EVALUATING DRUG UTILIZATION IN PRACTICE-ECONOMIC EVALUATION BEYOND THE CLINICAL TRIAL

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The information requirements of health services have altered throughout the world. Although clinical trials undoubtedly provide valuable information on the safety and efficacy of new drugs in a strictly controlled and regulated environment they provide very limited evidence concerning how well such drugs will perform in real life clinical practice. New drugs are increasingly being required to prove their cost-effectiveness to ensure that they provide value for money in the consumption of scarce health care resources. In this changing environment pharmaceutical companies must alter and augment their clinical trial programme to generate economic as well as clinical information that can be used to inform the decision making of clinical pharmacologists. In addition assessments must be made of the extent to which the benefits observed in a highly controlled clinical trial can be replicated in the far less controlled and stable environment of real world clinical practice. A drug that provides health benefits that are entirely dependent on access to specialist equipment and expertise is unlikely to perform as well in mainstream clinical practice where such elements are unlikely to be readily available. Equally a drug whose therapeutic effect is dependent on being taken in strict accordance with manufacturers instructions(which will be routinely followed in a clinical trial)would be likely to perform poorly when patient behaviour and compliance is reduced in real world clinical practice. Clinicians do not need to know how well a new drug performs in the unreal environment of a clinical trial but rather how well it would be likely to perform if it was to be incorporated into their routine clinical practice. Information on the 'foregiveness' exhibited by drugs(how well their therapeutic effect is maintained in the face of factors such as non-compliance)may therefore be of greater value to clinical pharmacologists in assessing drug use in practice than point estimates derived from trials of what efficacy is potentially achievable but only in 'perfect' prescribing conditions.

The applicability and interpretation of both clinical and economic data collected in the context of a clinical trial is different from the conditions in which routine clinical prescribing is undertaken and it is important for clinical pharmacologists to be aware of the implications of such differences for the quality and cost-effectiveness of their prescribing practice. The real world environment is characterised by clinical uncertainty with therapy being prescribed and taken in less than ideal conditions. The economic focus on cost-effectiveness implicitly incorporates the impact of real world clinical issues such as non-compliance and suboptimal drug utilization to provide information concerning the anticipated impact on real patients in real world clinical practice of drug prescribing. This can be achieved in a number of ways. Observational trials or medical databases can be used to identify costs and benefits that arise in clinical practice but are artificially controlled by the research protocol and hence do not impact on clinical trials. Alternatively economic modelling (perhaps based on the Pharmacokinetic and Pharmacodynamic profile of the drug) can be used to specifically incorporate the large number of confounding variables that interfere with the pure(but unrealistic)relationship between drug use and patient response that is isolated in clinical trials. The aim is to ensure that clinicians have the optimum basis on which to base their therapeutic choices in the explicit recognition that routine prescribing is subject to the confounding elements that exist in the real world and not undertaken in the artificial world that is routinely (and quite correctly) controlled in the context of a clinical trial.