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Response to Federal Register Docket 01D-0056
Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines

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01D-0056

The American Medical Informatics Association (AMIA), representing over 3,000 medical informatics professionals, applauds the thoughtful and clear Guidance for postmarketing surveillance recently published for public comment. AMIA's Public Policy Committee, chaired by Paul C. Tang, MD, has extensively reviewed the Draft Guidance.

While AMIA is strongly in favor of a unified coding standard for adverse events in postmarketing surveillance, we are concerned about the wide-scale adoption of MedDRA because the MedDRA classification has no logical or semantic connections to clinical encoding terminologies, with which the vast majority of adverse clinical events will be recognized and captured. This lack of integration may lead to inconsistent or non-comparable recording of adverse events, which would contribute to misclassification bias in any analyses derived from these data.

We recognize that the main thrust of this document focuses upon the administrative details of circumstances requiring report, forms and timing for reporting, and procedures for exceptions, waivers, or foreign contexts. We further acknowledge the intention that clinical personnel ("physician, physician assistant, dentist, pharmacist, nurse" – line 320-1) clarify adverse events to reporting organizations, and that medical record documentation should accompany these communications. Nevertheless, the increasing use of Electronic Medical Records (EMRs), and the heightened interest in public health surveillance data deriving from EMRs makes it inevitable that adverse events will increasingly derive from clinically encoded data in EMRs.

MedDRA, in its present form, exhibits the following undesirable barriers to information interchange and consistent application:

1. It has no logical or semantic linkage to any clinical encoding system. Indeed, the National Library of Medicine (NLM) has not yet been able to conclude an agreement that would allow its MedDRA's inclusion in the Unified Medical Language System (UMLS) Metathesaurus, where the only, albeit preliminary, attempt at such linkage has been made.
2. It is not accompanied by implicit or explicit rules for consistently aggregating discrete clinical observations into the classification rubrics.

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3. License fees for the use and application of MedDRA pose a significant burden to providers, clinicians, or investigators who may have responsibility for adverse event reporting, e.g. those applicants holding NDAs or ANDAs.
4. There is no accommodation for non-drug related researchers or educators, such as the informatics community, to access MedDRA for study and evaluation without paying the considerable full licensing costs.

AMIA believes that proposals for standard terminology should be evaluated as part of the HIPAA process for evaluating standard codes and terminology because of their widespread impact on clinical care. We recommend that this issue should be examined by the National Committee on Vital and Health Statistics (NCVHS) at a minimum, and should adhere to the goals for data interoperability and comparable interchange advocated by NCVHS in their July, 2000 report to the Secretary of DHHS.

To ensure that scientific reports which derive from adverse event data, and which will directly impact patient care and quality, do not suffer from misclassification bias or under-reporting due to barriers for MedDRA access, AMIA recommends that:

1. FDA submit the question of MedDRA encoding to the NCVHS for evaluation under the HIPAA process.
2. MedDRA should not be required for adverse event reporting by individual clinicians or small practices, even if they are participating in a drug trial. An example would be clinicians who enroll patients in a cancer clinical trial.

Should the FDA adopt MedDRA, a clean and unambiguous rule set for mapping conventional clinical terms (such as SNOMED RT, LOINC, or Medcin) should be freely available. Furthermore, software tools should be developed to implement this mapping and made widely available at a cost of no more than that required for their distribution.

We recognize the advantages of an internationally harmonized coding system for adverse events. However, such a system should be considered in the context of clinical information standards and coding systems, which form the primary repository of patient conditions, interventions, and outcomes.

Sincerely,

Dennis Reynolds

Dennis Reynolds
Executive Director