Opinion

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How Reliable Are Doctor's Prescriptions?

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Manufacturers invest a great deal in the promotion of new drugs. It is very much in their interests to persuade doctors to switch to the new drugs rather than to continue with the older, tried and proven therapies.

The use of new drugs, however, is not always in the best interests of consumers. First, doctors are less familiar and less experienced with the use of new drugs and their side effects. Second, long term side effects and less common side effects, and adverse reactions and interactions with other drugs, may take time to become known. Third, new drugs cost the Pharmaceutical Benefits Scheme more and are thus a greater drain on taxpayers. At the same time new drugs may be easier to use, have fewer side effects, and be more effective.

There are several faults with the system. Firstly, doctors depend heavily on the promotional information about new drugs. But the manufacturers' promotional information is not designed primarily to provide comprehensive, easily accessible information to the doctor. Rather, it is aimed at changing prescribing habits away from older therapies to the new drugs.

Prescribing habits are subject, then, to poorly informed fashion, with fashion determined in large part by the promotion of new drugs.
The evaluation of new drugs is obviously crucial in ensuring safety, effectiveness, and appropriate applications for new therapies. The so-called gold standard for drug evaluation is the randomised clinical trial.

A group of patients is randomly selected and divided into two groups. One group is given the new therapy and the results compared to the other group receiving established therapies or no therapy. In that way, a set of figures can be produced listing the proportion of benefits, side effects, and adverse reactions which can be attributed to the new drug.

A second form of evaluation is the use of historical trials in which a new drug is tried on a group of patients and the results compared to the historical results of other therapies or no therapy. Historical trials require greater time frames to establish validity and are not regarded as having the objectivity of a randomised controlled clinical trial (RCT).

In recent times, RCTs have been criticised and their validity questioned. Firstly, a serious ethical problem arises in giving controlled groups a placebo if it is thought that there is an effective treatment already available. As soon as a new drug starts to gather

evidence that it is a successful treatment, then it becomes an injustice to keep the control group on a placebo or a less effective established therapy and vice versa.

Gaining informed consent to an RCT can be a problem, too, for the patients' knowledge about whether they are being given the new therapy or a placebo may affect their reporting of symptoms and skew the results.

Second, RCTs are conducted in strictly controlled circumstances by specialists in the field who are familiar with the pharmacology of the drug, and who are carefully monitoring the patients, both the group using the drug and the control group.

The circumstances are thus markedly different from those in which a drug may be applied by a general practitioner out in the community who is unlikely to be as pharmaceutically informed, who does not and probably cannot undertake the same high level of monitoring, and whose patients are similarly less informed, more likely to combine the drug with other drugs with which it may interact, and more likely to be less compliant in taking the drug in the prescribed manner, given less monitoring.

Third, RCTs are undertaken on a relatively small group over a relatively short period of time. Hence less common side effects, adverse reactions, and drug interactions may not become evident until the drug has actually been approved for general use and has been used for some time in the broader community.

Fourth, the nature of the monitoring in a clinical trial is significant. The range of effects and side effects that could reasonably be expected will be likely to be monitored, but the unexpected results may not be. Again, it may take time and widespread use for the latter to become recognised and even longer for that information to filter down to prescribing doctors in the community.

Once a drug has been evaluated and approved there is much less effort expended on the systematic gathering of information about it.
Further, there are considerable barriers to anecdotal information being gathered. The gold standard of the original RCTs tends to limit the monitoring of the drug. An effect which was not discovered then is unlikely to be recognised as such by a prescribing doctor as an effect of the drug because, even if the doctor is familiar with the written prescribing information, it will not have been listed there as an effect of the drug.

Patient reporting of side effects is unlikely to be conveyed to a doctor in categorical medical terms but more likely to be received by the doctor in the patient's own language with the doctor struggling to find a medical explanation to best fit the patient's account.

The doctor's explanation will be conditioned by the information from the trials. The combination of the doctor's limited pharmacological knowledge with the patient's inability to explain may well mask the actual effect and its cause. Even then, there are few avenues which a doctor in the community has for communicating the information to where it will be notified, verified and acted upon.

There are now numerous examples of the very slow and difficult process by which consumer information actually filters up to the level where it can be confirmed and then filters back down to the prescribing doctors in such a way as to bring about appropriate change in prescribing habits.

The recent publicity given to the withdrawal effects for addicted users of prescribed minor tranquillisers is a good example. The information has taken the best part of twenty years to be processed, confirmed, and then communicated to prescribers.

Similarly the restriction of the prescription of the contraceptive pill to non-smokers and the acknowledgment of the greater risks to older women took a long time to occur and the information was not available at the time the first approvals were obtained.

The greater risks of pelvic infection from the use of IUDs was only slowly and reluctantly recognised. The financial consequences at the end of the day for the manufacturers were great, as the many court cases attest.

It is most unfortunate when the process is so slow that litigation ultimately is the only effective reason for changing prescribing habits. Many people, consumers, prescribers, and manufacturers, are hurt in that process.

Nothing can really replace the RCT as a short term way of evaluating new drugs and satisfying the manufacturers' need for rapid approval. But there is a problem with the confidence that the RCTs produce and the way in which they impose limits on the reportability of consumer experiences and the lack of effort subsequently expended on systematically gathering data based on consumer experience.