Adverse drug event reporting in U.S. beset by incompleteness and inaccuracy

High proportion of health care professionals have no ADE reporting experience

- More than two-thirds of all adverse drug event (ADE) reports do not include dosage level, and 90% lack lot numbers.
- ADE report completeness and accuracy vary by therapeutic area, with those for CNS drugs posting the highest drug name accuracy and some of the lowest lot number completion rates.
- ADE reports submitted by patients tend to be more complete than reports submitted by health care professionals.
- Pharmacists are more aggressive about ADE reporting, compared to nurses and physicians.
- Difficulty verifying a drug as the cause of an adverse event is the top reason given by health care professionals for not filing an ADE report.
- Better biosimilar naming conventions could improve completeness and accuracy of ADE reports.

Adverse drug event reporting has received increased attention of late with the United States Food and Drug Administration (FDA) and the European Medicines Agency beginning to approve generic versions of biologics, while social media and electronic medical records are expected to play a growing role in early detection of side effects. Critics of voluntary pharmacovigilance systems in the U.S., e.g., MedWatch and the Adverse Event Reporting System (AERS), are quick to cite the drug industry’s slow and delayed response to ADE reports. At the same time, pharmaceutical and biotechnology companies are challenged to verify the accuracy of ADE observations.

While ADE reporting aims to ensure and enhance patient safety, recent studies conducted by Tufts CSDD indicate that the U.S. national system of ADE reporting is inaccurate, incomplete, and inefficient. Inaccurate reporting, in particular, is problematic; it may mislead drug safety professionals to draw incorrect conclusions, cause manufacturers to wrongly suspend and withdraw medical interventions, lead health professionals to mistakenly alter their clinical practices, and deny or limit patient access to safe and effective treatments. This report summarizes key findings of those studies.