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Presenting:

Is This Thing Safe?
Decision Analysis in Consumer Product Safety

Jeremy Jokinen

DAAG Conference 2013

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Is This Thing Safe?

Decision Analysis in Consumer Product Safety

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Overview:

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- Product safety built-in to design/manufacture and testing of pre-marketed medicinal and medical device products
  - Limited patient exposure
  - Selected patient exposure (biased sample)

- Post-market, need to conduct surveillance to insure safety of products

Post-Market Surveillance

- Consumer contacts need to be monitored for potential product safety issues

- Job #1: Identify potential safety issues for marketed products and take action as quickly as possible
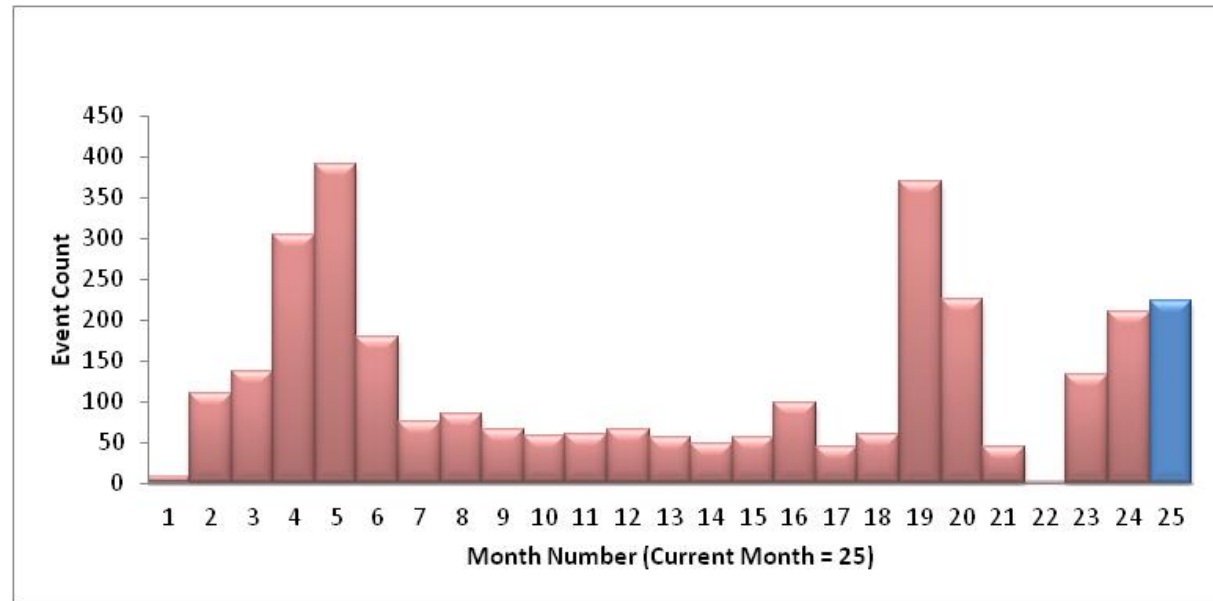
Surveillance

- Quantity and Quality of consumer contacts:

"I tried this product and every time I use this product I get a urinary tract infection."

"It tastes kind of funny."

"Upon using this cream it stung and removed my nail polish."

Lots of Data, Little time

- Call center   now internet   both
- Inconsistent data/missing data
- Inconsistently applied data evaluation criteria
- Regulatory responsibility
- Consumer responsibility

Our commitment to the consumer is that our products are safe and effective

What constitutes a safety signal?

- Could be a single event
  - Serious medical event temporally associated with use of product
  - Medical Determination
- Could be a huge spike in reports of events
  - Product that traditionally received very few reports now receives hundreds
  - Statistical Determination

Those are the black & white examples

- More frequently, some combination qualities and quantities of data
  - Medical judgment combined with statistical output

Unite Medical Judgment and Statistical Analyses

- Describe basics of the medical evaluation of an event report
  - What characteristics indicate a safety signal
  - Which of these characteristics are more interesting than others
- System of analytics that results in probabilities
  - P(observing Product-Event) e.g. P(Tylenol-Headache)

- Pieces of the Expected Utility puzzle

Anticipated Result

- Consistency

- Efficiency
  - FOCUS TIME ON CASES MOST IN NEED OF REVIEW

- Explicitness
  - Documented priorities
  - Added benefit: Inspection Ready

Idea Generation and Workshop

- Pre-Work: SMEs asked to record 'interesting/eye catching' cases
  - What makes the case medically significant?
  - What makes the case inconsequential?
  - Submitted thoughts to me (independent of one another)
- Day-long workshop
  - Posted factors that affect judgment, e.g.
    - Case is serious
    - Case is rare* for this product
    - Case contains evidence of medical confirmation
    - Case event is labeled/expected
  - Discuss   and discuss   and discuss
    - *Defined certain ambiguous terms

Prioritization

- Identified 17 factors that were indicative of medically interesting cases

- Some factors were more medically interesting than others
  - Bucket factors into High, Medium, Low informativeness
    - High: Serious
    - Medium: Rechallenge (drug => event STOP drug=> event again)
    - Low: Dechallenge (event stopped when drug stopped)
  - Within each bucket, assign numerical values (Priority Scores) to each factor
    - Value indicates how important the event is for identifying a potential safety signal
    - 9=Very Important to 1=least important
  - Compared Priority Scores across buckets to insure logical consistency
    - "Does it feel right that a serious event is twice as informative as knowing an event is rare (but not serious)"

Compile Priority Scores and Probabilities

- Large computer, expensive software
- Any event may have priority scores for several factors:
  - A serious event that is also rechallenge event
  - Priority scores are added for these (9 for serious plus 5 for rechallenge)
- Probabilities computed (and reversed)
  - Closer the value is to 1.0, the more statistically unexpected the event

- Review Priority = Priority scores X Probability
  - The higher the value, the more immediate the need for medical review
  - Prioritizes the MASSIVE amounts of events
  - Consistent, efficient, explicit

What worked...what could have been better...what else...

- Seek professional help
  - Consulted with a Pharmacovigilance organization
  - DA not their area of expertise
- Sell it internally
  - Everyone needs to buy-in
    - Statistics will not replace medical judgment
  - One champion is critical, but it takes a village
  - Corporate memory – Levitan *et al.* Drug Safety (2008)

- Future Developments
  - Re-evaluation of prioritization scores
  - Re-evaluation of addition of prioritizations
  - Sensitivity/specificity and data mining
    - Look at growing database of escalated safety events and Review Priorities