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Assessing the impact of prescribed medicines on health outcomes

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Abstract

This paper reviews methods that can be used to assess the impact of medicine use on population health outcomes. In the absence of a gold standard, we argue that a convergence of evidence from different types of studies using multiple methods of independent imperfection provides the best bases for attributing improvements in health outcomes to the use of medicines. The major requirements are: good evidence that a safe and effective medicine is being appropriately prescribed; covariation between medicine use and improved health outcomes; and being able to discount alternative explanations of the covariation (via covariate adjustment, propensity analyses and sensitivity analyses), so that medicine use is the most plausible explanation of the improved health outcomes. The strongest possible evidence would be provided by the coherence of the following types of evidence: (1) individual linked data showing that patients are prescribed the medicine, there are reasonable levels of patient compliance, and there is a relationship between medicine use and health improvements that is not explained by other factors; (2) ecological evidence of improvements in these health outcomes in the population in which the medicine is used. Confidence in these inferences would be increased by: the replication of these results in comparable countries and consistent trends in population vital statistics in countries that have introduced the medicine; and epidemiological modelling indicating that changes observed in population health outcomes are plausible given the epidemiology of the condition being treated.

Background

Many developed countries publicly subsidize selected medicines on the assumption that their use will improve the health of patients who take these drugs [1]. Improved health outcomes might include: reduced incidence of disease (if medicines prevent new cases of disease in persons at risk); reduced mortality and morbidity (if medicines are used to treat early or established cases of a disease); and reduced morbidity and disability or improved quality of life (if medicines are used to slow the progression or palliate the symptoms of an established disease).

Drugs are usually only subsidised if they have been shown to be safe and effective in randomised controlled trials (RCTs). Although data from RCTs provides good reasons for expecting that widely prescribed medicines may improve health outcomes, the improved health outcomes observed in such trials may not occur in routine clinical use. Controlled clinical trials may provide optimistic estimates of effectiveness under routine clinical care because the medicines are used to treat more seriously ill patients in the community than were studied in clinical trials [2,3]. Drugs may also not be prescribed, they may be prescribed