To assess the incidence of and risk factors for such drug reactions, we implemented a formative study of comprehension and satisfaction with the IC process of the ODARs. As 3HP is used in clinical practice, monitoring for drug reactions is critical. We evaluated the events considered to be eligible for analysis and excluded those that did not satisfy the case definition of "possible hepatotoxicity" (n=121) and excluded those with a low score (n=15) as well. Our findings indicate a need for further investigation into more specific details.

Limitations & Summary

• More qualitative process data and more ICAT results will help to reveal specific details of the IC process.
• The formative study of comprehension and satisfaction with the IC process was limited to a small sample size and therefore may not be representative of the IC process in its entirety.

Conclusions

• A method for estimating the probability of severe drug reactions in ODARs.
• The signs and symptoms observed in ODARs varied widely, and were generally not consistent with immuno-mediated reactions.
• A laboratory test to confirm ODARs is needed.
• The Naranjo system deserves further evaluation in clinical trials of severe AEs.

References


Affiliations

4. Center for Clinical Pharmacology and Clinical Toxicology, Macquarie University, Australia
5. Department of General Internal Medicine, New York, NY, USA
6. National Institute on Aging, Division of Allergy and Clinical Immunology, Johns Hopkins University

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Clincion of TB Elimination

Results

• PREVENT TB patients with the highest likelihood of a ODAR were those treated with 3HP, of whom non-Hispanic race/ethnicity, and of female sex. The only statistically significant risk factor for severe ODARs was non-consumptive drug medicine given 7 days or before.

Variables

ODAR = Other Drug Reaction

3HP = Isoniazid rifapentine

9H = Isoniazid rifampicin

TB = Tuberculosis

LTBI = Latent Tuberculosis Infection

HIV = Human Immunodeficiency Virus

STD = Sexually Transmitted Diseases

TEN = Toxic Epidermal Necrolysis

DRESS = Drug Reaction with Eosinophilia and Systemic Symptoms

AER = Adverse Drug Event Report

ADR = Adverse Drug Reaction