Patient relevant outcomes associated with generic drugs in the FDA Adverse Event Reporting System

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BACKGROUND

- Generic drugs accounted for about 88% of all prescriptions dispensed in the US in the year 2015.[1]
- Anecdotal reports about the safety of generic drugs may potentially impact their utilization.
- The extent to which adverse events associated with generic drugs reported to the FDA's Adverse Event Reporting System represent patient relevant concerns is unknown.[2]

OBJECTIVE

- To classify spontaneously reported Adverse Events (AE) associated with generic tamsulosin, levothyroxine, amphetamine/dextroamphetamine in FDA's Adverse Event Reporting System (FAERS) as patient relevant concerns using the physical mental and social domains of the National Institute of Health Patient Reported Outcomes Measurement Information System (PROMIS) framework.

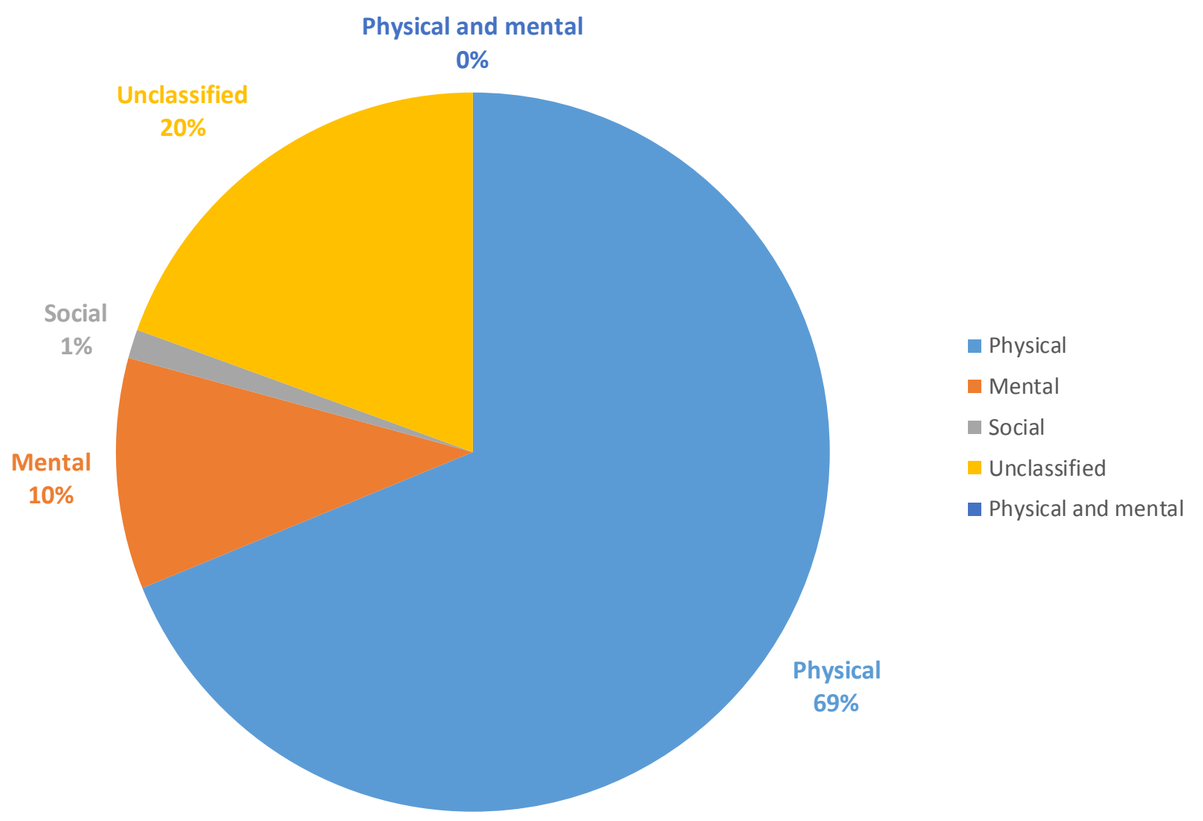
METHODS

- Descriptive analysis of data on generic drugs from publicly available FAERS data and source narratives were obtained from the FDA under the Freedom of Information Act.
- Case reports (n=1237) in FAERS 2011-2013 associated with complete information on age, sex, suspected drug name and AEs related to tamsulosin, levothyroxine, amphetamine/dextroamphetamine as the primary suspect drug were identified.
- Reports of generic tamsulosin, levothyroxine and amphetamine were identified using an algorithm which combined manufacturer name, New Drug Application (NDA) number and presence of the word generic or brand in text
- 147 reports (39 for tamsulosin,67 for levothyroxine and 42 for amphetamine/dextroamphetamine) reporting on 381 AEs (77 for tamsulosin, 144 for levothyroxine and 160 for amphetamine/dextroamphetamine) were selected for analysis.
- Two reviewers independently mapped adverse events onto the physical, medical, social and global health domains of the most widely used framework for Patient Reported Outcomes-NIH PROMIS (third reviewer adjudicated disagreements)

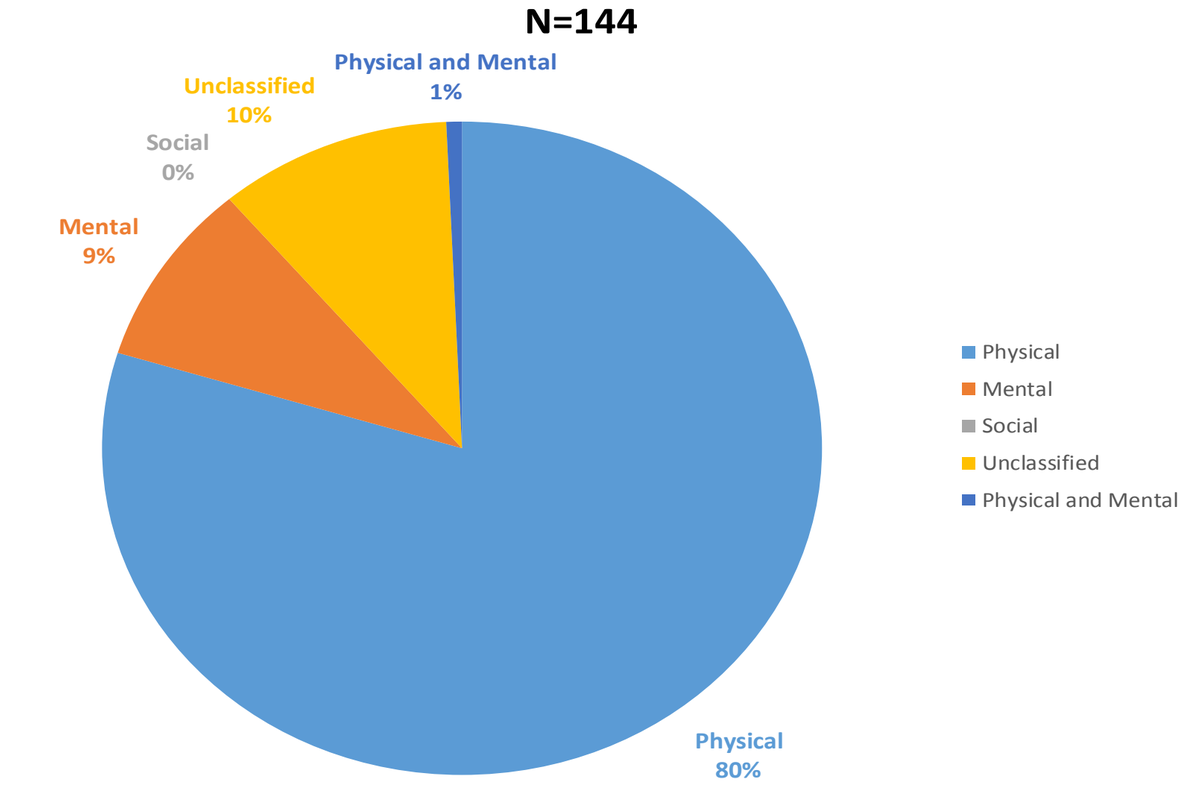
RESULTS

- 381 AEs associated with generic tamsulosin (n=77), levothyroxine (n=144), amphetamine/dextroamphetamine (n=160) selected for analysis.
- The physical domain was the most commonly reported domain for all three drugs (tamsulosin=76%, levothyroxine=80%, amphetamine/dextroamphetamine= 71 %), followed by the mental domain (9.0 % for tamsulosin, levothyroxine=9%, amphetamine/dextroamphetamine=18%).
- Very few AEs mapped onto the social domains. A small minority of additional 44 AEs were mapped onto the NIH -PROMIS domains after using data from the source narratives.
- Approximately 1/3 of reports could not be mapped onto any of the domains due to missing data.

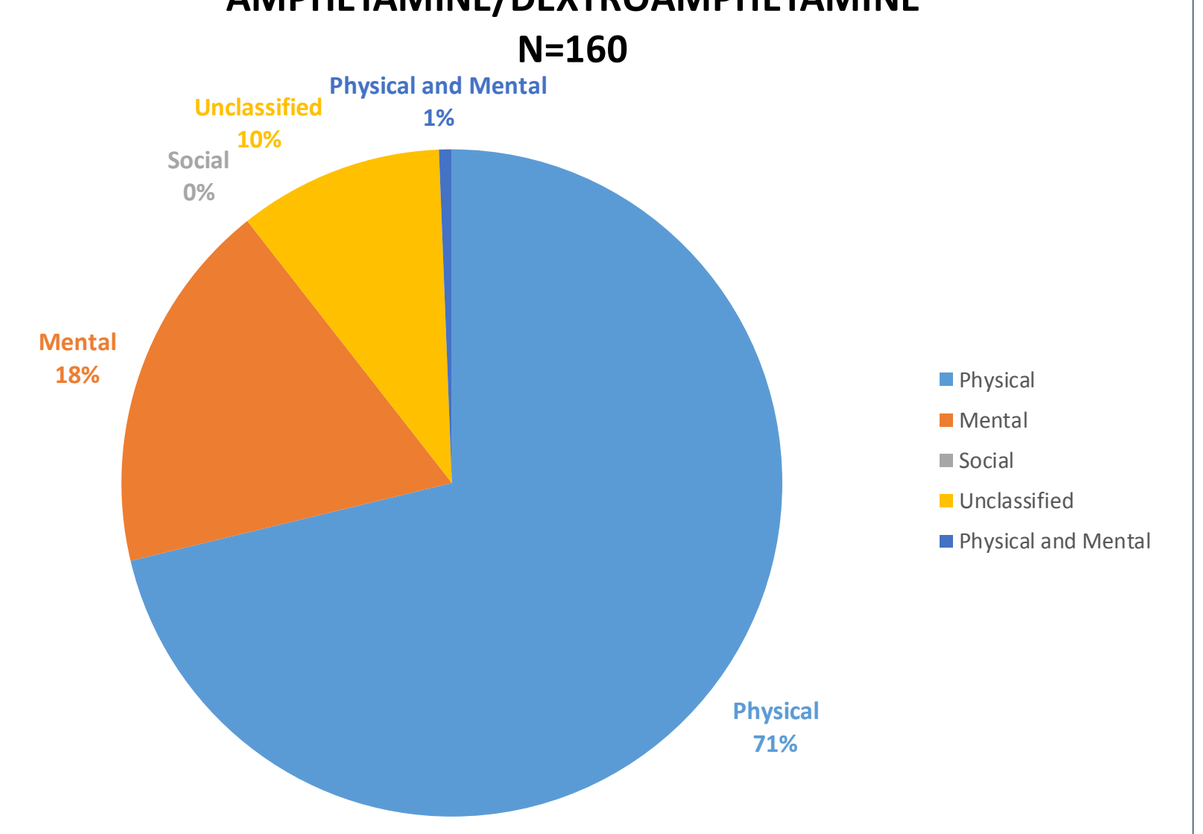
NIH-PROMIS DOMAINS FOR TAMSULOSIN
N=77



NIH-PROMIS DOMAINS FOR LEVOTHYROXINE
N=144



NIH-PROMIS DOMAINS FOR AMPHETAMINE/DEXTROAMPHETAMINE
N=160



LIMITATIONS

- Relative differences should be interpreted with caution because of incomplete reporting and non-representative data in FAERS.
- We retrospectively mapped adverse data onto a prospective patient oriented outcome data collection tool.

CONCLUSIONS

- AEs associated with generic drugs can be mapped to the domains of NIH-PROMIS framework to identify a spectrum of patient relevant outcomes.
- Future efforts to improve the completeness of reporting in FAERS are needed to improve understanding of patient relevant concerns

REFERENCES

1) http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf
2) Banerjee AK, Okun S, Edwards IR, Wicks P, Smith MY, Mayall SJ, et al. Patient Reported Outcome Measures in Safety Event Reporting: PROSPER Consortium Guidance. Drug Saf 2013; 36:1129-49

ACKNOWLEDGEMENT

Funding for this study was made possible by the Food and Drug Administration through grant U01FD005267. Views expressed in written materials and by speakers do not necessarily reflect the official policies of the Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government. The authors have no conflicts of interest to disclose