For the past four decades, voluntary spontaneous reporting of suspected adverse drug reactions has been the cornerstone of postmarketing drug safety surveillance in many countries. The key to this system is the recognition, at the point of care, that an untoward sign or symptom may be the result of a medicine. This suspicion, which is no less important for medical care than it is for drug safety surveillance, only fulfills the goals of the latter system if the practitioner or patient takes the time to submit a report to the drug regulatory authority, national pharmacovigilance center, or the product’s manufacturer that provides a summary of the medical facts surrounding the suspected adverse drug reaction.

These reports are useful to drug safety specialists only if they contain sufficient information for an independent assessment of the relationship between the medicine and the adverse event. Such reports need not be long, though they generally should contain a narrative of the event that includes its time course, clinical features, any treatments administered, and its outcome. To put the event in context, medical history, concomitant medication use, relevant laboratory and imaging data, and pertinent histopathological data should be included.

What are the barriers today to effective voluntary reporting of suspected adverse drug reactions? In the United States, there are no general requirements that practitioners submit reports either to the US Food and Drug Administration (FDA) or to the drug’s manufacturer. Thus, busy practitioners often do not think of submitting a report; many, in fact, are unaware of this system. To compound this general lack of awareness, completing a MedWatch form requires an estimated 36 minutes, time that busy practitioners almost always do not have. Finally, many reports are often submitted with insufficient clinical details to allow for an independent assessment of the relationship between the medicine and the adverse event.

Can modern technology help improve awareness of reporting suspected adverse drug reactions, simplify the reporting process for practitioners, and improve the quality of reports?

In this issue of Pharmacoepidemiology and Drug Safety, Linder and colleagues describe a pilot project within the Partners Healthcare System to test an alternative, semi-automated method for reporting adverse events. Partners uses a Longitudinal Medical Record (LMR) system that specifically codes adverse drug events, which allowed the researchers to identify 26 physicians who had discontinued a medication due to an adverse event in the year prior to the pilot program. When a physician noted in the LMR that a medicine had been discontinued due to an adverse event, the LMR triggered ASTER, which then collected data from the LMR, populated an ADE reporting form, and made
the report available to the clinician for review. The clinician then provided additional information on the outcome of the adverse event and its earliest date of occurrence, after which ASTER coded the adverse events and submitted the report.

Over a five-month period, the 26 physicians discontinued 319 medications due to an adverse event. For largely technical reasons, only 217 reports were submitted. Ninety-five percent of reports contained some information on co-morbid conditions, 89% reported on concurrent medications, and 99% had some laboratory data.

In demonstrating the technical feasibility of an automated adverse event reporting system that can trigger reporting within an electronic medical record system, compile the report, provide for clinician input, and submit the report, ASTER represents an important first step in bringing spontaneous reporting from the point of care into the electronic age. Nonetheless, the value of the system will depend on the data it provides to drug safety scientists. Toward that end, several questions remain unanswered.

First, do the reports contain the necessary narrative information to allow for an independent assessment? Second, are the data on co-morbid conditions, laboratory tests, and concomitant medications the most relevant and up-to-date data? Third, can the system handle other types of information such as diagnostic imaging results or pathology findings? Finally, can this system identify adverse events not previously known to be associated with a medicine, or does it report only on well-known adverse drug reactions?

While FDA has received these reports, and has used individual reports in the course of its day-to-day drug safety surveillance work, we have not specifically assessed the quality of reports submitted by ASTER. (FDA provided logistic and technical advice to the ASTER investigators in order to receive these direct-to-FDA reports, as we would work with any person or organization who wishes to submit such reports to FDA. FDA was not otherwise involved in the ASTER project.) FDA plans to assess the quality of the ASTER reports as a whole, so that we can provide feedback to the ASTER investigators and others who wish to pursue electronic adverse event reporting directly from the point of care.

As the use of electronic healthcare data expands into areas of active surveillance, it is important to remember that well written, individual spontaneous reports are a valuable component of drug safety surveillance. Attempts to improve this reporting system and to automate it, such as those reported by Linder et al., are important step toward that goal.

CONFLICT OF INTEREST

The views expressed are those of the author and not necessarily those of the US FDA or US Government.