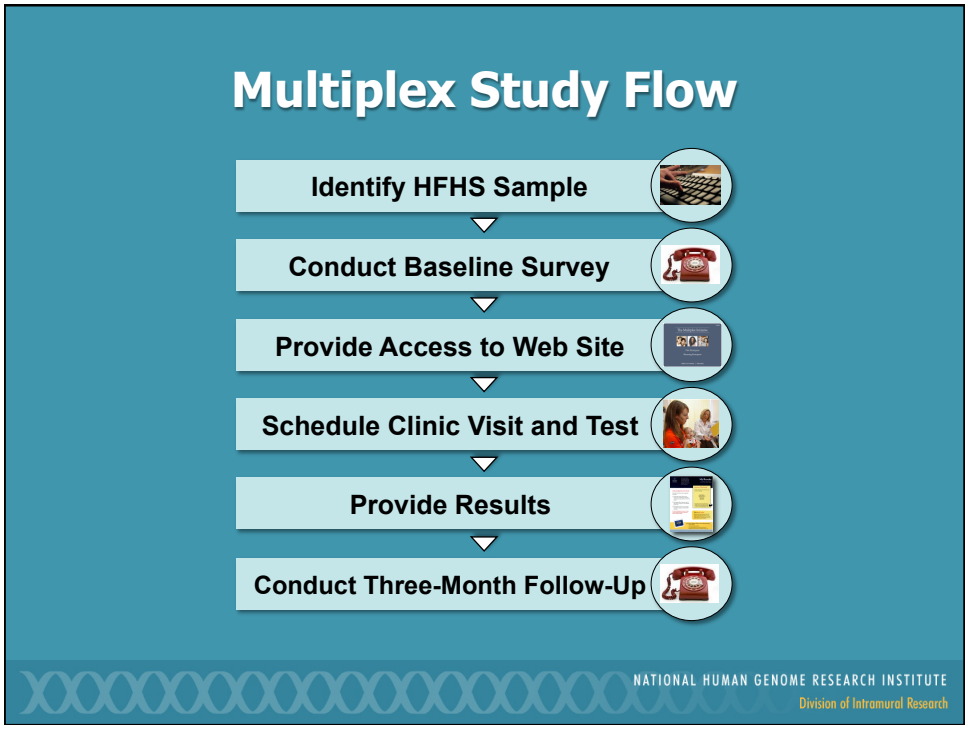
Multiplex Study Flow
Identify HFHS Sample
Conduct Baseline Survey
Provide Access to Web Site
Schedule Clinic Visit and Test
Provide Results
Conduct Three-Month Follow-Up
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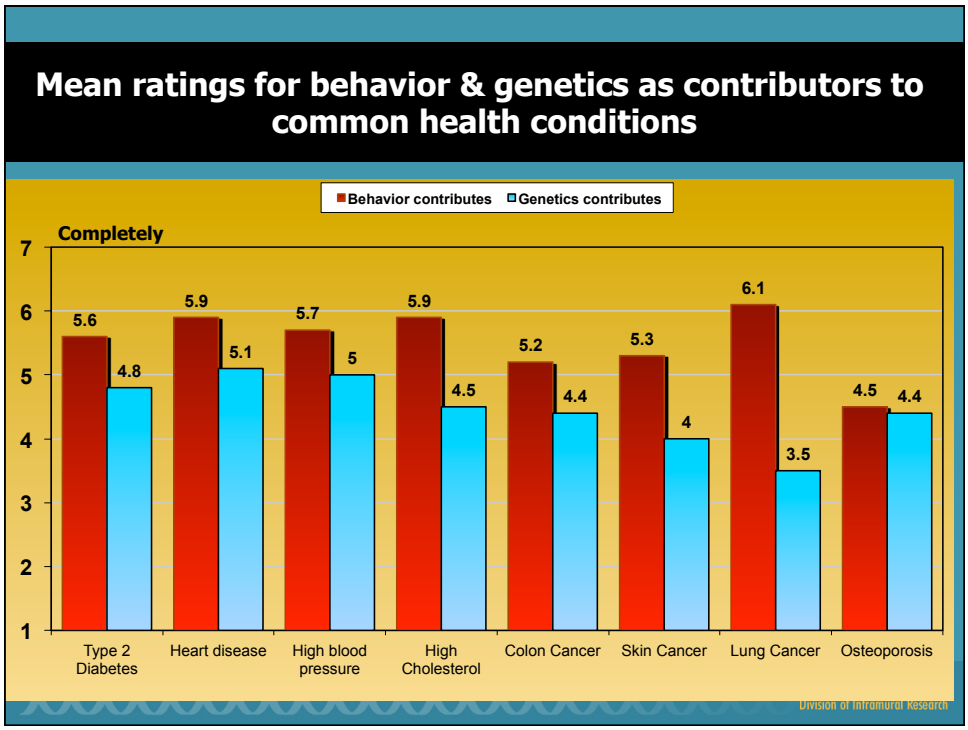
Mean ratings for behavior & genetics as contributors to common health conditions
Behavior contributes
Genetics contributes
Completely
7
6
5
4
3
2
1
5.6
4.8
5.9
5.1
5.7
5
5.9
4.5
5.2
4.4
5.3
4
6.1
3.5
4.5
4.4
Type 2 Diabetes
Heart disease
High blood pressure
High Cholesterol
Colon Cancer
Skin Cancer
Lung Cancer
Osteoporosis
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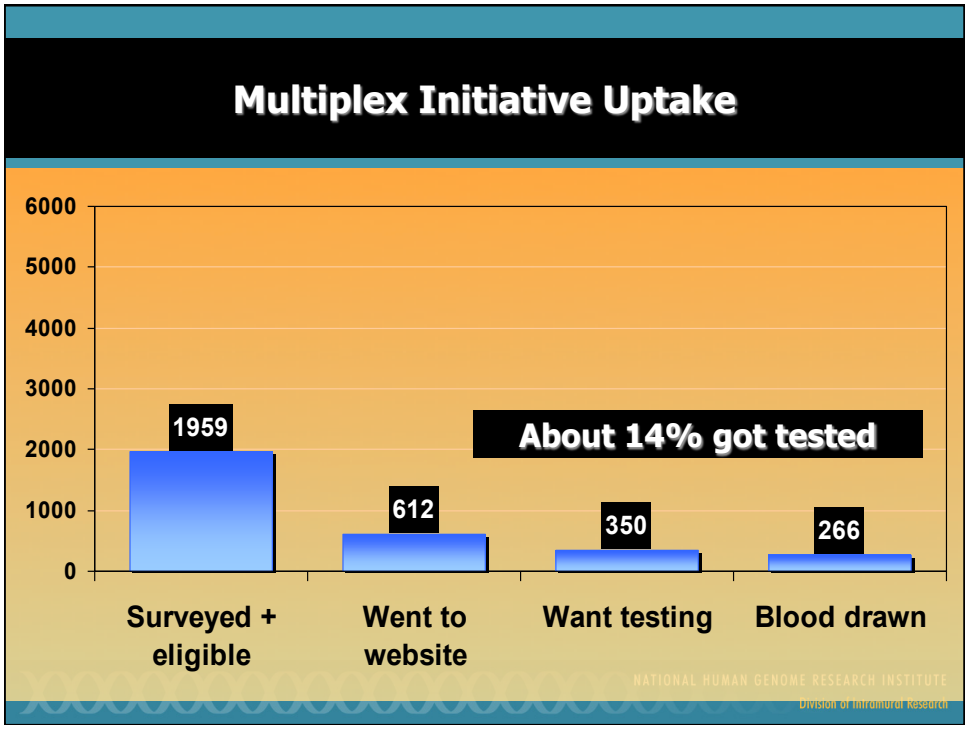
Multiplex Initiative Uptake
6000
5000
4000
3000
2000
1000
0
1959
612
350
266
About 14% got tested
Surveyed + eligible
Went to website
Want testing
Blood drawn
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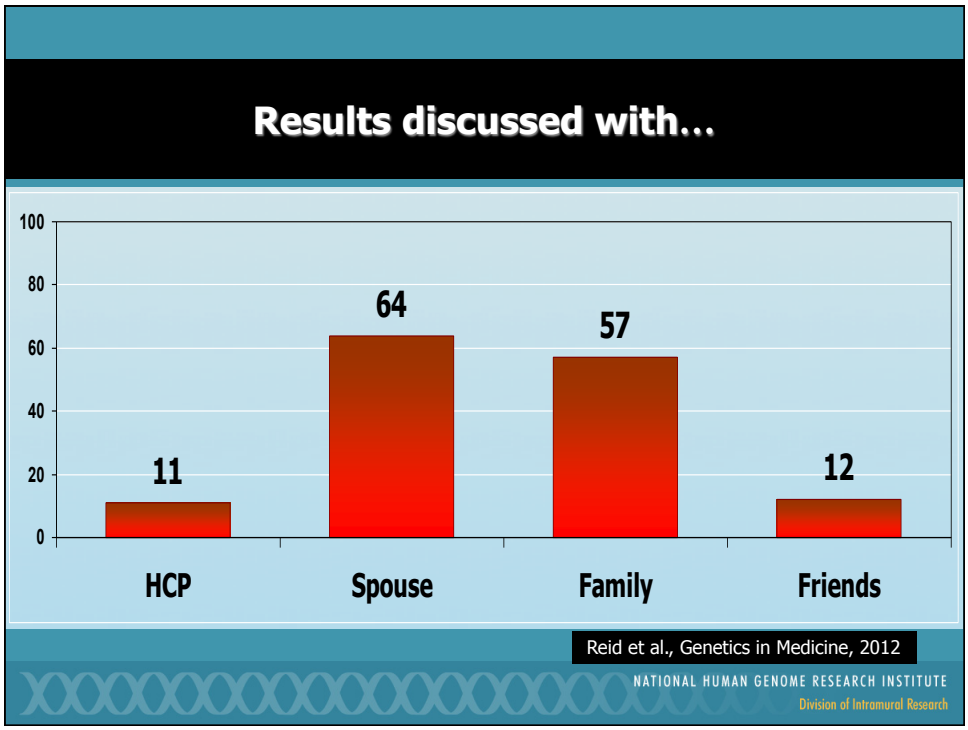
Results discussed with…
100
80
60
40
20
0
11
64
57
12
HCP
Spouse
Family
Friends
Reid et al., Genetics in Medicine, 2012
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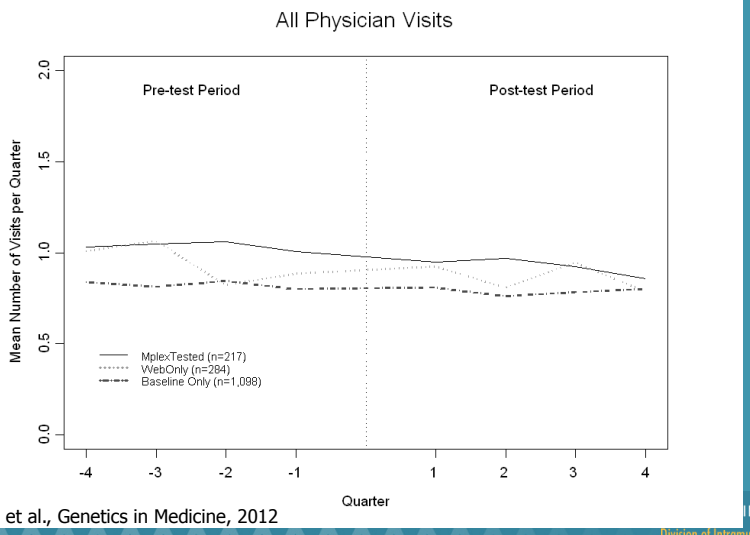
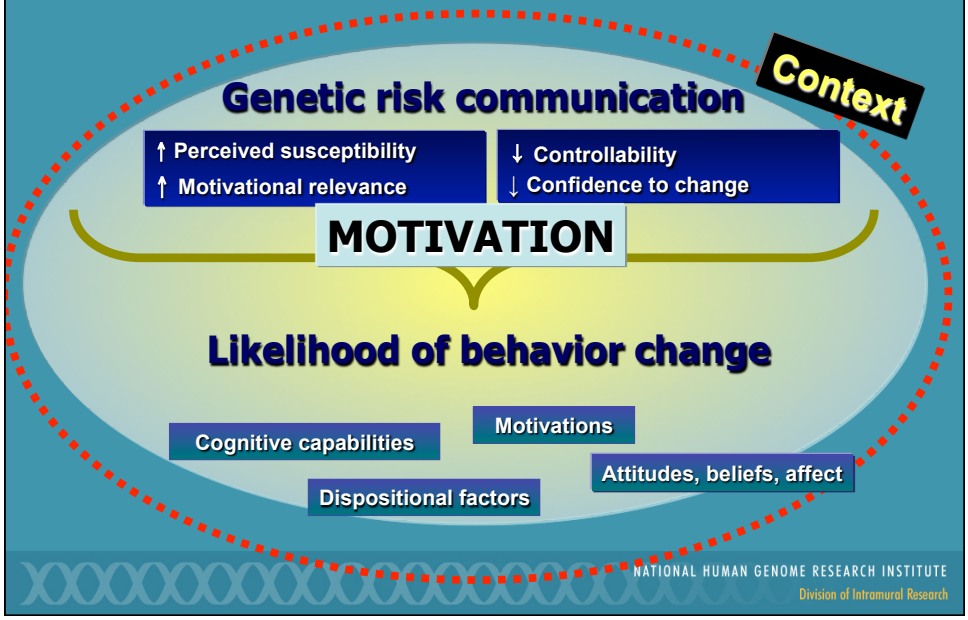
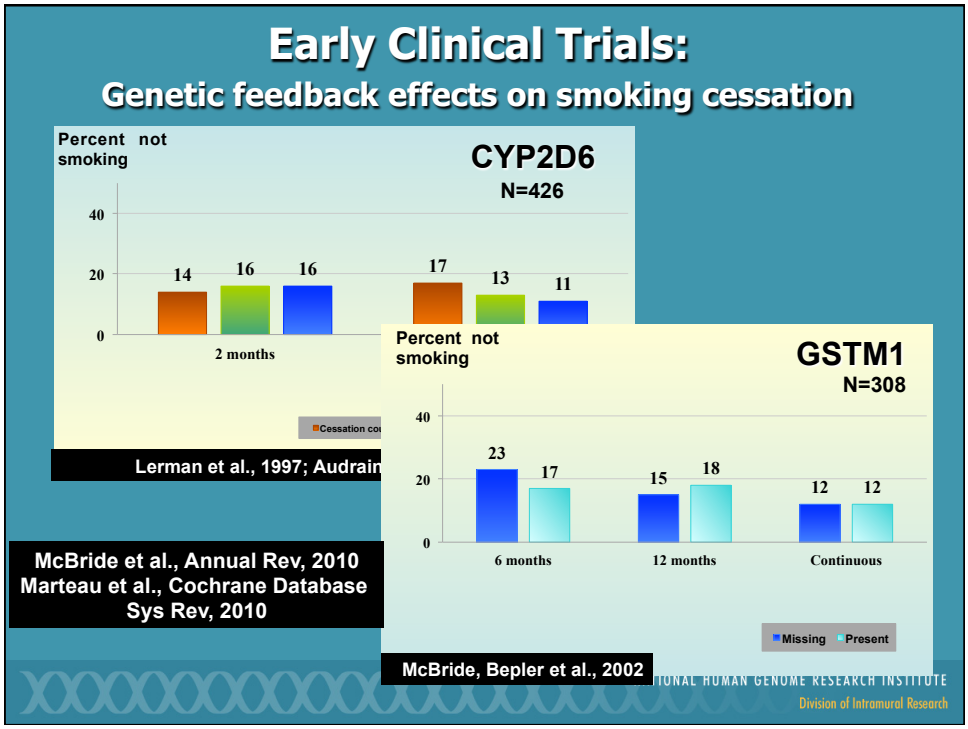
Health Care Use by Test Group



Reid et al., Genetics in Medicine, 2012

Potential to motivate behavior change




Early Clinical Trials:
Genetic feedback effects on smoking cessation
Percent not smoking
CYP2D6
N=426
40
20
0
14
16
16
17
13
11
2 months
Lerman et al., 1997; Audrain
Percent not smoking
GSTM1
N=308
40
20
0
23
17
15
18
12
12
6 months
12 months
Continuous
Missing
Present
McBride et al., Annual Rev, 2010
Marteau et al., Cochrane Database Sys Rev, 2010
McBride, Bepler et al., 2002
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Can genetic risk information motivate smokers to quit?
Welcome to the
FAMILY RISK AND LUNG CANCER STUDY
Thank you for Participating!
NEXT

Which smokers visited the website to consider genetic testing?

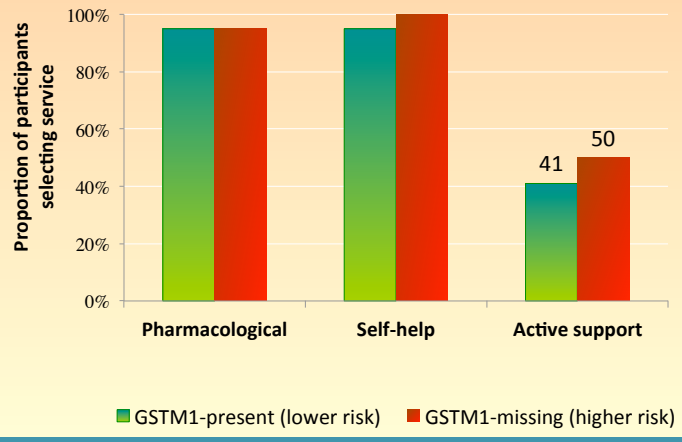
Demographics	Logged on (n = 58)	Did not log on (n = 58)	Sig.
			NS
Female	59%	48%	
Mean Age (yrs)	40.1 (8.3)	36.5 (10.5)	<0.05
Education			
High school or less	28%	36%	NS
Technical degree / some college	50%	41%	
College degree	22%	23%	
Unemployed	14%	14%	NS
Non-Hispanic white	96%	96%	NS
Daily internet use	85%	62%	<0.05
Aware of cancer genetic testing	61%	42%	<0.05
Motivation to quit smoking[1]	**6.3 (1.1)**	**5.6 (1.7)**	**<0.01**
Closeness to patient[1]	5.5 (1.1)	5.2 (1.1)	NS

[1]1-7 scale

O'Neill et al., Genetics in Medicine, 2008

Uptake of offered cessation services

Sanderson et al., Cancer Epi, Biomarkers & Prevention, 2009



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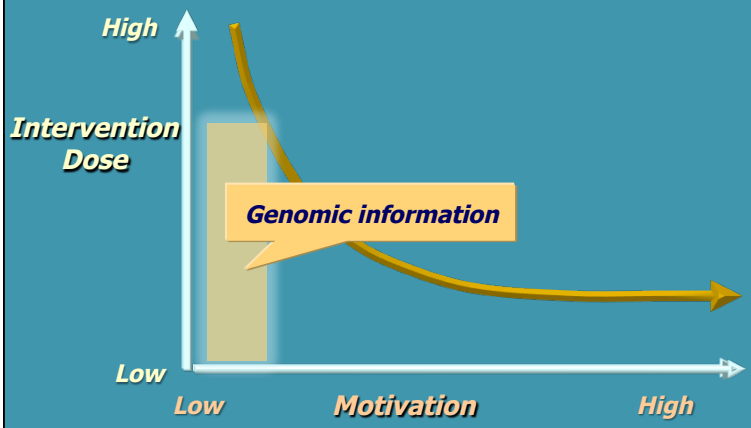
Optimal contexts for genomic information?



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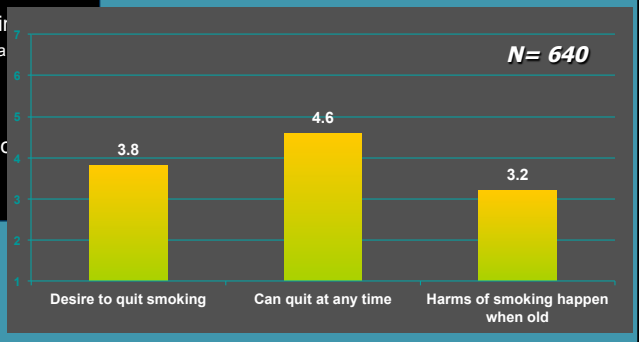
College smokers' responses to genetic risk of lung cancer

Lipkus PI (NCI-funded)

- **Primary Prevention:**
  - College smokers important target group (Patterson, Lerman et al., 2004)
  - Interested in genetic testi risk (McBride, Lipkus, Jolly, Lyna
- **Conceptual models**
  - Protection motivation theo (Rogers, 1983)



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Use genomic information to counteract backfiring public health messages

Another major theme reported by 32% of participants related to media reports of speed and ease of lung repair after individuals quit smoking, e.g. *"Possibly lung cancer, but I'm not too worried about that. On a scale of 1 to 10, I'm a 2 on that worry. It (smoking) helps with school stress and they say that once you quit your lungs will repair within 2 years, or something. So I figure I can quit after graduate school and my lungs will be great by the time I'm 25".*

33 structured interviews

Docherty et al., Journal of Community Genetics, 2011

Leverage points for genetic risk communications

- ***Young smokers do not understand association between susceptibility & exposure***
- ***Underestimate potential for addiction***

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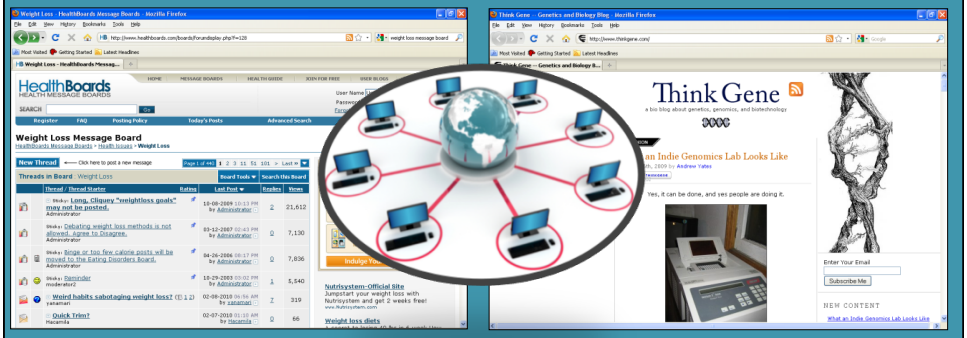
Could social media be a viable tool for engaging target groups in discourse for learning?



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Challenges for Research on Clinical Integration of Genomics

- Changing nature of genomic technology
- Future situations difficult to envision, predict
- Concepts & contexts complicated, technical, unfamiliar

- IVETA useful tool:
  - Improves upon hypothetical scenarios
  - Enables rigorous behavioral outcomes
  - Avoids practical challenges of food preparation

Persky, Kaphingst, Condit & McBride, 2007

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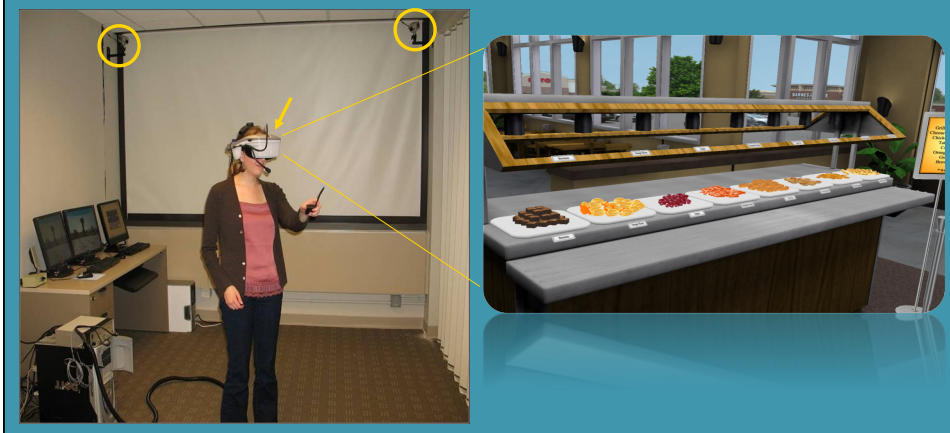
Immersive Virtual Environment Testing Area



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Mothers' TAKE: Virtual Reality Assessment of Mothers' Behavioral Responses to Children's Genomic Risk

Aims

- Explore concerns that genetic risk info for obesity may increase restrictive parenting practices
- Evaluate behavioral effects of providing family history-based obesity risk information about children to parents

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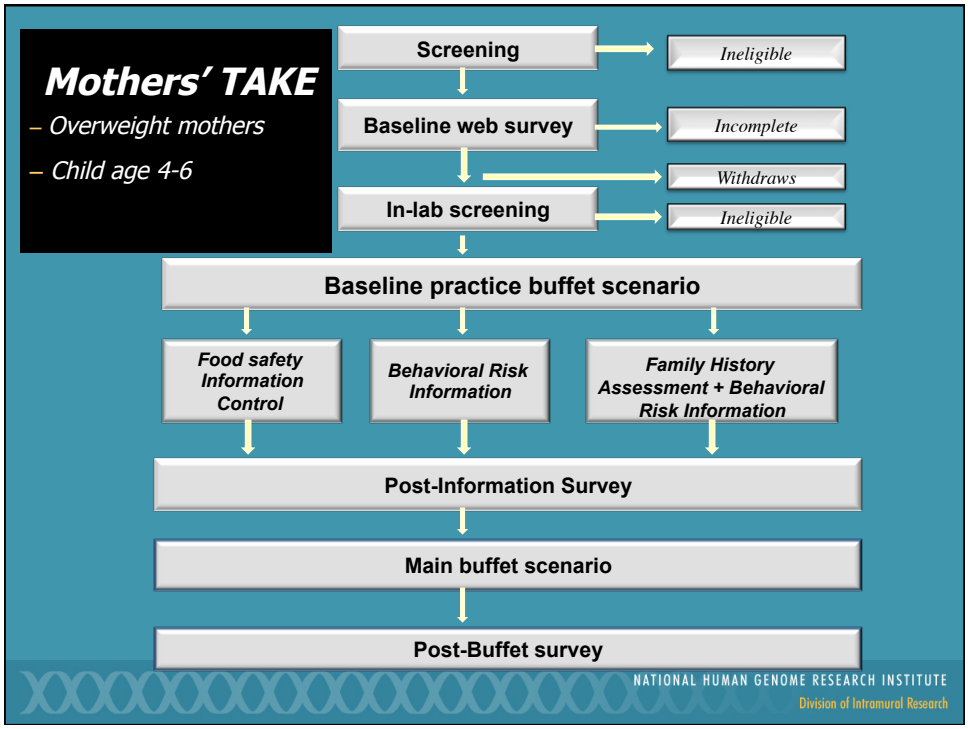

Total Calories by Experimental Arm

	Estimate	SE
Intercept	248.73**	88.83
Pre-calorie	0.67***	0.20
Mother's age	-2.68	1.61
Mother is white	-34.65	18.22
Mother's BMI	2.75	1.80
Beh. Risk arm	-35.48	21.10
Beh + Fam hx arm	-45.26*	21.19
Index child is overweight	15.19	17.80
Index child is male	35.72*	17.32
Family has one child	0.48	20.13

*$p \leq 0.05$; **$p \leq 0.01$; ***$p \leq 0.001$; ****$p \leq 0.0001$

McBride, Persky et al., *Obesity,* 2012

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Influence of Risk Message on Total Calories for Family Hx Arm

	Estimate	SE
Intercept	176.92	140.27
Pre-calorie	0.73	0.38
Mother's age	-2.66	3.05
Mother is white	21.23	33.29
Mother's BMI	0.75	3.19
Two overweight parents	71.48*	31.97
Index child is overweight	19.38	32.49
Index child is male	23.55	30.47
Family has one child	-23.93	37.91

**p≤0.05*

McBride, Persky et al., *Obesity,* 2012

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Is the effect of risk message specific to the family history arm?

	Food Safety			Beh Risk Info			Beh Risk + Fam Hx		
	Number of overweight biological parents			Number of overweight biological parents			Number of overweight biological parents		
Outcome	One n=31	Two n=42	sig	One n=29	Two n=43	sig	One n=22	Two N=53	sig
Plated calories	372.20	406.52	0.275	359.50	368.49	0.784	286.9	360.9	0.051
Sweetened beverage	45.2%	47.6%	0.835	48.3%	51.2%	0.810	13.6%	37.7%	0.039

McBride, Persky et al., Obesity, 2012

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Promoting Global Public Health?

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Promoting footwear among genetically high-risk children

- Podoconiosis - non-filarial elephantiasis
- Inflammatory lymphatic response to soil irritants
- Clusters in families in Highland Ethiopia.
- Preventable with consistent footwear > inconsistent adherence
- 50% of population < age 15
- Inadequate public health infrastructure
- Targeting shoes to high risk

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The Characteristics of Study Sites

	Site 1	Site 2	Site 3	Site 4
Number of Cases* *Registered annually with MFTPA	1,754	2,420	2,233	868
Duration of Relationship with MFTPA (Years)	11			
Distance from MFTPA (Km)	35			

28 Focus groups
38 Individual interviews
7 Case studies
307 Participants

Ayode et al., Am. J. Tropical Medicine & Hygiene, 2012

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Common sense beliefs about the cause of podoconiosis

Heredity

- ↓ perceived importance of preventive behaviors
- ↑ interpersonal stigmatizing behavior

Not Heredity

- ↑ perceived importance to wear shoes for prevention
- ↑ empathy to patients
- Fear of contagion

Stigma

- Social distancing
- Partner selection
- Self stigma

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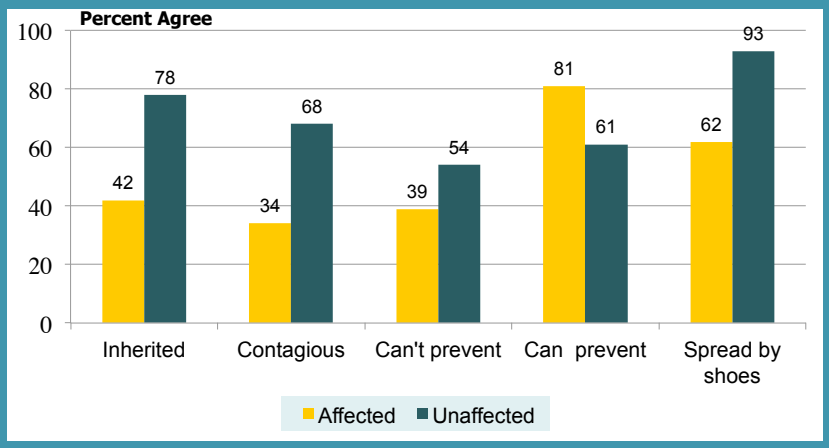
Baseline Beliefs about Podoconiosis

(Affected n=591; Unaffected n=1195)



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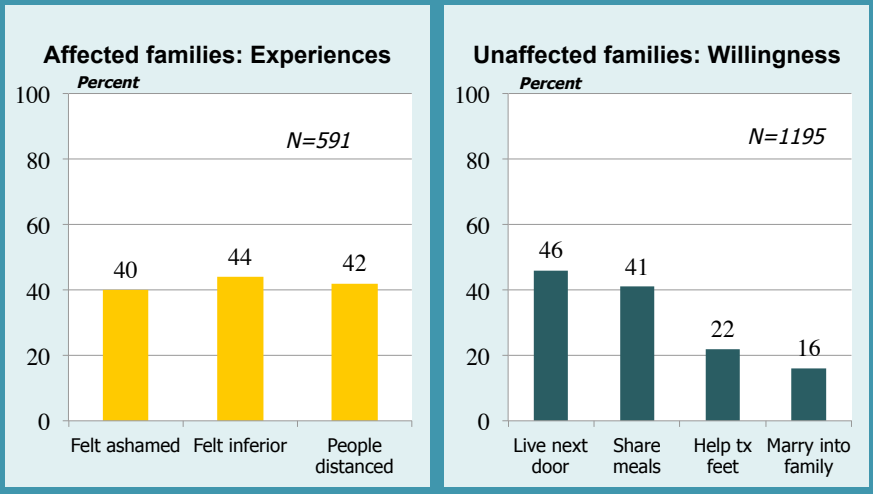
Stigma Experiences of & Reported Willingness to Socially Distance



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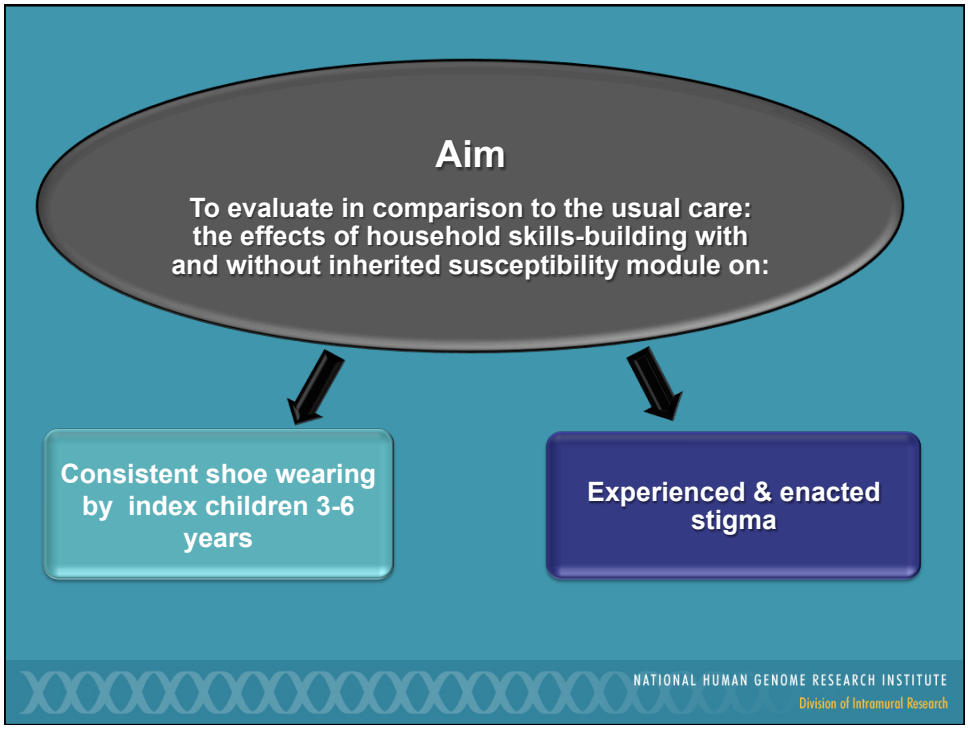
Aim
To evaluate in comparison to the usual care: the effects of household skills-building with and without inherited susceptibility module on:
Consistent shoe wearing by index children 3-6 years
Experienced & enacted stigma
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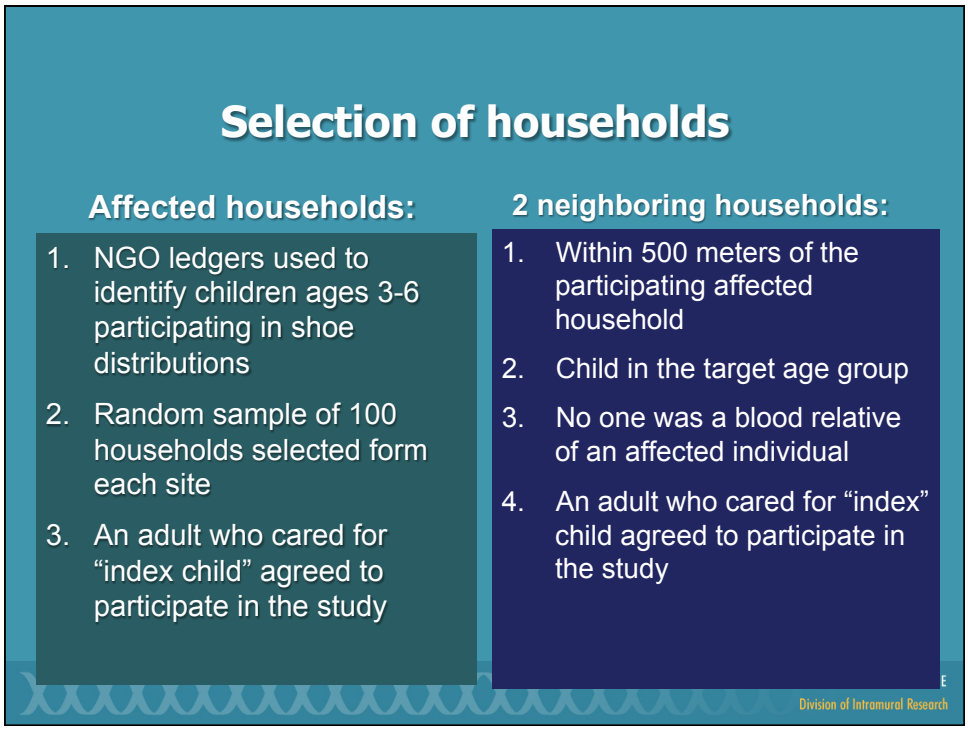
Selection of households
Affected households:
1. NGO ledgers used to identify children ages 3-6 participating in shoe distributions
2. Random sample of 100 households selected form each site
3. An adult who cared for "index child" agreed to participate in the study
2 neighboring households:
1. Within 500 meters of the participating affected household
2. Child in the target age group
3. No one was a blood relative of an affected individual
4. An adult who cared for "index" child agreed to participate in the study
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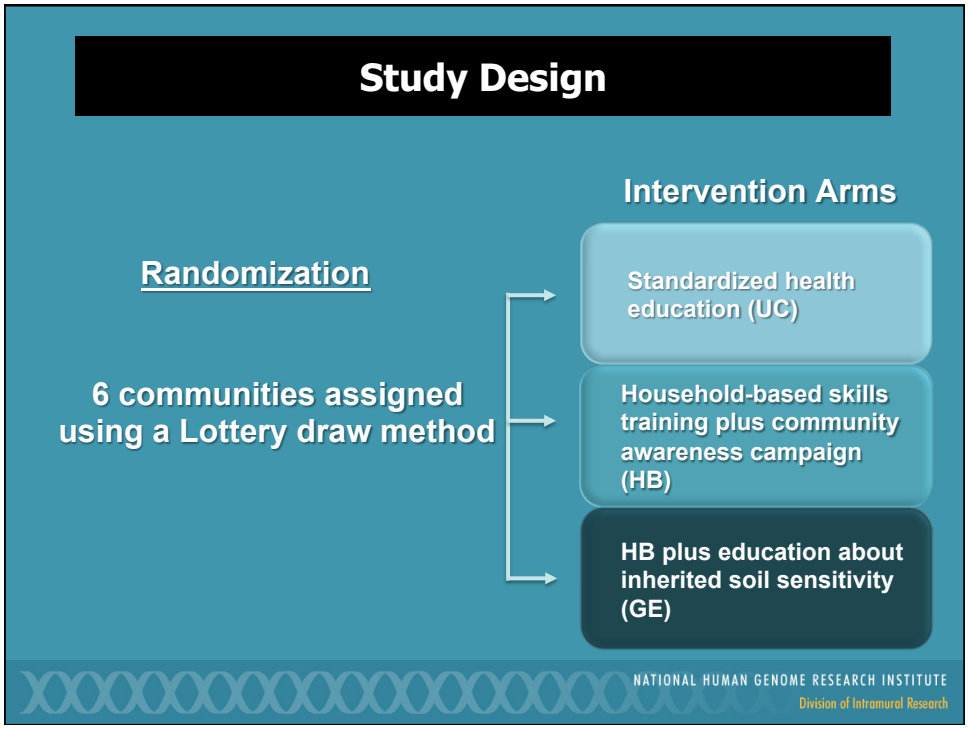
Study Design
Intervention Arms
Randomization
6 communities assigned using a Lottery draw method
Standardized health education (UC)
Household-based skills training plus community awareness campaign (HB)
HB plus education about inherited soil sensitivity (GE)
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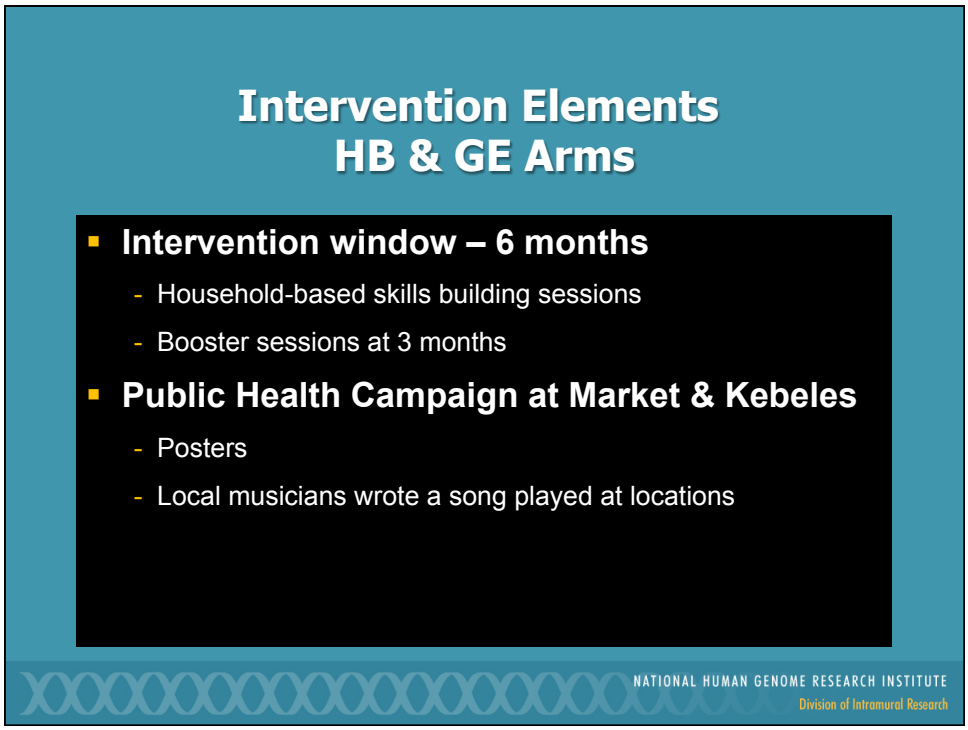
Intervention Elements
HB & GE Arms
Intervention window – 6 months
Household-based skills building sessions
Booster sessions at 3 months
Public Health Campaign at Market & Kebeles
Posters
Local musicians wrote a song played at locations
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Shoes keep you healthy in the FIELDS
Shoes keep you healthy while you work
Public Health Campaign
Shoes are for PLAY
Shoes are for CHORES
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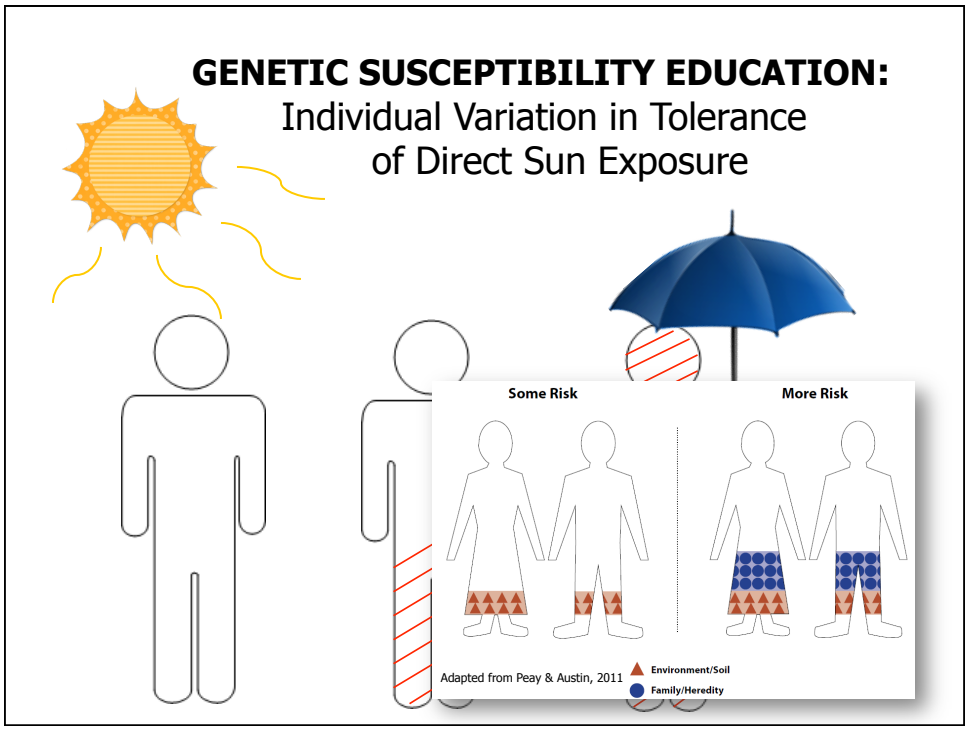
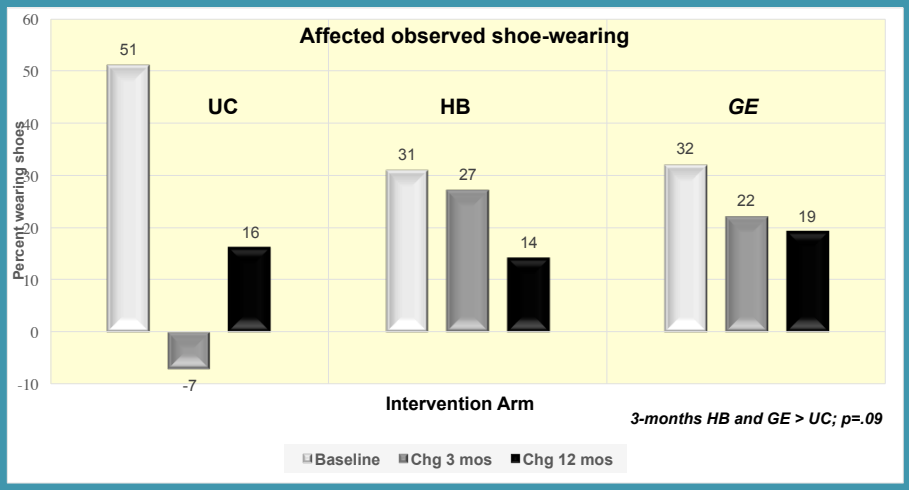

GENETIC SUSCEPTIBILITY EDUCATION:
Individual Variation in Tolerance
of Direct Sun Exposure
Some Risk
More Risk
Adapted from Peay & Austin, 2011
Environment/Soil
Family/Heredity

Primary Outcomes



McBride, Price et al., Intl J Health Sci, 2016

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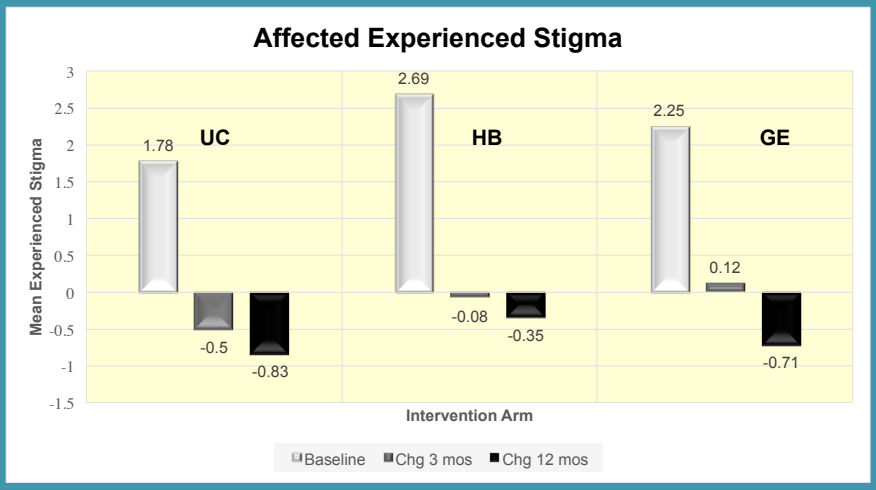
Affected Experienced Stigma



McBride, Price et al., Intl J Health Sci, 2016

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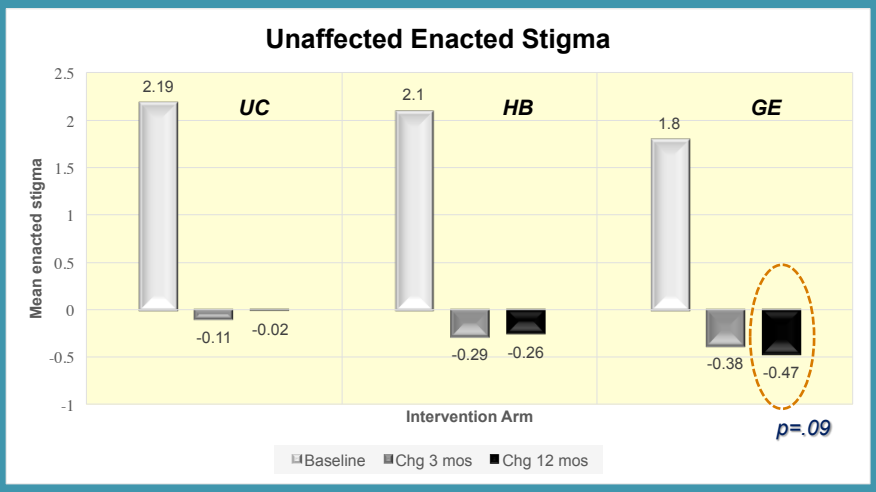


McBride, Price et al., Intl J Health Sci, 2016

The Precision Medicine Initiative"

- Move away from "one-size-fits-all" treatments
- Treat and prevent disease based on individual differences in genetics, environment and lifestyle

Precision Public Health for the Era of Precision Medicine

Muin J. Khoury, MD, PhD,[1,2] Michael F. Iademarco, MD, MPH,[1,3] William T. Riley, PhD[2]

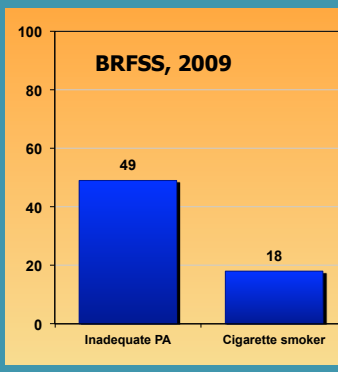
The Precision Medicine Initiative[1] promises a new healthcare era. A proposed 1 million–person cohort could create a deeper understanding of disease causation. Improvements in quality of sequencing, reduction in price, and advances in "omic" fields and biotechnology promise a new era, variably labeled personalized or precision medicine. Although genomics is one driver of precision health care, other factors may

evidentiary foundation for use. The following are examples of priority areas.

Role of Multidisciplinary Public Health Sciences

Though precision medicine focuses on individualized

Public Awareness
The Behavior – Intervention Disconnect



CLINICAL SIGNIFICANCE

- Over the last 18 years, obesity has increased from 28% to 36%; regular physical activity has decreased from 53% to 43%; and eating 5 or more fruits and vegetables a day has decreased from 42% to 26% among adults aged 40-74 years.
- Adherence to all 5 healthy habits has gone from 15% to 8% ($P < .05$).
- Adherence to healthy habits is no more likely in people with cardiovascular disease, hypertension, diabetes, or hypercholesterolemia.

King et al., AJPM 2009 -- NHANES

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Smoking Relapse

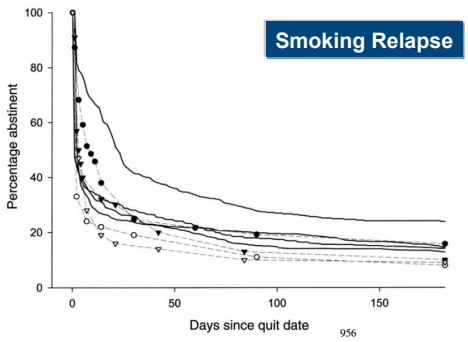

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Figure 1 True survival curves (solid lines) and line-graph relapse curves (dotted lines) in self-quitters (o
in control groups (solid circles and triangles) from studies in Table 1.

Weight Regain

TATE ET AL

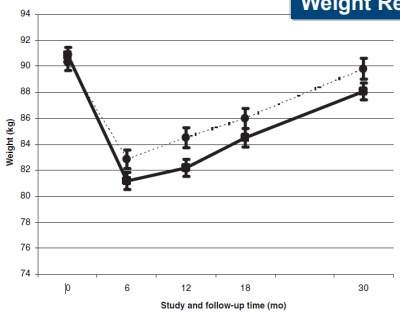


FIGURE 1. Weight by randomized group. ●, Standard behavior treatment group ($n = 66$); ■, high physical activity group ($n = 75$). Time effect, $P < 0.001$; treatment × time interaction, $P = 0.21$ (repeated-measures ANOVA).

Randomized controlled trial of four commercial weight loss programs in the UK

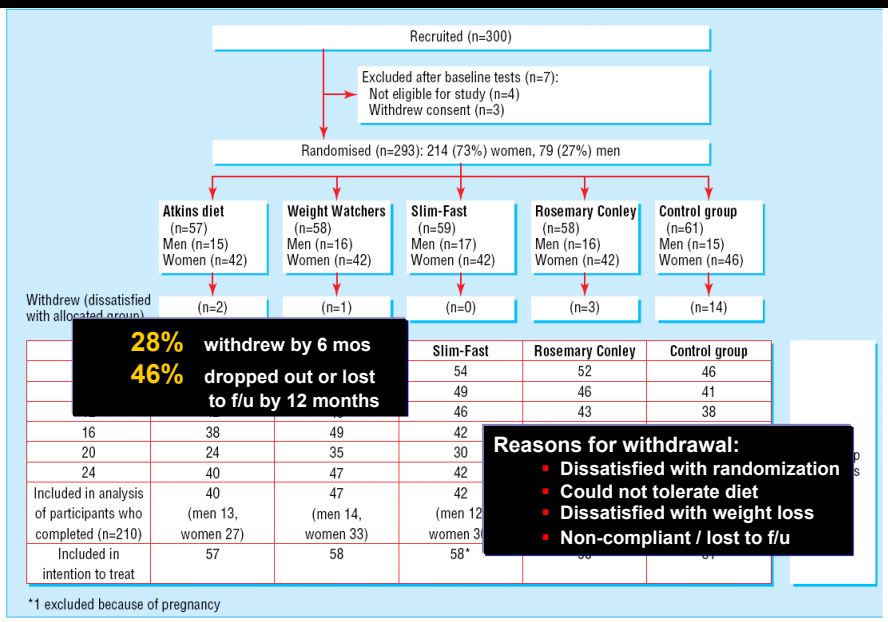
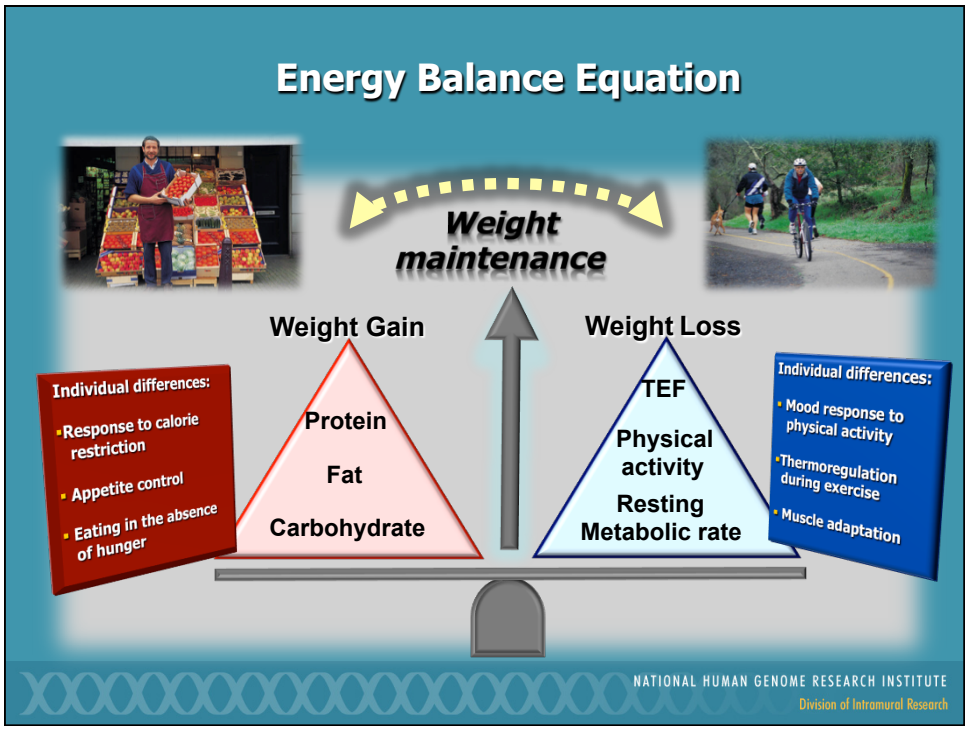
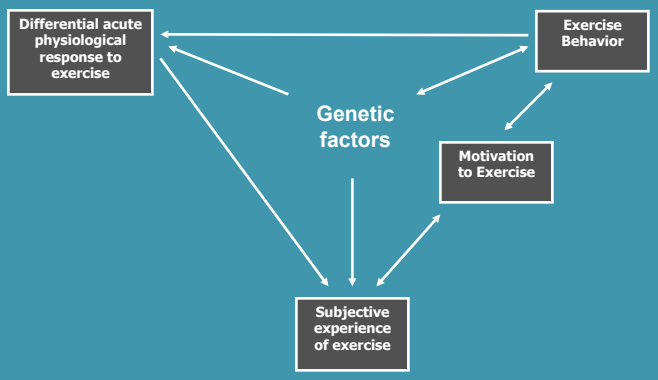


Fig 1 Flow of participants through the BBC diet trials

Truby et al, BMJ, 2006



A Transdisciplinary Model: Genetic, Physiological & Psychological Correlates of Voluntary Exercise



Bryan et al., 2007; *Health Psychology;* Bryan et al., 2010, *Psychology of Sport and Exercise*, Magnan et al., 2011

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International Journal of Obesity (2003) 27, 1028–1036

www.nature.com/ijo

PAPER

Difficulty in losing weight by behavioral intervention for women with Trp64Arg polymorphism of the β_3-adrenergic receptor gene

K Shiwaku[1]*, A Nogi[1], E Anuurad[1], K Kitajima[1], B Enkhmaa[1], K Shimono[1] and Y Yamane[1]

[1]Department of Environmental Medicine, Shimane Medical University, Izumo City, Shimane, Japan

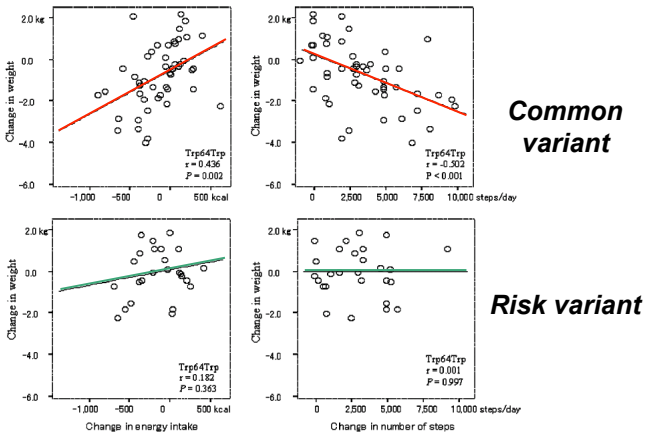

Figure 1 Correlation between weight loss and changes in energy intake or number of steps Pearson's correlation coefficients associated with weight loss and *P* values were expressed.

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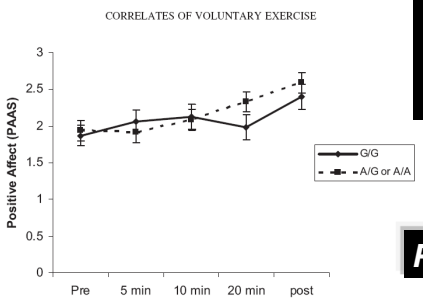
Bryan et al, 2007

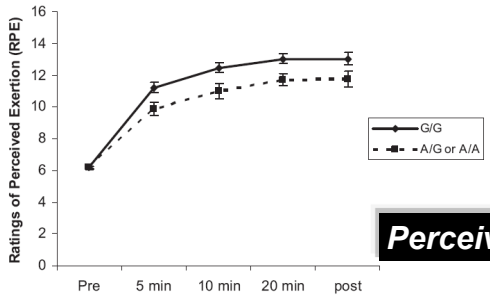


BDNF

N=64

63% GG, 37% G/A,A/A

Positive Affect



Perceived Exertion

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Nutrition Journal

Research

Improved weight mana personalize a calorie c

Ioannis Arkadianos[1], Ana Rosalynn D Gill[4] and Keit

- **Patients with hx of failed wt loss**
- **50 patients 43 controls**
- **19 genes 7 categories amenable to intervention**
- **Personal & specific advice based on genotype**

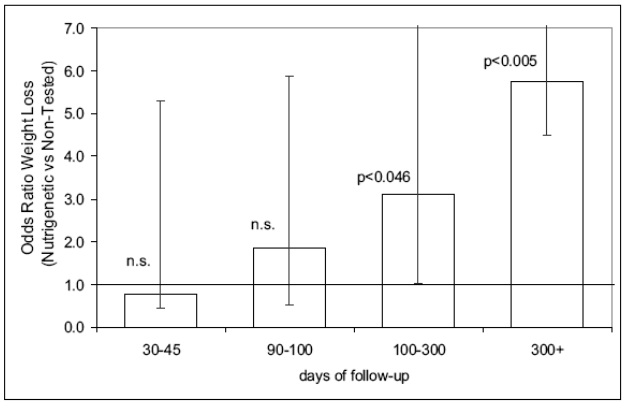
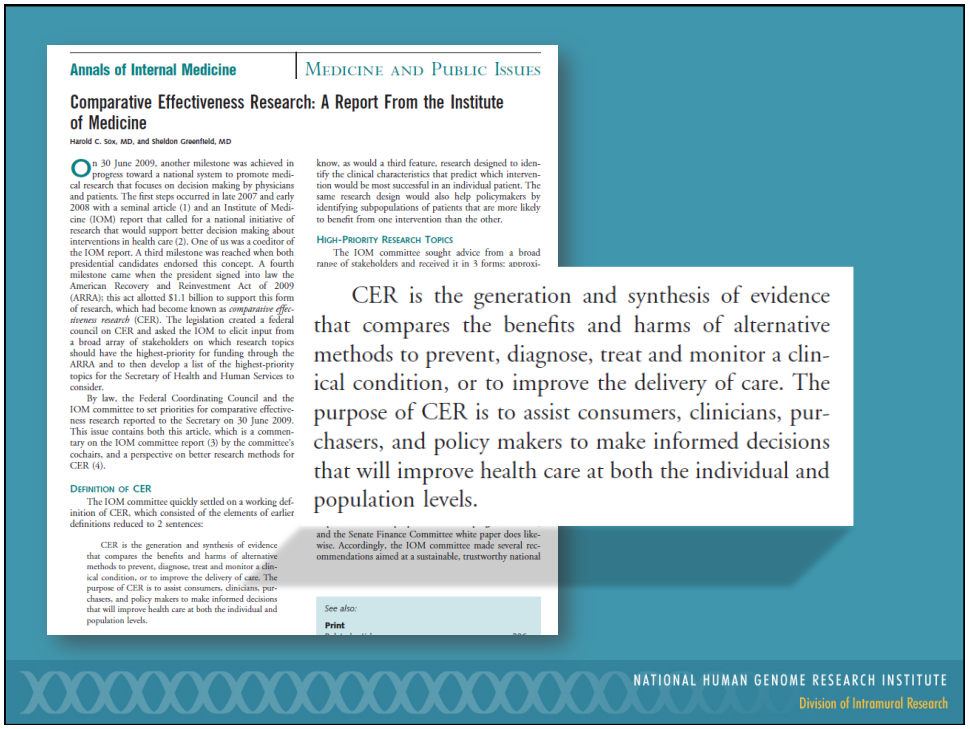


Figure 1

Odds ratio of losing weight (adjusted for age and gender) for individuals in the nutrigenetic test group compared to the control groups. age and sex adjusted odds ratio for weight loss > 0 between the nutrigenetic test group and the non-tested group.



Take home messages

- Translation research is important to do now!
- Many possible avenues for genomics to improve public health
- Conceptual models & practicability to guide research questions
- Full armamentarium of methods
  - to anticipate and test potential applications of genomics
- Research inherently interdisciplinary

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David Farrell, People Designs
Isaac Lipkus, Duke University
Susan Persky, NHGRI

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Thank You!

Colleen.marie.mcbride@emory.edu

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