Risk Prediction: lessons from 20+ years of research

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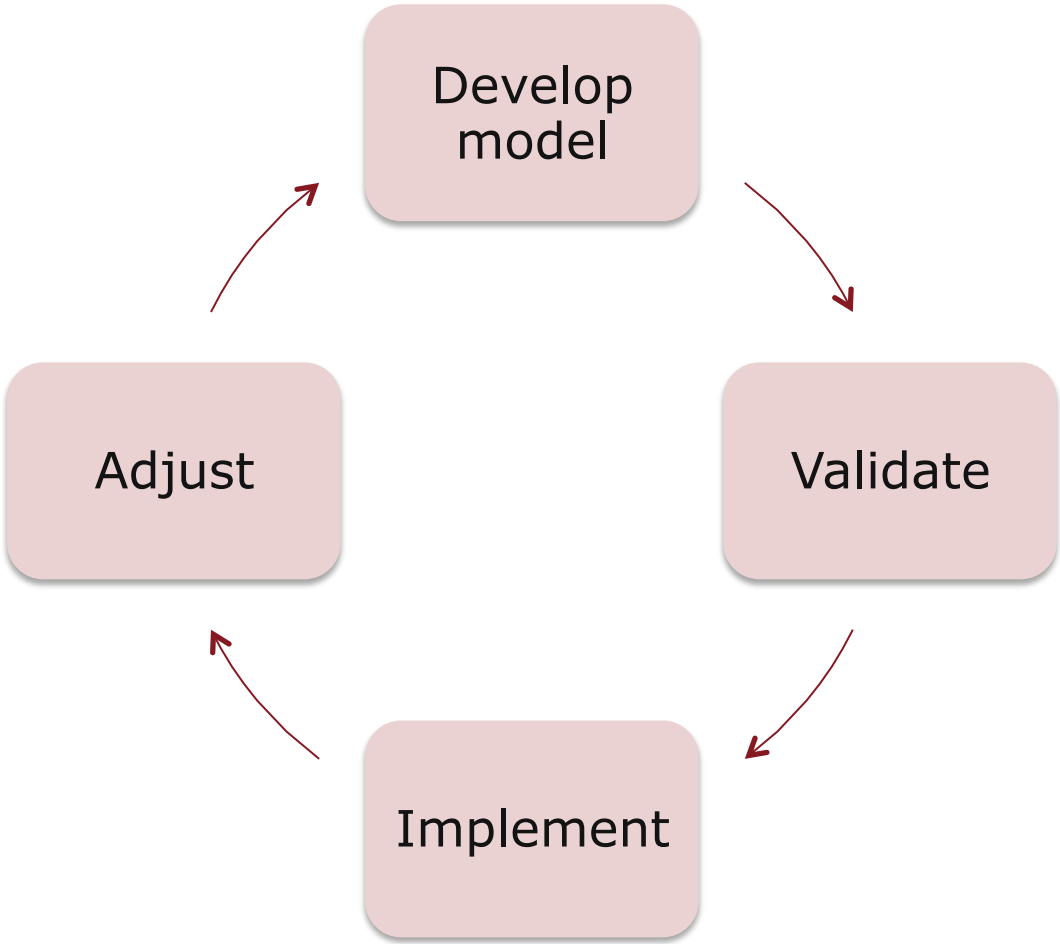
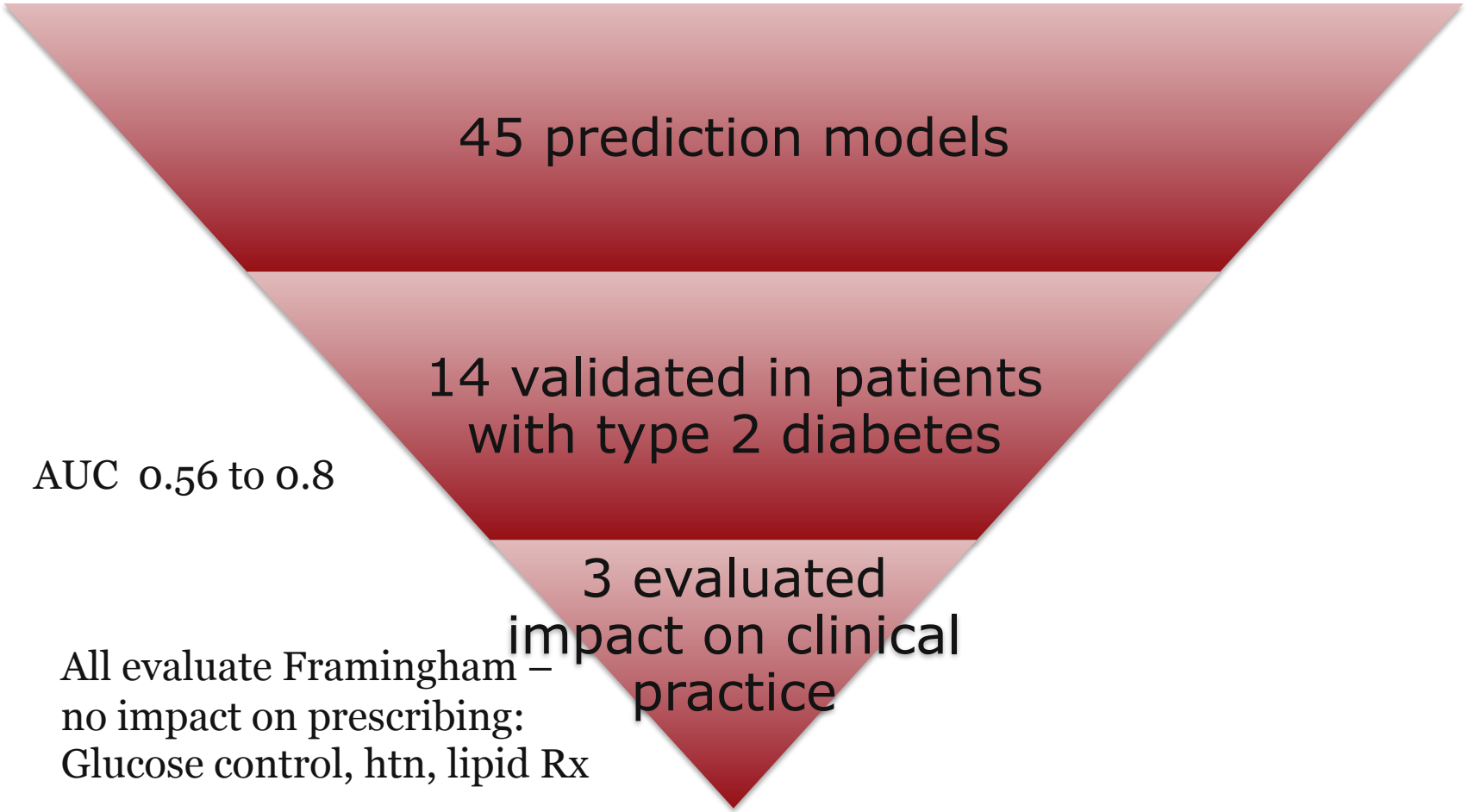
Purposes of risk prediction

- Determine study eligibility
- Risk stratification,
  - e.g, to counsel or guide lifestyle modification – prevention
- Intervention decision
  - Risk estimation ad classification for eligibility for services, eg MRI
- Understand disease etiology
  - Model incidence and temporal relations of risk factors

To fulfill purposes



Exploding literature – highlight gaps: CVD in patients with diabetes
(van Dieren, Heart 2012:98:360-9)

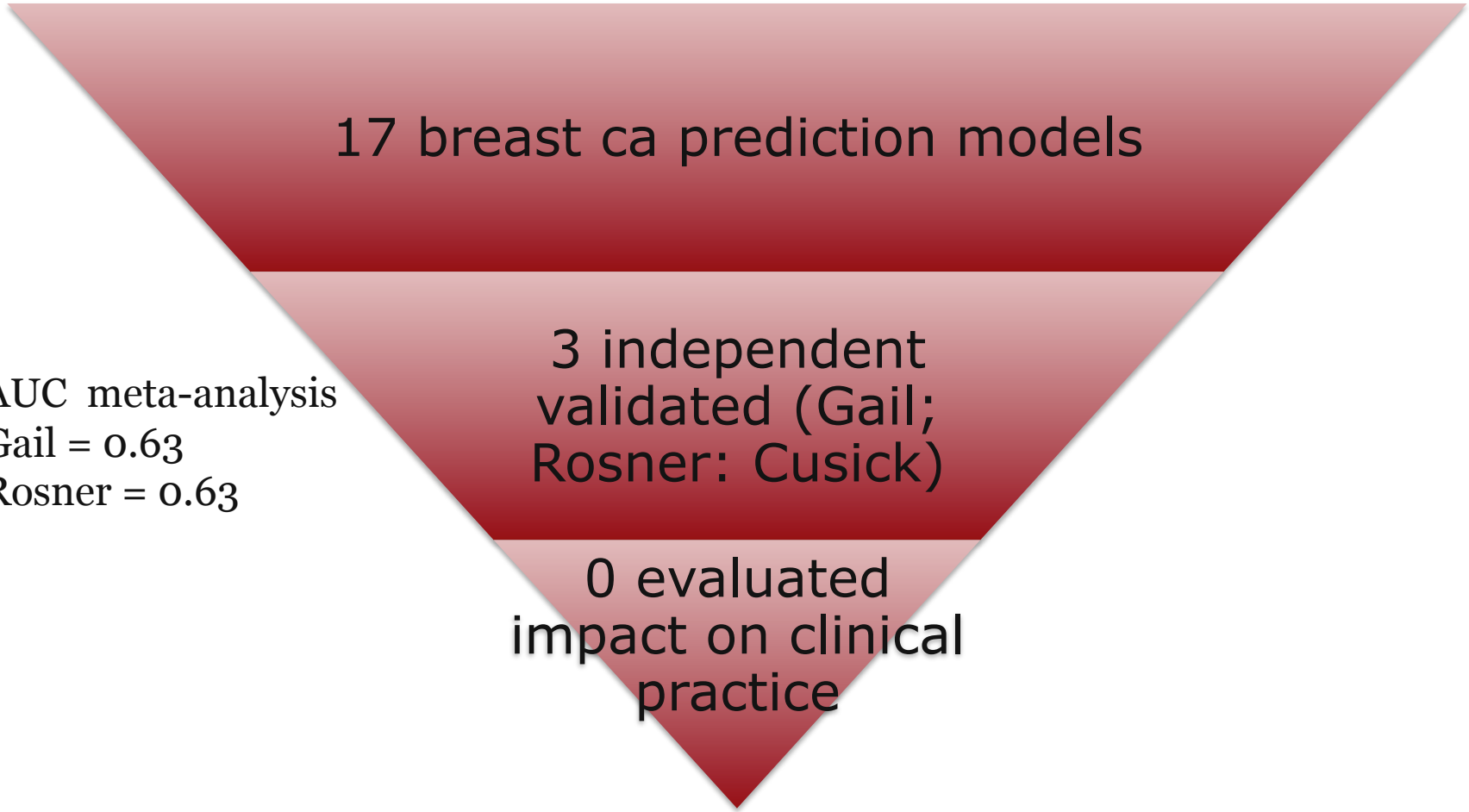


AUC 0.56 to 0.8

All evaluate Framingham – no impact on prescribing: Glucose control, htn, lipid Rx

Exploding literature – highlight gaps: Breast cancer risk

(Meads. Br Ca Res Treat 2012, 132:365-77)



AUC meta-analysis
Gail = 0.63
Rosner = 0.63

Approaches to model development

- Explicit selection of known causal factors
- Biologic/lifespan or life calendar approaches
- Data driven

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Origins in 1994

Creation of the Harvard Center for Cancer Prevention (Harvey Fineberg)

Goal: To bring additional focus to cancer prevention, drawing on Harvard's strengths in public health, medicine, molecular biology, statistics, and social and behavioral sciences.

"Through communication, behavior change, and cutting-edge research, the Center is enhancing society's capacity to stop cancer."

Initial priorities and next steps

To review and summarize evidence for **both** academic **and** lay audiences.

Etiology	Prevention
Harvard Report on Cancer Prevention. Volume 1: Causes of human cancer, summary. Cancer Causes Control. 1996;7 Suppl 1(3):S55-8.	Harvard Report on Cancer Prevention. Volume 2: Prevention of human cancer. Cancer Causes Control. 1997;8 Suppl 1:S1-50.

To develop tools to help *the public* understand that cancer can be prevented

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Inherently transdisciplinary

A wide range of knowledge, perspectives, and experiences

Competing standards of evidence and practice, including benefits and drawbacks to each approach

Successful resolution required a unified goal, compromise, accommodation, and excellent communication skills

Inherently transdisciplinary

Biostatistics

Epidemiology

Communication science

Computer science

Human factors

Web design

Decision science

Psychology

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Risk factor strength of association

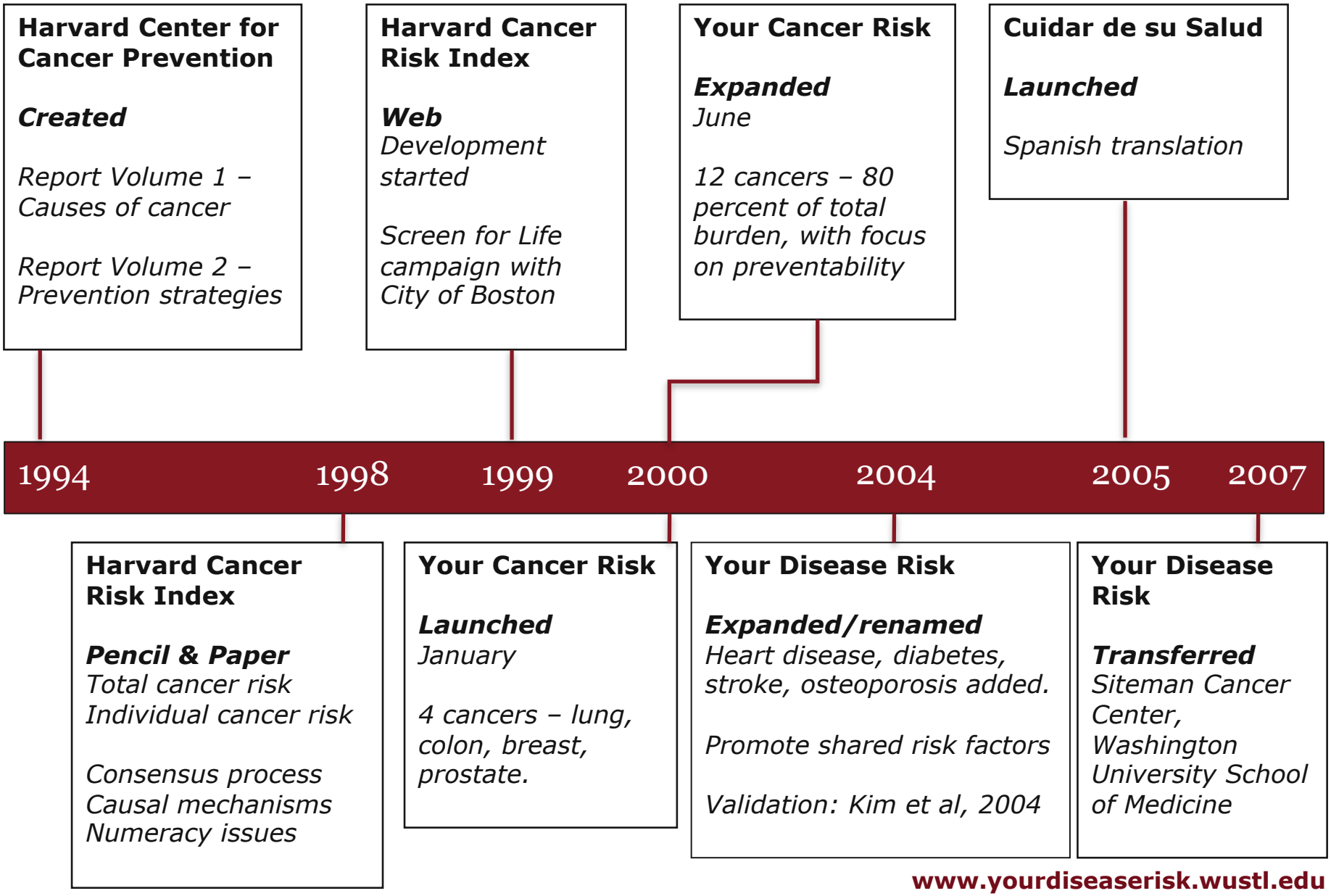
- To aid move toward consensus, we used a guide to assess the strength of the association.
  - Reduced the need to haggle over “exact” relative risks

Conversion from strength of association to risk points

Relative Risk	Strength of Association	Risk points
0.9<1.1	not discernible	0
0.7<0.9, 1.1<1.5	weak	5
0.4<0.7, 1.5<3.0	moderate	10
0.2<0.4, 3.0<7.0	strong	25
<0.2, 7.0+	very strong	50

Weight of Evidence – IARC approach

Definite Evidence	A relationship has been established between the exposure and outcome. That is, a relationship has been observed between the exposure to the agent and the outcome in which chance, bias and confounding can be ruled out with reasonable confidence.
Probable	An association has been observed between the exposure and outcome. The association is considered credible but chance, bias and confounding cannot be ruled out with sufficient confidence.
Possible	The available studies are of insufficient quality, consistency or statistical power to permit a conclusion of at least probable evidence of an association between the exposure and the outcome.



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Alternative approaches to model development

MV analysis – decisions for building

- Reduce number of variables
- Clean data

- Regression, beta-coefficients
- Summary score

Harbarth - MRSA

Goal: identify surgical patients at risk for previously unknown MRSA

- Data: 13,000 patients screened for MRSA
- Logistic regression
- Took bivariate OR $\geq$ 2 or p<0.1
- Entered these in forward stepwise logistic regression
- Evaluate about 20 bivariate risk factors
- Take 3 into multivariable model – clinical prediction rule

Harbarth et al
J Am Coll Surg 2008

Table 2. Variables Associated with Newly Identified MRSA Carriage at Admission to Surgery Department, Excluding Formerly Known MRSA Carriers (Derivation Cohort)

	Odds ratio (95% CI)	
Risk factor	**Bivariate**	**Multivariate**
Male gender	1.5 (0.8–2.7)	
Age 75 years or older	2.3 (1.3–4.1)	1.9 (1.0–3.8)
Emergency admission	0.8 (0.4–1.5)	
Previous hospitalization (past 12 mo)	5.6 (2.7–11.7)	2.7 (1.1–6.4)
Previous operation (past 12 mo)*	3.6 (1.9–6.8)	
Previous stay in longterm care	3.1 (1.2–7.9)	
Charlson score (per 1-point increment)	1.1 (1.0–1.3)	
Ultimately or rapidly fatal disease	1.1 (0.5–2.3)	
Ischemic heart disease	3.1 (1.3–7.7)	
Diabetes mellitus	1.5 (0.7–3.3)	
Malignancy	1.0 (0.4–2.5)	
Chronic renal disease	1.6 (0.5–4.7)	
Recent antibiotic therapy (< 6 months)	7.7 (3.7–16.0)	4.5 (2.0–10.1)
Origin of patient		

Harbarth et al
J Am Coll Surg 2008

Predictive score

- Age MV OR 1.9 (1.0 - 3.8)
- Previous hospitalization 2.7 (1.1 - 6.4)
- Recent antibiotic therapy 4.5 (2.0 – 10.1)

Score:

- 2, 3, and 4 points giving total of 9 points,
- range 0 to 9

Classify score:

- low score (< 2 points); intermediate (2 to 6 points) and high (≥7)

Application:

- validation subset of data
- Outcome % carriers identified by screening rules

Harbarth et al
J Am Coll Surg 2008

Robicsek et al

- MRSA again predicted from analysis of 23,000 patients US hospitals consecutive admission
- 46 variables
- Took about 18 forward and appear to use them fixing the OR at the observed level from the MV development model
- Validated in 26,690 patients in 2 additional hospitals

Robicsek Infection Control + Hospital Epidemiol 2011 32: 9-19

TIMI – UA/NSTEMI – RCT data

- Patients with unstable angina
- Broadly applicable,
- Easily calculated at patient presentation,
- No computer required,
- Identifies patients with different responses to treatment

Antman et al JAMA 2000 284:835-44

Model development on TIMI patients

- Multivariable model for prognosis – using RCT patients
- Endpoint, patients experience at least one element of primary endpoint
- Baseline characteristics easily identified at presentation
- 12 baseline characteristics evaluated in dichotomous structure
- Logistic regression
- Those achieving significant at $p<0.2$ proceed to MV
- Assessment of model for classification (c-statistic) and impact of missing data on classification

Antman et al JAMA 2000 284:835-44

TIMI

Table 1. Baseline Characteristics Analyzed for Development of TIMI Risk Score for UA/NSTEMI*

Characteristics†	Univariate Analysis			Multivariate Analysis		
	β Coefficient	*P* Value	OR (95% CI)	β Coefficient	*P* Value	OR (95% CI)
Age, ≥65 y	0.4681	<.001	1.60 (1.25-2.04)	0.5575	<.001	1.75 (1.35-2.25)
At least 3 risk factors for CAD‡	0.3717	.009	1.45 (1.10-1.91)	0.4336	.003	1.54 (1.16-2.06)
Significant coronary stenosis (eg, prior coronary stenosis ≥50%)	0.5473	<.001	1.73 (1.34-2.23)	0.5284	<.001	1.70 (1.30-2.21)
Prior MI	0.2386	.06	1.27 (0.99-1.63)			
Prior CABG	0.3004	.07	1.35 (0.97-1.88)			
Prior PTCA	0.4828	.004	1.62 (1.16-2.26)			
ST deviation	0.3356	.02	1.40 (1.06-1.85)	0.4125	.005	1.51 (1.13-2.02)
Severe anginal symptoms (eg, ≥2 anginal events in last 24 h)	0.4521	<.001	1.57 (1.24-2.00)	0.4279	.001	1.53 (1.20-1.96)
Use of aspirin in last 7 days	0.6179	.002	1.86 (1.26-2.73)	0.5534	.006	1.74 (1.17-2.59)
Use of IV unfractionated heparin within 24 hours of enrollment	0.1665	.19	1.18 (0.92-1.51)			
Elevated serum cardiac markers§	0.3486	.004	1.42 (1.12-1.80)	0.4420	<.001	1.56 (1.21-1.99)
Prior history of CHF	−0.1058	.70	0.90 (0.53-1.53)			

*UA/NSTEMI indicates unstable angina/non–ST elevation myocardial infarction; OR, odds ratio; CI, confidence interval; CAD, coronary artery disease; MI, myocardial infarction; CABG, coronary artery bypass graft surgery; PTCA, percutaneous transluminal coronary angioplasty; IV, intravenous; and CHF, congestive heart failure.
†Bold indicates variables that remained statistically significant in the multivariate analysis and were used as the final set of predictor variables.
‡Risk factors included family history of CAD, hypertension, hypercholesterolemia, diabetes, or being a current smoker.
§Creatine kinase MB fraction and/or cardiac-specific troponin level.

Baseline characteristics TIMI score UA/ NSTEMI

Characteristic	OR
Age, >65	1.75
At least 3 risk factors	1.54
Significant coronary stenosis	1.70
ST deviation	1.51
Use aspirin in last 7 days	1.74
Severe angina symptoms	1.53
Elevated serum cardiac markers	1.56

Antman et al JAMA 2000 284:835-44

TIMI score

- After MV analysis TIMI score developed
- Simple arithmetic sum of the number of variables present at presentation
- Event rates according to level of TIMI risk score evaluated by chi-square goodness of fit
- Score then validated in 3 separate cohorts

- => Basis for clinical decision making

Antman et al JAMA 2000 284:835-44

Summary: model building

- No standard approach
- No clear or consistent approach to missing data
- Target of model may not be well defined in terms of outcome for the ultimate use of model

Contrast with YCR-YDR

- Consensus approach
- Definite or probably causes of cancer as original model.
- Applied more broadly to CHD, Stroke, Diabetes, osteoporosis
- Plans to add dementia going forward
- Design with end user in mind

Your Disease Risk
THE SOURCE ON PREVENTION

YDR: Usage

Heavy usage, varies over time

Conservatively we can estimate

1000 visitors per day,

365 days a year,

for 12 years

4,000,000 visitors


February 03, 2000

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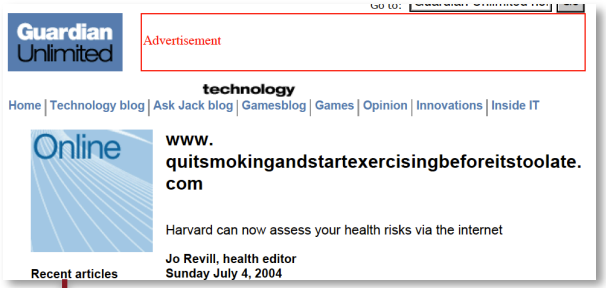
New Cancer Risk Website Logs Record-breaking Launch

More than 13,000 visits were logged on to a new Website of the Harvard Center for Cancer Prevention within the first week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Harvard can now assess your health risks via the internet

Jo Revill, health editor
Sunday July 4, 2004

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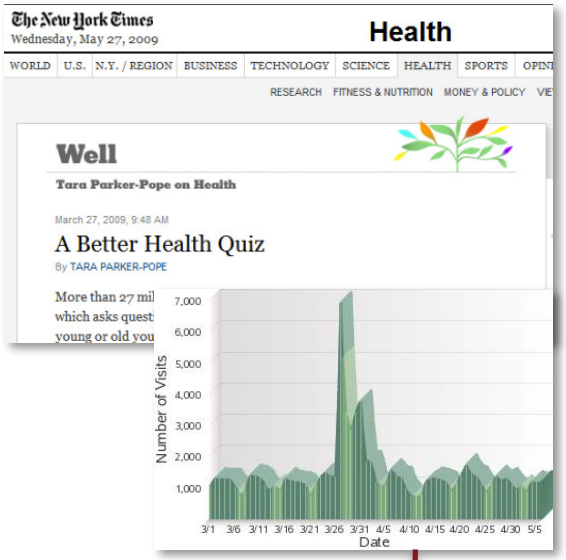
The New York Times
Wednesday, May 27, 2009

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Tara Parker-Pope on Health

March 27, 2009, 9:48 AM

A Better Health Quiz

By TARA PARKER-POPE

More than 27 mil
which asks quest
young or old you

Number of Visits

7,000
6,000
5,000
4,000
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WSJ.com THE WALL STREET JOURNAL. ONLINE

October 31, 2006

HEALTH JOURNAL
By TARA PARKER-POPE

Web Site Tallies Your Risk Of Disease And Tells You What You Can Do About It

October 31, 2006; Page D1

Everybody worries about cancer, heart disease and other illnesses, but


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Harvard News Office
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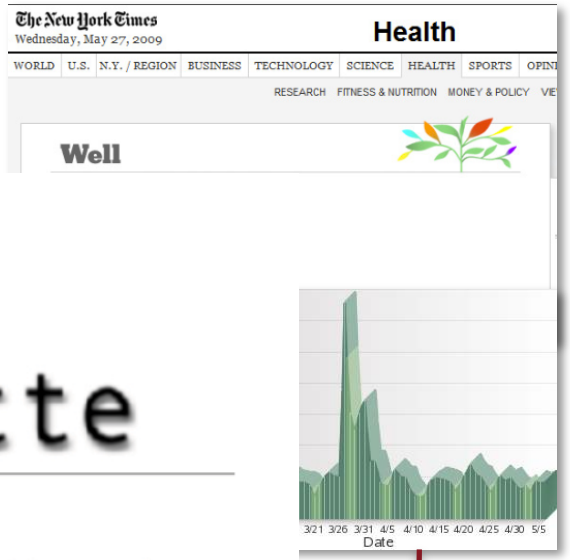
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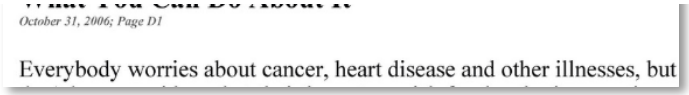
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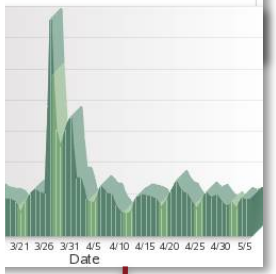

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Harvard can now assess your health risks via the internet

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Sunday July 4, 2004
The Observer

It is a hypochondriac's dream come true. Harvard, the Ivy League

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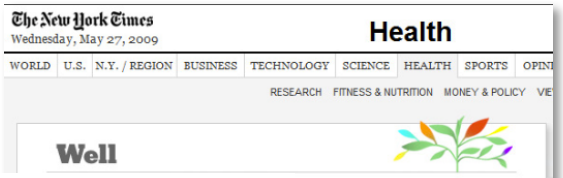

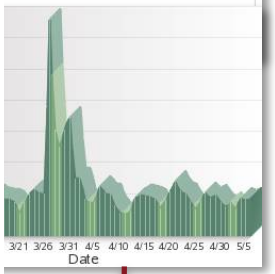

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Web Site Tallies Your Risk Of Disease And Tells You What You Can Do About It

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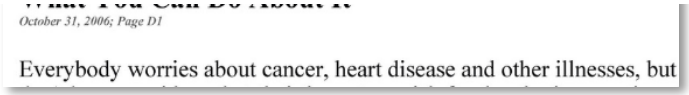
Everybody worries about cancer, heart disease and other illnesses, but most people don't have any idea what their long-term risk for developing a serious health problem really is.

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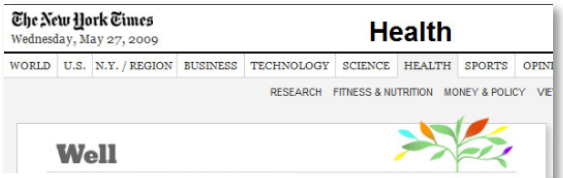
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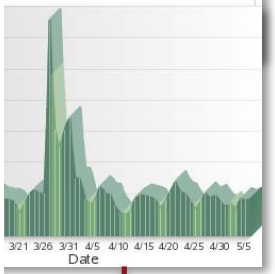
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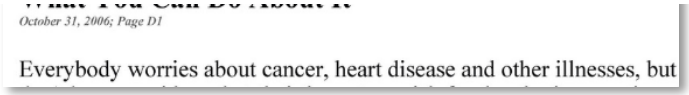
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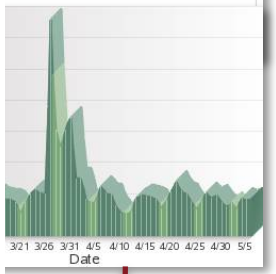

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Tara Parker-Pope on Health

March 27, 2009, 9:48 AM

A Better Health Quiz

By TARA PARKER-POPE, Editor

More than 27 million people reportedly have taken the RealAge health quiz, which asks questions about lifestyle and family history to determine how young or old your habits make you. But a recent story in The New York Times notes that RealAge often targets its members with health information that may be sponsored by drug marketers.

My problem with the RealAge quiz is its lack of scientific validity. The notion that health behaviors can translate into a meaningful "biological age" is just marketing hype, not real science.

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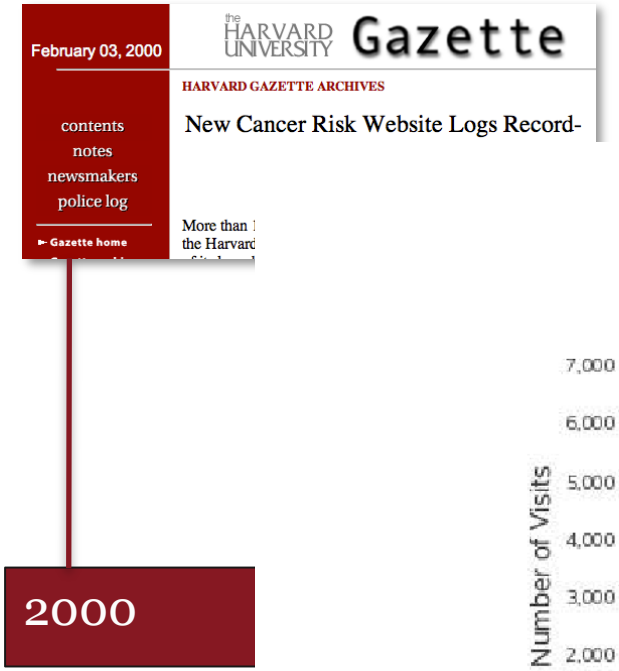
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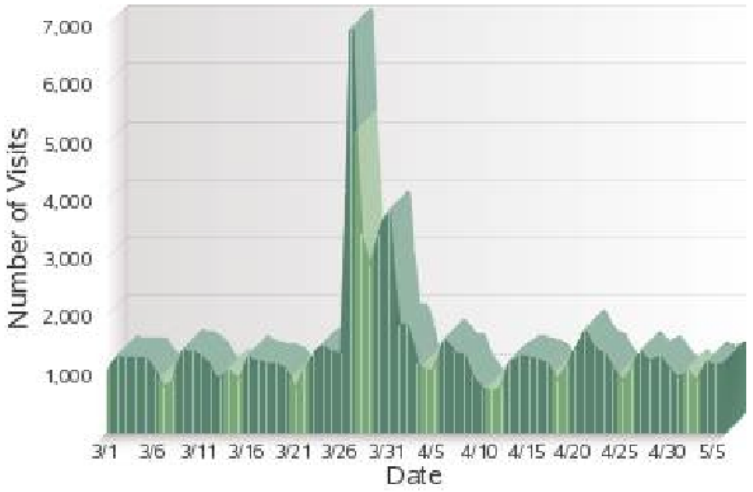
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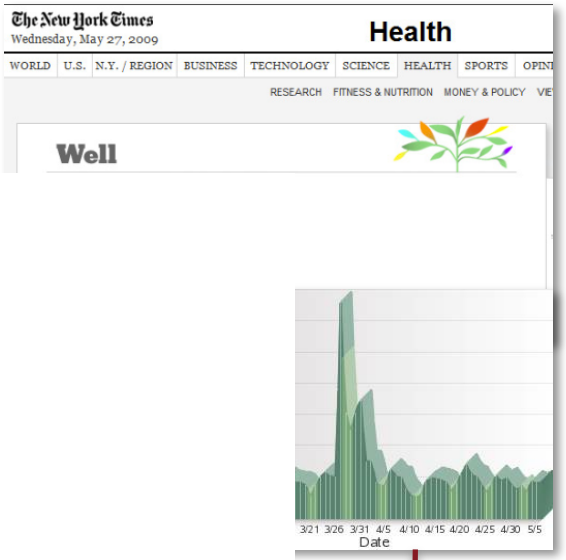
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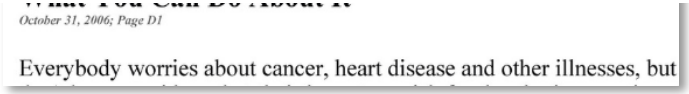
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Site development – Communication and usability

Research conducted by Neil D. Weinstein, Karen M. Emmons, Mike Atkinson, Hank Dart, and others

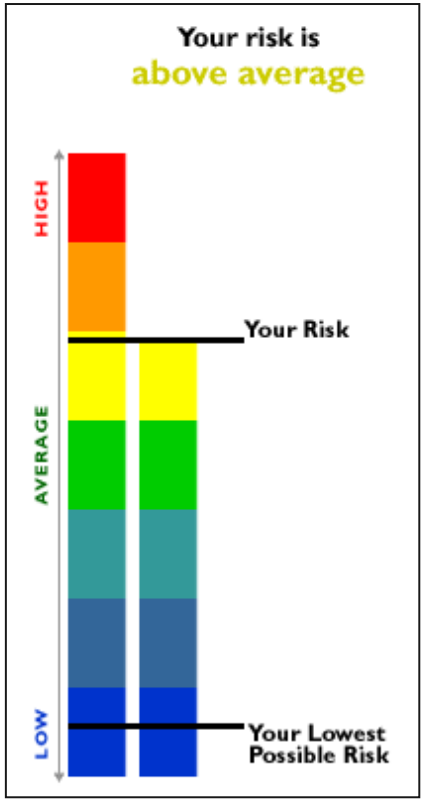
Communication strategies based on principles of risk perception, risk communication, and health behavior change

Help people recognize that they can change their risk (i.e., specific behavioral recommendations)

Site development – Communication and usability

Issues considered

- Principles of risk communication
  - Number of risk levels (5 vs 7)
  - What types of words as descriptors
  - What type of visual display (thermometer, speedometer, bar)
  - Conveying an approximation of personal absolute risk



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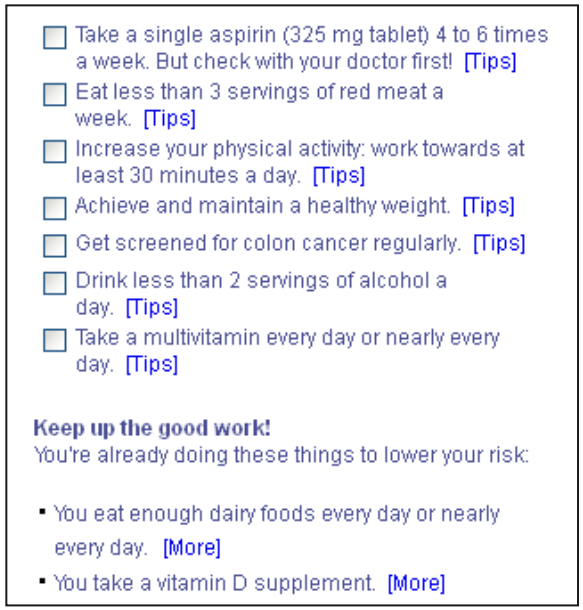
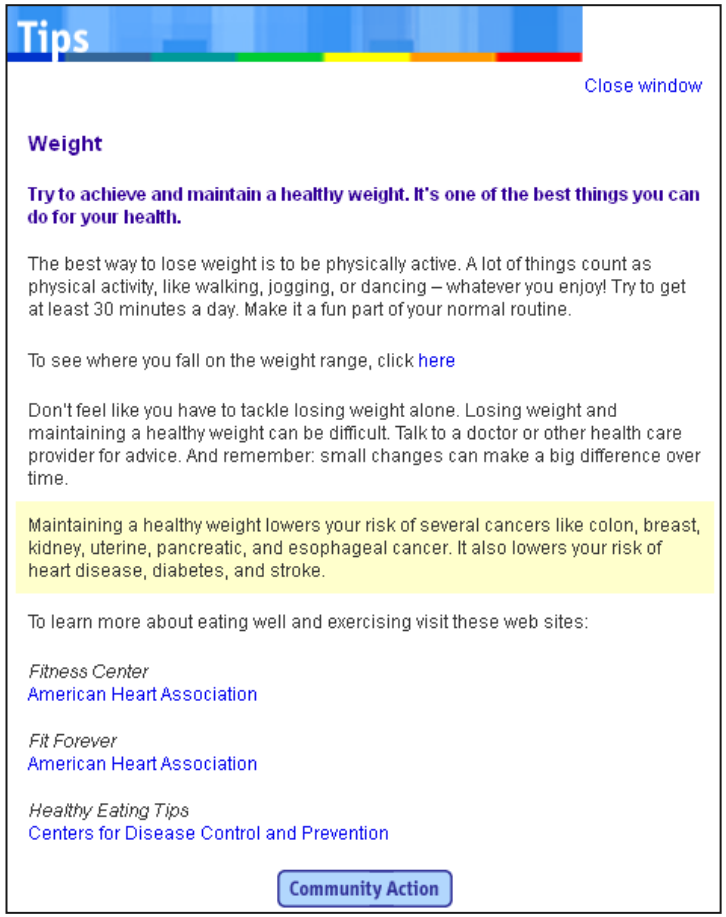
Site development – Communication and usability

Issues considered

- Principles of risk communication
- Principles of health behavior change
- Need to provide personalized risk reduction strategies and tips for complex behaviors





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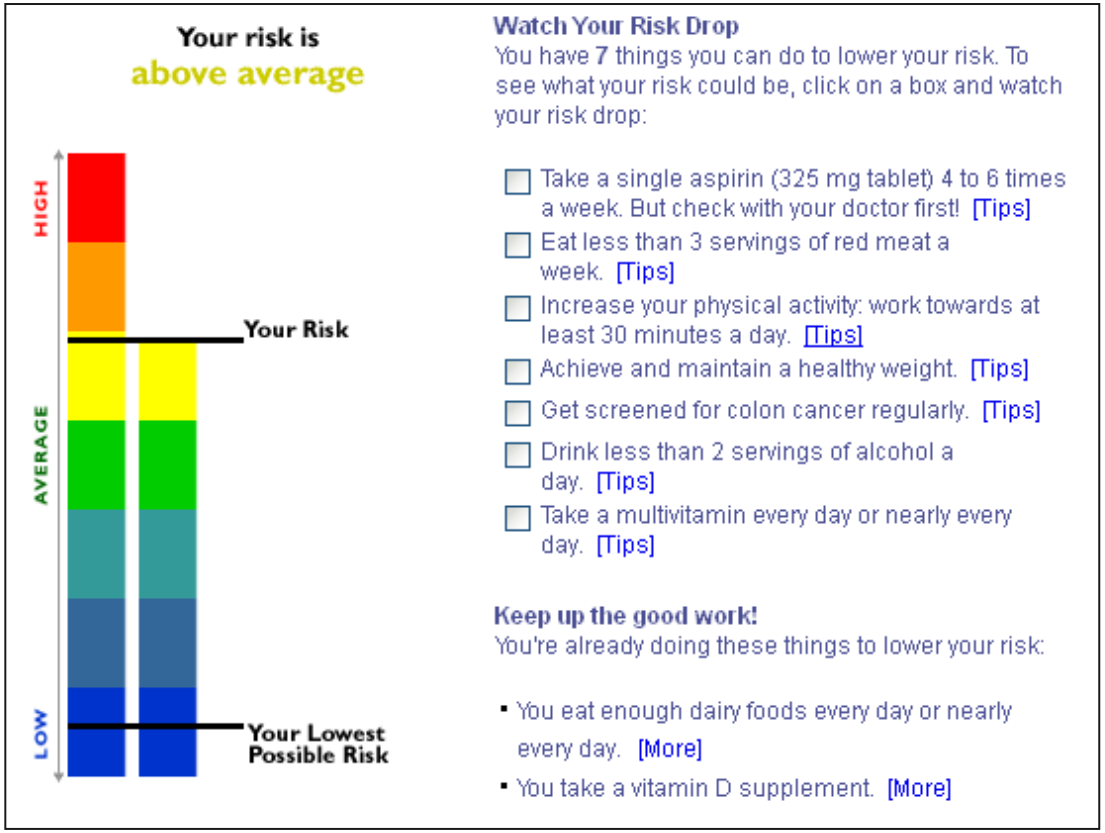
Site development – Communication and usability

Issues considered

- Principles of risk communication
- Principles of health behavior change
- Principles of persuasion and adult learning

Site development – Communication and usability



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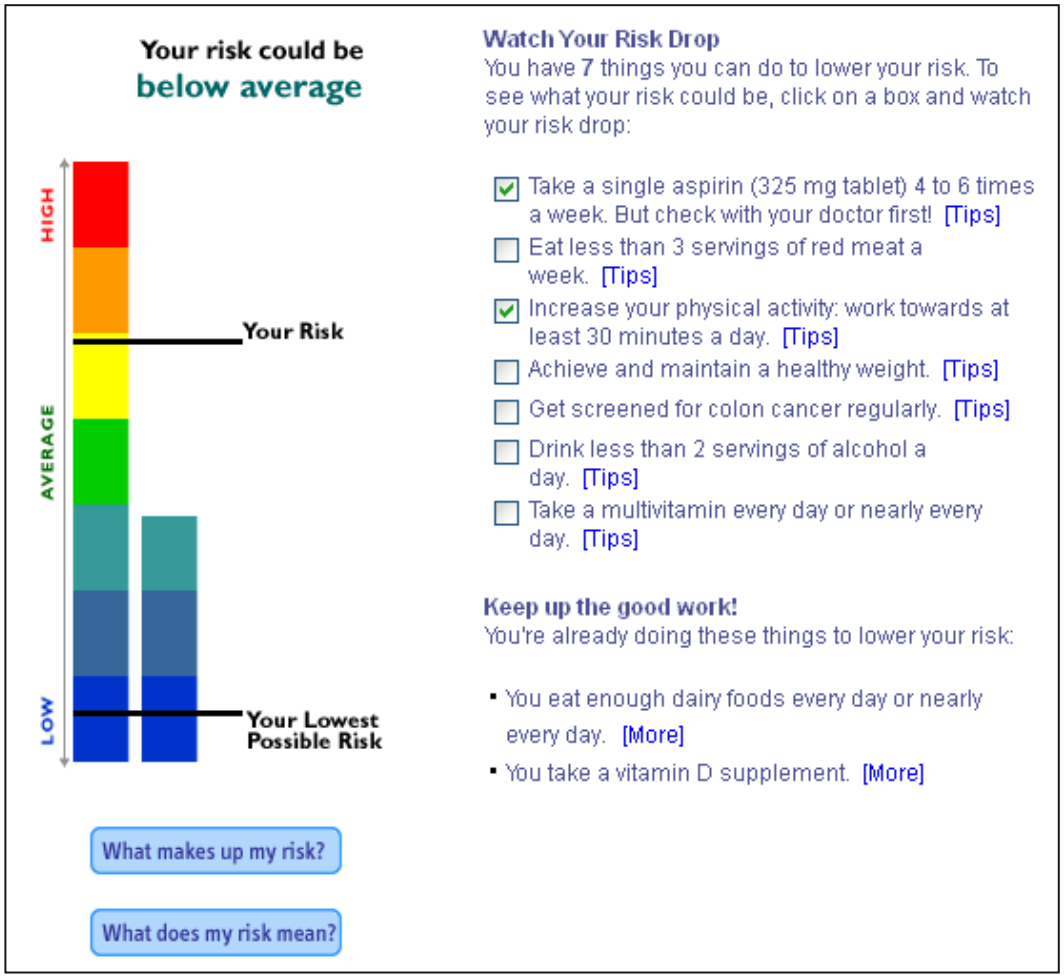
Site development – Communication and usability

Key points

•"Watch Your Risk Drop" function provides "active involvement" in learning about risk.

•"What makes up my risk?" and "What does my risk mean?" buttons provide options for examining more detailed information.



Site development – Communication and usability

Issues considered

- Principles of risk communication
- Principles of health behavior change
- Principles of persuasion and adult learning

- User ability/facility
  - Access to and familiarity with computers
  - Numeracy
- Website interaction and navigation
  - Colors
  - Location of buttons
  - Branding

Going live

Go live when the science, communication, and technical aspects are solid

1. Is the science in line with the latest consensus review?
2. Are the messages and communication strategies scientifically sound?
3. Do the changes impede the website's usability?
4. Have the bugs/errors in programming been resolved?
5. Does the website follow good e-health practices (e.g., privacy policy)

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Broader questions

- When is prediction model ready for use?
  Moons et al for life cycle of prediction model
- Develop
  - Single study
- Validate
  - Independent or bootstrap methods (both preferred)
- Implement
  - Comparative study of model vs usual care
- Evaluate
  - Impact on decision making (individual consumer or provider)

Validation

- Internal
  - How good is the method
- External
  - Are data sources available
  - Does validation report characteristics of population broadly enough to inform subsequent use?
- Different patient population
- Lack of performance may reflect deficiencies in model or differences in patient population

Validation

Your Disease Risk
THE SOURCE ON PREVENTION

Assessed the predictive validity for cancers of ovary, colon and pancreas: Breast and CHD ongoing.

- Concordance statistics calculated using 10-year risk from NHS and HPFS

Also compared relative risk estimates

- Supports overall assessment of performance and application in general population

Validation

Your Disease Risk
THE SOURCE ON PREVENTION

- Used prospective data from Nurses' Health Study and Health Professionals Follow-up Study to assess 10-year risk of cancer
  - Challenge – operationalizing all variables is not straightforward
- Calculated relative risk of cancer
- Calculated goodness of fit and
- Discriminatory accuracy

Results

- Prevalence estimates varied substantially between US general population and cohort based estimates
- Compared the observed relative risks with the consensus based estimates.
- Agreement was good.

Results (con't)

Your Disease Risk
THE SOURCE ON PREVENTION

- Concordance statistics
  - Colon men: 0.71 (0.68-0.74)
  - Pancreas men: 0.72 (0.67-0.77)
  - Colon women: 0.67 (0.64-0.70)
  - Ovary women: 0.59 (0.56-0.62)

    - Kim, Rockhill, Colditz. J Clin Epi 2004:57:332-40

When to implement?

- How much development and validation is needed before implementation?
- Do you need to validate before implementing in a practical setting?
- Does the validation population look anything like the implementation setting?
  - Do you then need to adjust model?
- Does media (paper vs hand held device vs web etc) matter?

Implementation issues

- Do different populations want different output, answers, etc?
  - Users: say MDs vs patients
- What is success for implementation?
  - How is this defined? How is it measured?
- Does MD/health care provider use constitute success?
- Does patient understanding of output constitute success?
  - If so, how is understanding measured?
- Is this research or evaluation of implementation – or both?

Log-incidence model: Integrating exposures across lifecourse

- Our approach to incidence modeling is different from standard analytical approaches.
- Risk factors are assumed to have an effect on the rate of increase of breast cell proliferation.
- The cumulative number of breast cell divisions at age *t* is a latent variable that is assumed to be proportional to incidence at age *t*.

Interpretation

- The effect of most risk factors is cumulative over more than one year; although possibly differential in different periods of life
  - e.g., premenopause vs. postmenopause.
- This makes it more difficult to quantify associations of risk factors with disease
- But our approach is more consistent with the evidence that tumors take many years to develop and are affected by risk factors early in life even when very few cases are present.

Moving Rosner to breast health center: Missing data

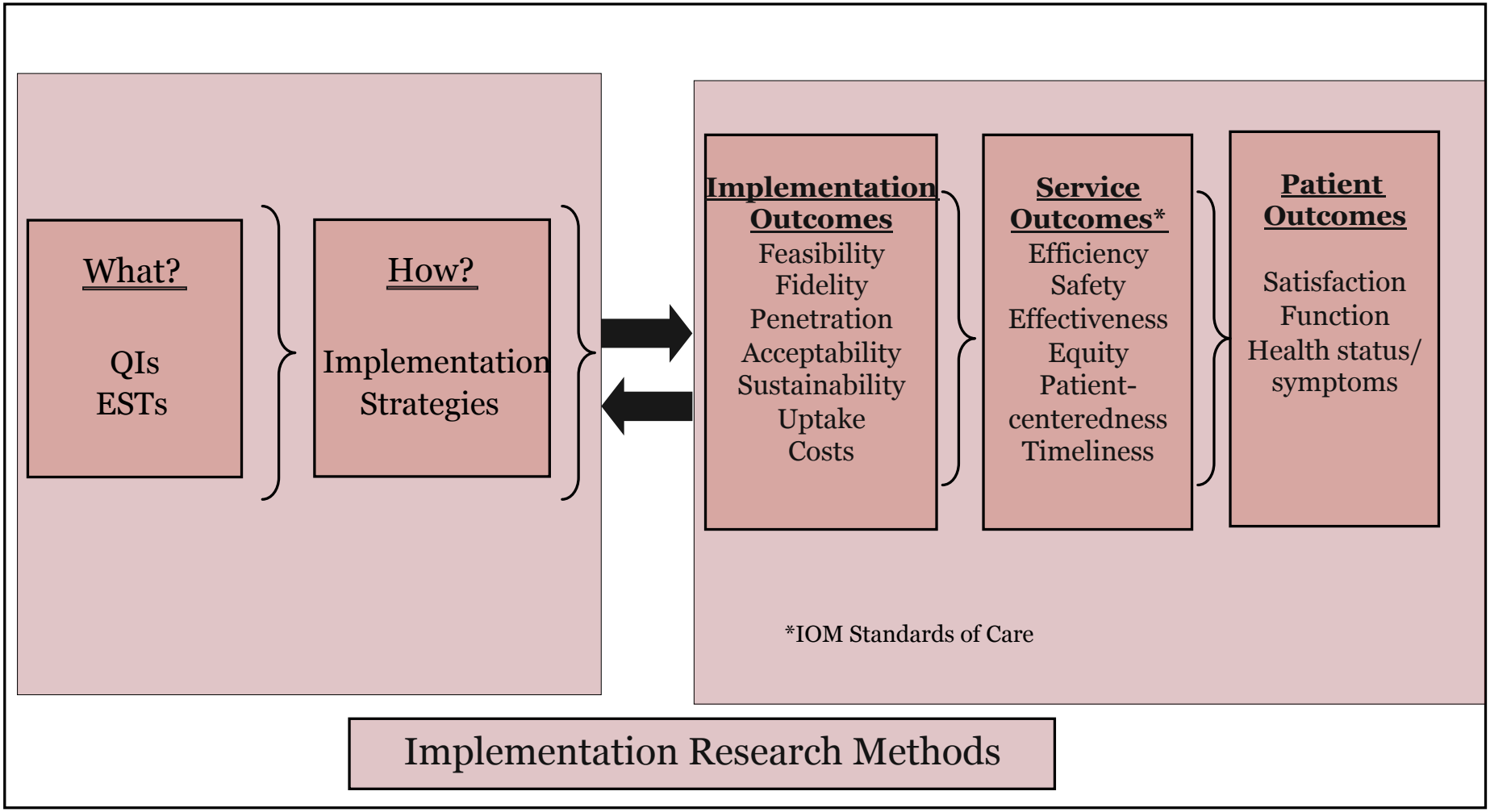
- Menarche, first birth, age at each birth, menopause, type of menopause (bilateral oopherectomy; hysterectomy), use of hormones after menopause;
- Alcohol, weight, weight at age 18, height

- Different likelihood of missing for each, but it happens

Options

- Model development with missing indicator
- Imputation
  - Both approaches have implications for development

Conceptual Model for Implementation Research



Proctor et al 2009 Admin. & Pol. in Mental Health Services

Impact evaluation: Moons et al 2012

Objective: to quantify the impact of using information (prediction models) on behavior/ decision making of provider or individuals

- Ultimately change in health outcomes
- Effectiveness of care
- Cost-effectiveness of care

Moons et al Risk prediction models II Heart 2012

Implementation evaluation: Design

- Always a comparative design
- Ideally cluster randomized design with care providers, practices, or institutions being clusters
- Alternatives include individual level randomization; stepped wedge design; prospective before after study; decision analytic modeling, and cross sectional studies with decision making as outcome

Moons Heart 2012

Method of model presentation

- Assistive: individual's predicted probability by the models presented without corresponding decision recommendations.
- Directive: with corresponding decision or management recommendations

Analysis

- Compare outcomes in the index group (with prediction model output) and control group – usual care

Moons Heart 2012

Considerations for application in practice

- Simpler model may aid clinic use
- Simpler model may aid use in general public
- No consensus on model building approaches
  - Royston, BMJ 2009 as noted earlier

- What will you measure for assessment of implementation?

Conclusion on impact

- Prognostic models generalize best to populations that have similar range of predictor variables to those in development population
- When performance is not great, adjust or modify model rather than beginning over
- Need unambiguous definition of predictors and outcomes
- Design of impact studies differs from validation design…

Moons BMJ 2009

Comparison of characteristics of validation study and impact study for prognostic models

Characteristic	Validation study[7]	Impact study
Control group	No	Yes. Index group includes doctors exposed to or using the prognostic model; control group is usual care (without using the model)
Design	Prospective cohort (preferred); retrospective cohort	Cluster randomisation (preferred); before and after
Outcome	Usually occurrence of event (eg, death, complication, treatment response) after a certain time or follow-up period	(Change in) doctors' decisions or behaviour
		Patient outcome (eg, events, pain, quality of life)
		Cost effectiveness of care
Follow-up	Yes	No, if outcome is doctors' decisions or behaviour
		Yes, if outcome is patient outcome or cost effectiveness of care
Statistical analysis and reporting	Model's calibration and discrimination	Comparison of outcome between index and control group—eg, using relative risks, odds ratios, or difference in means
	Defining particular risk groups by introducing thresholds	
	Improving or updating a model (if needed)	

Moons BMJ 2009 338: 1487-90

Conclusions

Essentially transdisciplinary, cooperative, and dynamic arrangements can grow, support, and enhance a risk assessment website.

Developed with end user in sight from beginning. Immediacy of action from model may change uptake.

Despite growth, fundamental principles remain the same

1. Scientific rigor
2. Source transparency
3. Bug-free and highly usable website/tool
4. Message consistency
5. Avoid financial conflicts of interest
6. Good e-health practices

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Resources

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Resources

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