

Public Awareness and Utilization of Direct-to-Consumer (DTC) Genetic Tests

presented by
Katrina Goddard, PhD

ASHG Fellow
National Office of Public Health Genomics
Centers for Disease Control and Prevention
&
Associate Professor
Epidemiology & Biostatistics
Case Western Reserve University

Commercial Genetic Tests

- **Direct-to-consumer genetic tests have recently exploded onto the market**
 - **Non-health related examples:** DNA banking, paternity testing, identity testing, ancestry testing, recreational genetics
 - **Health-related examples:** nutrigenetics, fetal gender, caffeine metabolism, HIV progression, clinical testing
 - The Internet gives *everybody* immediate access

Concerns Raised in GAO Report, 2006

GAO	United States Government Accountability Office
	Testimony Before the Special Committee on Aging, U.S. Senate
For Release on Delivery Expected at 10:00 a.m. EST Thursday, July 27, 2006	NUTRIGENETIC TESTING Tests Purchased from Four Web Sites Mislead Consumers

- Misleading, unsubstantiated, and ambiguous predictions
- Recommended costly dietary supplements
- Supplements may be harmful for some people
- Recommendations not based on unique genetic profile

Regulatory Guidelines

- CLIA
 - Genetic tests that provide information on health must be performed in a laboratory certified under the Clinical Laboratory Improvements Amendments (CLIA) (1988)
- FDA draft guidance documents
 - “analyte specific reagents” September, 2006
 - <http://www.fda.gov/cdrh/oivd/guidance/1590.pdf>
 - “in vitro diagnostic multivariate index assays” September, 2006
 - <http://www.fda.gov/cdrh/oivd/guidance/1610.pdf>
- FTC/FDA/CDC consumer alert July, 2006
 - <http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf>

Public Awareness and Utilization of DTC Nutrigenomic Tests

Surveillance to inform about:

- Public demand and interest in nutrigenomic tests
- Provider knowledge & experience with DTC tests
- Impact of policies and public or provider education
- Evolution of the availability and demand for DTC tests

National Surveys

- **HealthStyles, 2006:** National marketing survey conducted by Synovate, Inc. with 5250 respondents
 - Recruited from a consumer mail panel of ~450,000 potential respondents
 - Response Rate: 66% (80%) for the first (second) phase
- **DocStyles, 2006:** Online survey of primary care physicians, internists, and pediatricians with 1250 respondents
 - Recruited from Epocrates Honor Panel, an opt-in, verified panel of 142,000 physicians
 - Response Rate: 61% of eligible, invited physicians

2006 State BRFSS Surveys

- **CDC-funded State Programs in Public Health Genomics**
 - Oregon
 - Michigan
 - Utah
- **Behavioral Risk Factor Surveillance System (BRFSS)**
 - CDC-sponsored health survey system in all 50 states
 - Recruitment of adults through Random Digit Dialing
 - Response Rates: 51.7%, 52.4%, 63.4%

Questions for each Survey

Oregon & Utah

Some companies are offering **genetic** tests of your **DNA** that are advertised to **improve your health and prevent disease**. You can order these tests directly, **without the involvement of a healthcare provider**. Have you heard about these tests?

Have you **ever** used any of these tests?

Michigan

Some companies are advertising new ways to **improve your health** by testing **a sample from the inside of your cheek**. This sample is mailed **directly to the company without involving a doctor, nurse, or other health care professional**. A few weeks later, the company **provides you with a personal health profile and lifestyle recommendations** based on their findings. In the **past 12 months**, have you heard or seen anything about this type of test?

In the past 12 months, have you or anyone you know obtained this type of test?

National

Genetic tests that analyze your **DNA, diet, and lifestyle for potential health risks** are currently being **marketed by companies directly to consumers**. Have you heard or read about these genetic tests?

Have you **ever** had a genetic test that analyzes your DNA, diet, and lifestyle for potential health risks?

Results of Surveys

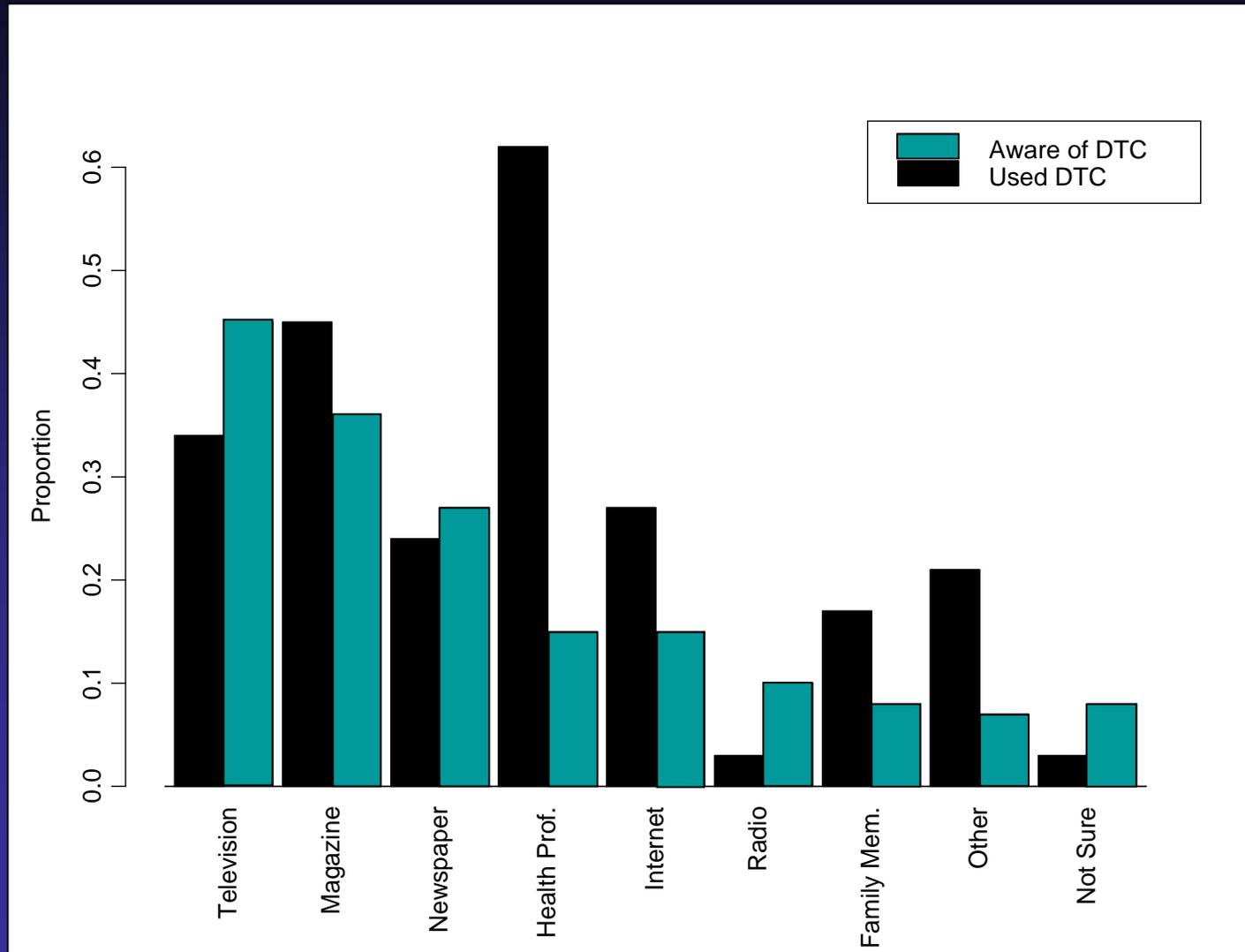
	Oregon	Michigan	Utah	National
Total Sample Size	1867	5499	2441	5250
Awareness of DTC Tests (% Yes, CI)	24.4% [22.2%,26.7%]	7.6% [6.8%,8.4%]	19.7% [17.7%,22%]	14% [12.7%,14.6%]
Use of DTC Tests (% Yes, CI)	0.3%	0.9%	-	0.6% [0.4% - 0.8%]

CI = 95% Confidence Interval

Results of State BRFSS Surveys

Characteristic	Oregon		Michigan		Utah		National	
	%	p	%	p	%	p	%	p
Total Aware of DTC Tests	24.3		7.6		19.7		14	
Sex		.6602		.0394		.0548		.056
Race/Ethnicity		.1031		.7944		.4826		.066
Age, y		.0002		.0072		.0006		.0001
18–24	10.3		3.7		14.3		15	
25–34	20.3		7.6		15.3		17	
35–44	24.0		7.5		17.5		14	
45–54	27.8		9.7		26.9		15	
55–64	33.9		8.6		26.9		14	
65+	26.8		7.2		21.4		9	
Household income		.0308		<.0001		.0735		.0001
Low	21.6		4.7		14.2		11	
Intermediate	21.4		6.6		18.8		13	
High	28.2		9.5		21.4		16	
Education level		.0001		<.0001		<.0001		<.0001
High school or less	16.3		5.2		13.1		9	
At least some college	25.4		6.9		18.1		15	
College graduate*	33.0		11.6		28.6		19	10

Consumer Sources of Information on DTC Genetic Testing



73% of respondents heard/read about DTC genetic tests through the media

DocStyles Survey

Characteristic	Not aware of DTC (n = 557)	Aware of DTC (n = 555)	P value
Specialty			.042
Family/General practitioner	62 (11)	73 (13)	
Internist	359 (64)	380 (68)	
Pediatrician	136 (24)	102 (18)	
Work setting			.098
Individual practice	99 (18)	97 (17)	
Group practice	380 (68)	354 (64)	
Hospital/Clinic	78 (14)	104 (19)	
Sex			.008
Male	353 (63)	394 (71)	
Female	204 (37)	161 (29)	
Age	44.7 (8.3)	44.1 (8.4)	.676
Number of patients per week	120 (69)	121 (69)	.837
Number of years of practice	14 (7.6)	14 (7.5)	.441

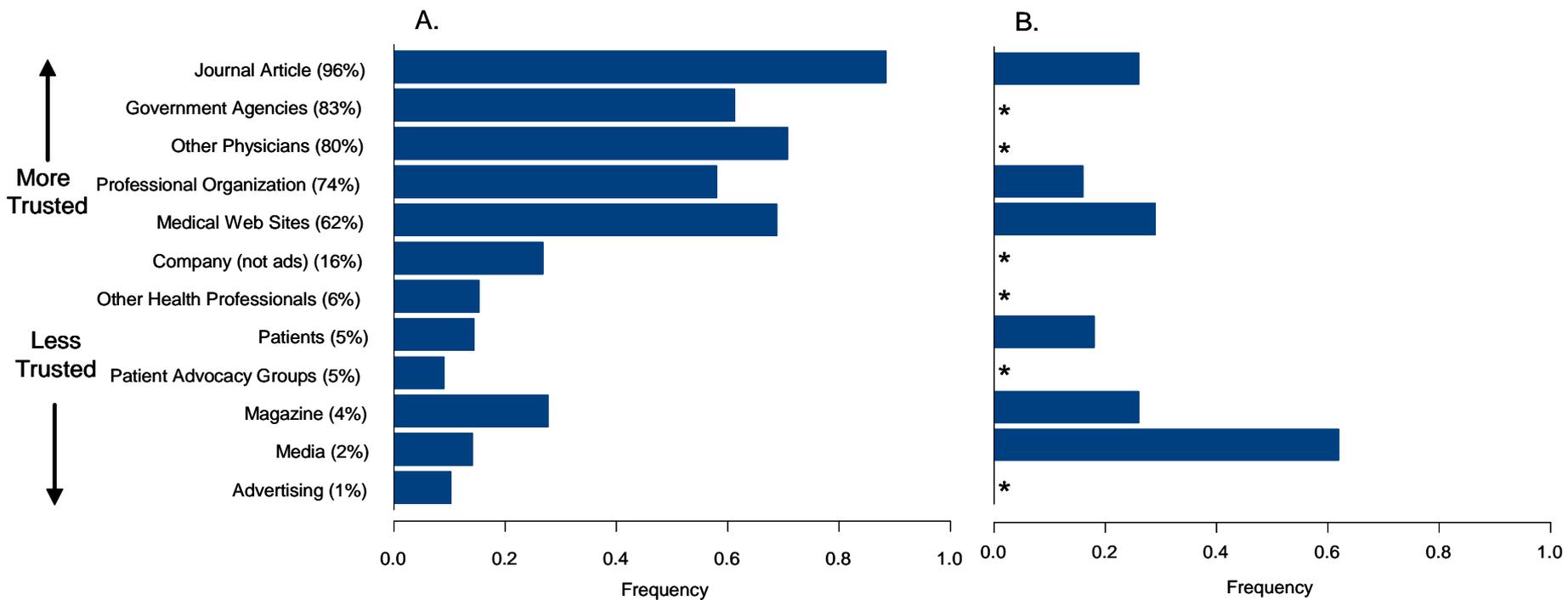
DocStyles Survey

Characteristic	Aware of DTC (n = 555)
% Patients asking about DTC	
None	225 (41)
<1%	192 (35)
1-10%	118 (42)
>10%	20 (4)
% Patients discuss DTC results	
None	409 (74)
<1%	105 (19)
1-10%	30 (5)
>10%	11 (2)

Physician Sources of Information

“Patient Health-Related”

DTC Genetic Testing



Conclusions

- Only a small percentage of the U.S. population is aware of or has used DTC Genetic Tests
- The media is the most frequent source of information for both consumers and physicians
- Limitations of existing surveys:
 - Small number of respondents who used a DTC test
 - Some confusion over wording of questions
 - Do not assess health outcomes

Acknowledgements

- **National Office of Public Health Genomics, CDC**
 - Muin J. Khoury, Linda Bradley, Cynthia Moore, Denae Ottman, & Kathleen L. Szegda
- **Michigan Department of Community Health**
 - Debra Duquette, Ann Annis, and Ann Rafferty
- **Michigan State University**
 - Michelle Cook and Deb Ruiz
- **Oregon Department of Human Services**
 - Amy Zlot
- **Utah Department of Public Health**
 - Jenny Johnson, Patrick W. Lee, and Rebecca T. Giles
- **University of Washington**
 - Karen Edwards