Clinical trials' limits or reunifying epidemiology

Emch et al., have provided evidence in a recent article published in Health & Place that the efficacy obtained in clinical trials is not homogeneous and depends on contextual variables. The authors used the data from a double-blind assay whose object was to evaluate the effectiveness of two anti-cholera vaccines for 62 285 people in Bangladesh; the results after three years' follow-up were 50 % for one vaccine and 52 % for the second one (1).

Data from demographic surveys and geographic information systems was then added to data regarding households for the same regions from which the participants came, plus the three-year follow-up results. This revealed that efficacy depended on the residents' average age, the percentage of vaccinated individuals, population density, the percentage of Hindus, the illiteracy rate, the percentage of country-dweller homes, the net migratory rate, the distance to a river and distance to a health-centre (1).

These findings again called into doubt the idea of a clinical trial as an ideal epidemiological design (2,3) and highlighted the importance of understanding the causal inference process from different viewpoints/levels (4). Finding that environmental variables are associated with a differential in efficacy is no more than a test of the existence of a psychological fallacy (i.e. inferential error associated with not including ecological variables when carrying out studies having individually measured variables, as often happens in epidemiological studies).

How many clinical trials and observational studies might suffer from this type of problem? This still unresolved question provokes many worries since there are no standard methods for making these evaluations. Its impact is not predictable, but highlights the importance of not very conventional epidemiological approaches (such as social epidemiology) regarding topics which (until a few years ago) seemed to be far removed from distal determinants, reducing individuals' health-disease to simple consequences regarding individual risk-factors.

Integrating clinical epidemiology with social epidemiology (usually considered impossible due to its very dissimilar approaches) is now required. Evidence such as that reviewed here shows the need for reunifying all epidemiological aspects in one, renewing its concepts and methods and thus being more able to understand the complexity of individuals and populations' health-disease.

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