Australia needs a better system for health care evaluation

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Is it unethical to avoid using all available information to monitor drug safety?

Adverse effects of health care have recently been in the news, from the worrying unexpected cardiovascular risks associated with use of the cyclooxygenase-2 inhibitor rofecoxib (Vioxx) to reports of high percentages of complications following routine surgery.[1,2] As medical care becomes more complex, sophisticated and expensive in Australia, it is paramount that we have the best systems in place to monitor its impact and evaluate its safety and efficacy.

In this issue of the Journal, Kelman and colleagues (*page 249*) acknowledge the limitations of randomised controlled trials (RCTs) in detecting all harmful effects of medicines and make a plea for modernising Australia's system of pharmacovigilance by building upon the latest technological and data capabilities that we have. They recommend shifting from the existing archaic system of postmarketing surveillance, which relies on piecemeal reporting of adverse events, to a more systematic approach that would include using existing centrally collected, administrative health care databases. Kelman et al claim that by merging information from prescriptions and the Pharmaceutical Benefits Scheme with readily available data on major health outcomes (eg, deaths, hospital admissions, registers of cancer and other diseases), Australia would have a powerful capacity to evaluate the effects of drugs in real-world situations.

What are the advantages and disadvantages of such a proposal, and what is happening internationally?

The system proposed by Kelman et al has several advantages:

- The data already exist, and it may even be irresponsible to not use them for important evaluations of health care outcomes;
- Such data linkage would provide more comprehensive information on both drug use and outcomes and hence would be less likely to be biased than RCTs, which use selected samples with variable participation;
- The data would cover a large patient population, increasing the likelihood that any adverse effects would be rapidly identified; and
- It is an inexpensive system compared with very large RCTs or other epidemiological studies, and it would allow greater capacity for pharmacoepidemiology to evaluate the appropriate use of drugs across the whole population.

However, there are also potential disadvantages associated with such a data linkage system:

- There are privacy concerns surrounding the use of individual patients' data;
- The analysis and interpretation of linked datasets pose considerable challenges; for example, with common adverse events such as heart attacks or stroke, any associations found must be analysed in relation to other known risk factors, details of which may not be available or may not be accurately reported in the linked data; and
- There will be costs involved in establishing a national capacity for data linkage.

In some jurisdictions, such as Western Australia (through the WA Data Linkage Unit), such data linkages have been carried out for many years, both to evaluate medical care and to conduct epidemiological studies on heart disease, cancer, birth defects, and other health problems.[3-5] As a result, the WA Data Linkage Unit and the researchers it serves have considerable experience in linking, analysing and interpreting the complexities of such data, and have developed best practice in relation to privacy concerns. These analyses have had a major impact on improving health services in the state (see Brook et al[5] for examples). If all Australian health care data were linked to drug exposure data (from the Pharmaceutical Benefits Scheme), this linkage could provide very precise estimates of the risks and benefits of drugs for the whole population, as well as for subgroups that are often excluded from RCTs, such as children, pregnant women, and people with multiple diseases or other risk behaviours, such as smokers. If linked data are routinely evaluated for outcomes associated with new drugs, adverse events could be detected before considerable harm is done to patients.

We must be able to demonstrate to the community that linking data for the sake of the public good does not invade their privacy. Both the National Health and Medical Research Council and the Australian Law Reform Commission are preparing reviews that will help to clarify and, we hope, support these activities. The WA Data Linkage Unit has developed a protocol for linkage that aims to protect privacy.[6] This "win–win" approach means that researchers who require linked data on drug exposures and patient outcomes never see any patient-identifiable information. Since the WA Data Linkage Unit's protocol has been in place, requests for access to identifiable data have reduced markedly.[7] When people in the general community were asked if they approved of their information being used in this way, they were found to be not only supportive of it, but they questioned why it was not already being done (C Kelman, Associate Professor in Population Health, Australian National University, personal communication, 2005).

Most international developments in pharmacoepidemiology are taking place in the United States, Canada and the United Kingdom, with relevant authorities in these jurisdictions concerned about the safety and cost of drugs, and ensuring efficacy and appropriate prescribing.[8] Their recommendations generally support those of Kelman and colleagues. While health care data linkage systems similar to that in WA exist in England, Scotland, the US and Canada, none of these systems are nationwide or have the routine ability to link health care records with drug prescription data; Australia could perhaps lead the world in this regard.

We strongly believe that Australia has an opportunity to establish a cutting-edge capacity to monitor its health care system. We also believe that if society has the capability to better monitor the safety of new drugs, it may be unethical *not* to do so — avoiding the use of information that would help reduce risk to individuals suggests a willingness to allow people to be harmed. At the very least, this conflicts with the physician's duty to patients to "first, do no harm". We think the time has come to expect more — not simply to avoid harm and reduce risk to individual patients, but to actively seek to maximise the wellbeing of all citizens. Improved pharmacovigilance is one important step towards this goal.

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