Identification of Generic Drugs in the FDA Adverse Event Reporting System

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BACKGROUND

- Nearly 88% of the prescription drugs used in the United States in 2015 were generics.[1]
- Approximately 84% of reports of antiepileptic drugs in FAERS could not be identified as generics or brands in a recent study.[2]
- Few reliable and valid methods to identify generic drugs in the FDA Adverse Events Reporting System (FAERS) exist.

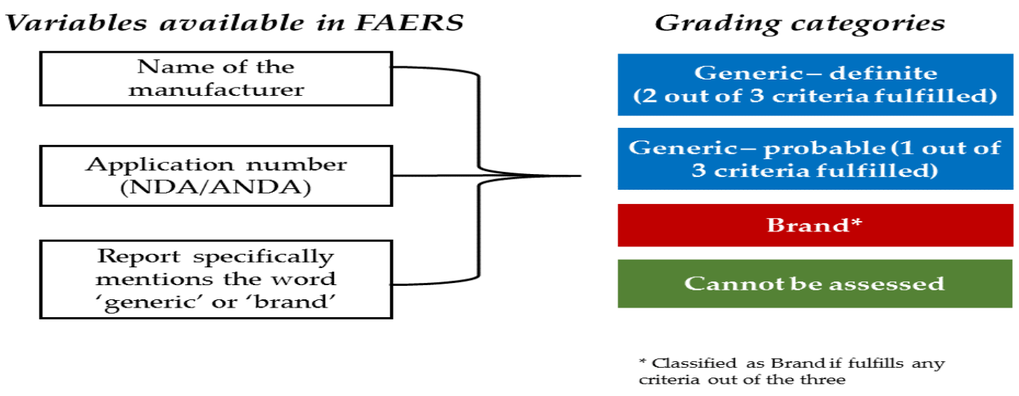
OBJECTIVE

To evaluate the reliability and validity of an algorithm for identifying generic drugs in FAERS

METHODS

- Used 1237 publicly available reports in FAERS (2011-13) with complete information on age, sex, drug name and AE for three drugs: tamsulosin (n=234), levothyroxine (n=742) and amphetamine/dextroamphetamine (n=261)
- Extracted data on AEs where these three drugs were implicated as the primary suspect.

Fig1. Algorithm to identify generics



Grading algorithm.

- Drug was classified as generic (definite or probable), brand or could not be assessed using: a) Name of manufacturer; b) New Drug Application number (NDA/ANDA number); and c) presence of the word 'generic' or 'brand' (Figure 1)
- Dual and independent review with a third reviewer adjudicating differences.

Reliability. Cohen's kappa to measure concordance and internal consistency measured using Cronbach's alpha (α).

Validation. Case narratives for all generics and a random sample of non generics obtained from the FDA via Freedom of Information Act (FOIA).

- Cohen's Kappa used to assess concordance.
- Assessed proportion of generics in public FAERs that were classified as generics in the gold standard source data.

RESULTS

- 15.8% of reports for tamsulosin, 9% for levothyroxine, and 16.1 % of stimulants were generics
- 37% of reports could not be classified.

Reliability. Overall Cohen's κ 0.89 (95% CI 0.84 – 0.93).

- Cronbach's α using manufacturer name and NDA/ANDA variable: 0.92 for tamsulosin, 0.80 for stimulants and 0.59 levothyroxine.
- Cronbach's α using all three variables : 0.52 for tamsulosin, 0.33 with levothyroxine and 0.47 with stimulants.

Validity. 277 case narratives with levothyroxine (n=119) tamsulosin (n=77) and stimulants (n=81).

- Overall κ of 0.89 (95% CI 0.81 – 0.97).
- 95% of reports of generics in public FAERs were identified as generics in the source data

Table 1. Comparison of generics in public FAERS vs the gold standard.

Categories	Generics in source	Non-generics in source	Total
Generics in public FAERS	141	7	148
Non-generics in public FAERS	27	102	129
Total	168	109	277

LIMITATIONS

- Access to a limited random sample of the source narratives for non generics.
- A large proportion of the case reports with insufficient information.

CONCLUSIONS

- Ability to identify generics in FAERS depends on drug class, variables selected and completeness of reporting.
- An algorithm using the manufacturer name and NDA/ANDA variable was reliable with high concordance and PPVs
- Physicians, patients and manufacturers should accurately report on these variables.

REFERENCES

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