

The Importance of Pharmacoepidemiology in Iran

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Pharmacoepidemiology is rarely taught to medical students and the amount of time devoted to it in clinical trainings is limited (1). However, the past few years have seen an emphasis on the safety of medicines and evidence-based prescribing which seems to be greater than at any time since the immediate aftermath of the thalidomide disaster 50 years ago.

Pharmacoepidemiology as a discipline is probably less than 50 years old. The word was first used only just over 25 years ago (2), and before that, 'pharmaceutical epidemiology' was a phrase used by Jan Venulet, with the same sense (3). It can be defined simply as the application of epidemiological methods to the effects of medicines, including vaccines and biological treatments. As a general point, pharmacoepidemiology shows some signs of losing its links to pharmacology and it is vital that it does not do so (1).

Clinically relevant harms may be rarer than clinically relevant benefits, but they can be serious enough to alter the benefit-harm balance of a marketed medicine. Pharmacoepidemiology comes into its own when there is limited information regarding harms and their frequencies. Hence, there is clearly a place for pharmacoepidemiology, especially in confirming clinical benefits in real practice and looking for harms, in the hope of failing to find them or at least showing that their rate is low, so that the goal of safety (absence of important harms) can be assured (1).

Areas in which advances are required:

The overall areas under consideration can be divided into three groups:

- 1) Problems of inferring causality when methods are the focus,
- 2) Application areas and related clinical questions,
- 3) The sources and quality of the available data.

I would like to emphasize on sources and quality of the available data. With increasing use of databases, there is a danger that errors in the recorded data, missing data for

expected variables, and the complete absence of some variables may not be fully recognized. Data that are recorded for routine care may be interpretable, even in the presence of errors, but may make research difficult or may produce misleading results (1).

Pharmacoepidemiology is a fascinating field with major intellectual challenges. There is a danger that whether or not industry funding leads to bias, the perception among the public and some journal editors is that it is likely to lead to results favorable to industry. There are financial pressures and pressures from patients to bring new drugs to market early, but there has not been the same pressure to have effective post-marketing monitoring (1). Drug safety leads to major public concerns, but these concerns have not been followed by notable public funding. There is a need for funding of the methods and infrastructure, especially in developing countries such as Iran, which allow groups to be able to carry out studies relatively rapidly. The pressure to have almost immediate answers is great, but this must not lead to a reduction in quality.

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