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
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