# Postmarketing drug surveillance: what it would take to make it work

Adverse drug reactions are an important cause of serious illness and death.[1,2] Yet we become aware of new adverse events only very slowly, long after the drugs have been widely prescribed. Even when serious drug interactions are discovered, physicians, pharmacists and patients appear to remain unaware of them.[3]

Problems with detection arise mainly because these events are rare. It takes a surveillance system with a high degree of sensitivity to detect such problems — a tall order for a voluntary system such as Canada's. Psychological and behavioural barriers to reporting are not difficult to surmise. One might expect an adverse event to be reported only if the physician has a sufficiently strong suspicion that the reaction was caused by a drug; judges that the event is worth reporting; has time to report it; and, depending on the circumstance, is willing to admit a mistake, or to report a colleague's mistake. The physician's work setting must also support the frank reporting of adverse events.

We felt compelled to take another look at what went wrong in the case of cisapride,[4] (page 1370) a drug with known contraindications and cardiotoxic effects that has been associated with 105 deaths in Canada and the US. The cisapride story demonstrates the failure of the reporting system to adequately influence prescribing behaviour, but it also points to more diffuse reasons why postmarketing surveillance fails.

Once data on a serious adverse event are collected, Health Canada makes a determination as to whether the event is causally related to a drug. The cooperation of the drug company is sought, in a relationship that is collegial more than adversarial.[5] This is an age of "partnerships." It is the drug company, not Health Canada, that issues the Dear Doctor letter, confirming its conscientious participation in postmarketing surveillance. Conscientious it may be. But why rely on a system in which initiatives to enhance patient safety are likely to compete with the bottom line? Even within Health Canada's purview, there is an inbuilt tension between the goal of making useful drugs available as quickly as possible and the need to proceed cautiously enough to ensure that those drugs do no harm.

We don't ask the airline industry and their federal regulators to investigate airline crashes: an agency independent of both undertakes this important task. Perhaps it is time to establish a parallel agency for the surveillance, investigation and dissemination of information about adverse drug reactions, one independent of pharmaceutical companies and of Health Canada. The agency would proactively investigate suspected events rather than waiting for reports to arrive, employ sophisticated bayesian causality analyses[6] and ensure (by ongoing evaluations) that physicians and patients get and use the information. Expensive? Yes, but the problem of adverse drug reactions is also costly and is measured not just in dollars but in lives. — *CMAJ*

## References

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