Impact of FDA Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review

Stacie B. Dusetzina, PhD
Department of Health Care Policy
Harvard Medical School

Disclosures

- The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:
  - No relationships to disclose.

Funding

- This work was supported by the Agency for Healthcare Research and Quality (RO1 HS0189960)
- I am funded through a NRSA Post-Doctoral Traineeship sponsored by NIMH and Harvard Medical School, Department of Health Care Policy, Grant No. T32MH019733-17.

Context

- The FDA is responsible for ensuring the safety of prescription drug products
  - Many safety issues are identified post-approval
  - After a safety issue is identified the FDA must communicate this information to the public

Risk Communication

- Notifying the public of emerging drug safety issues is complicated
  - Strength of existing information
  - Available treatment alternatives
  - Potential for unintended consequences
  - Desensitization of warning messages

Objectives

- To systematically review the literature on the impact of FDA drug risk communications on medication utilization, health care services use, and health outcomes

Search Strategy

- Search Details:
  - MEDLINE, Web of Science
  - January 1990 and November 2010
  - English Language
  - Included terms related to drug utilization, the FDA, and advisories or warnings

Study Selection

- Exclusions:
  - Letters, commentaries, news articles and non-US populations
  - RiskMAPs, market withdrawals, non-drug medical products or devices evaluations also excluded

Search Results

- Identified: 1,432 articles
  - 1,322 excluded from title and abstract review
  - 110 full articles reviewed for inclusion

    49 included in the systematic review

    * Agreement between reviewers = 98%, Kappa = 73%

Data Synthesis

- Categorized studies into four groups using agency recommendations regarding:
  - Greater clinical or laboratory monitoring
  - Avoiding co-prescribing due to drug-drug interactions
  - Avoiding use among a subpopulation
  - General caution regarding product use

Results

- Sixteen drug classes studied
  - 1/3 focused on antidepressants
  - Glitazones (6), Cisapride (3), LABAs (3), Droperidol (3), and Antipsychotics (3) were assessed by more than 1 study

Results

Communication Type Studied	***N (%)***
Black box warning	25 (51)
Public health advisory or safety alert	23 (47)
Dear Healthcare Provider letter	14 (29)
Data source	***N (%)***
Health plan claims	24 (49)
Pharmacy claims	12 (24)
Physician or parent surveys	8 (16)
Health records	5 (10)
Ambulatory prescribing audits	3 (6)
Poison center records	1 (2)
Focus groups	1 (2)
Vital statistics	1 (2)

Recommendation-Specific Results

- Recommendations to increase laboratory or clinical monitoring:
  - No evidence of large or sustained impacts
  - Repeated advisories had little additional effect
- Recommendations against co-prescribing:
  - Changes were gradual
  - Most examples showed significant declines in co-prescribing after over one year / repeated warnings

Recommendation-Specific Results

- Recommendations against use in certain subgroups of patients:
  - Declines in targeted population and non-targeted groups
- General cautions regarding use:
  - Large variation in response
  - Context mattered

Common Themes

- Changes were more likely among new users
- Reductions in use of a specific drug were more rapid if alternatives existed
- Repeated / specific messages were more effective
- Patients and physicians were largely unaware of specific recommendations

Limitations

- Study heterogeneity
- Unable to account for the impact of prior information or shifts in pharmaceutical marketing practices

Summary

- Communicating drug product risk is a priority for the FDA
- Communication opportunities will increase with improvements in drug surveillance science
- Advisory response varies; more likely when warnings are specific, treatment alternatives are available, with reinforced messages

Acknowledgements

- Ashley Higashi, MPH
- E. Ray Dorsey, MD, MBA
- Rena Conti, PhD
- Haiden A. Huskamp, PhD
- Shu Zhu, MPH
- Craig Garfield, MD MAPP
- G. Caleb Alexander, MD, MS