

*The Center for Translational and Policy Research
on Personalized Medicine*

What are the Costs and Benefits to the Health Care System of DTC Genetic Testing?

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NOT the Topic of Today

Google-Cash-Swapping-Orgy Blimp



***2-Day Symposium Raises
Concerns About Direct-To-
Consumer Genetic Testing***

THE

SUN SHINE

CELEBRITY NEWS AND GOSSIP

WORLD EXCLUSIVES

**Babies being
accidentally killed by
mothers:
Is yours next?**

Codeine and Nursing Mothers

April 2005: 13-day old infant dies of morphine poisoning from nursing (mother is ultra-rapid metabolizer of CYP2D6)

May 2006: First published article regarding infant death (Lancet)

Aug. 2007: FDA Issues “Alert on Use of Codeine Products in Nursing Mothers”

Oct 2007: Label for Tylenol w/ Codeine revised

Research on Codeine Use

- Media coverage analysis
- Ongoing Canadian research
 - ¼ babies whose mothers took codeine showed signs of central nervous system depression (Koren et al)
- American Academy of Pediatrics is reviewing but currently states that codeine is compatible with breastfeeding

Why Story of Codeine is Relevant

- Example of test available DTC
 - Several DTC companies offer CYP2D6 testing
 - One company cites FDA advisory but does not list nursing women as who should “consider testing for CYP450 drug response” & reports that little demand for test
- Illustrates costs & benefits of potentially wider use of genetic testing via DTC
- Characterizes unanswered questions

Objectives

- What do we currently know about the costs & benefits of DTC genetic testing?
- How can the economic toolbox be used to define and examine costs & benefits?

What is Known about Costs & Benefits



- Easy answer
 - Almost nothing
- Can we draw on experiences with other tests?
 - Pregnancy testing
 - Home HIV testing
 - Phillips et al NEJM 1995

Using Economic Toolbox

What are “costs” and “benefits”?



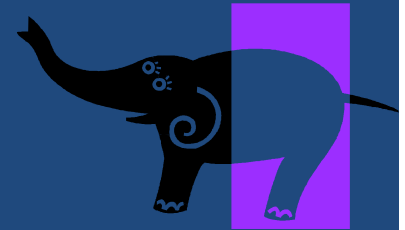
1. Cost-effectiveness of DTC vs. standard provision of testing

- Could examine for tests such as CYP2D6 & BRCA

2. Costs & benefits for health care system

- Downstream effects
- Substitution effects
- Shifting/movement of demand curve
- Of policies

Costs & Benefits to Health Care System: Elephant Problem



- Depends on perspective: patient, provider, insurer, industry, society
 - Patients' willingness to pay for genetic information
 - 2002 Harris survey: WTP \$300 (median) for genetic test for risk of serious, treatable condition
 - 2007, Van Bebber et al: WTP \$150 (median) for genetic test for colorectal cancer risk
 - Patients' willingness to have testing when not used in clinical decisions
 - 2002 Harris survey: 49% would be willing to have free genetic test even if no treatment (vs. 81% if treatment)

Costs & Benefits to Health Care System: One Armed Economist Problem



- Downstream effects on care & society
 - If patients seek additional care
 - If patients improve behaviors
 - Creation of databases
- Substitution effects
 - Does availability of DTC testing move patients from physicians or increase #'s of patients tested?

Costs & Benefits to Health Care System: One Armed Economist Problem

- Shifting/movement of demand curve
 - More patients may seek testing if price goes down with increased quantity
 - Demand curve as a whole could shift in or out
- Costs & benefits of policies
 - More stringent regulation may have benefits (reduction in costs of inappropriate testing) & costs (negatively impact innovation & reduce access)

Questions Codeine Case Illustrates

- Level of evidence needed to use genetic information?
 - Costs & benefits of lower threshold for DTC testing?
 - Different threshold for testing for risk vs. treatment?
 - Who decides?
- Costs & benefits of lag between report, FDA warning, & label change?
 - Does DTC availability impact these?
- Balancing of public right to be informed & access to testing vs. need for valid & cost-effective testing?
 - Limited media coverage on testing availability
 - Does DTC availability improve public knowledge?
 - Should women have ability to purchase OOP?

Conclusion

Supposing is good, but finding out is better

Mark Twain

There is no free lunch

Milton Friedman

- There are both costs & benefits
- We don't really know the costs & benefits
- Economic tools can figure it out