

When evidence-based medicine (EBM) fuels confusion: multiple sclerosis after hepatitis B vaccine as a case in point

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Abstract

Background: Evidence-based medicine (EBM) may be used to discard valuable data under the pretext that it does *not* correspond to the “best” criteria of proof, even when no results complying with these “best” criteria are available. Since their infrequent occurrences make it impossible to assess most adverse effects using randomised clinical trials (RCTs), drug safety offers frequent examples of selective assessment of data based upon this poor understanding of the fundamental tenets of EBM. While the gold standard of pharmaco-epidemiology (case/control studies) is usually ranked amongst the lower levels of evidence and is unattainable in many instances, the majority of safety problems are simply assessed using subjective specifications (“acceptable”, “hard to interpret”, “not enough evidence”, “not causally demonstrated”). This vaccine-safety example illustrates that such specifications are almost always biased by prejudices and application inconsistencies.

Methodology: Taking it for granted that any review of evidence must be complete, it must also be emphasized that such reviews must be fair. This means that the significance of the results must be assessed according to: a) the reliability of their sources (sponsoring, methods used, transparency of results, vested interests) and b) the weight of evidence which, *in previous instances*, was deemed to be “sufficient” to justify regulatory measures or practical recommendations.

Principal Findings: Applied to the issue of demyelinating disorders after vaccination against hepatitis B, this conceptual framework makes it possible to show that: (1) the authors of most studies challenging the reality of a neurological risk have vested interests (which are *not* always of financial nature); (2) the criticism directed by national (French Agency, U.S. CDC) and international health agencies (WHO) towards investigations supporting a neurological risk after hepatitis B vaccination ranges from nonsense to documented forgery; and (3) even in the greatest journals, the process of publication has been tainted by the self-serving influence of the drug makers.

Conclusions/Significance: (1) The level of evidence demonstrating a significant risk of central demyelinating disorder after hepatitis B vaccine is far higher than that normally accepted to justify strong regulatory measures as exemplified by the historical precedents of thalidomide, aminorex, diethylstilbestrol, practolol, dexfenfluramine, tolcapone, and cerivastatin. (2) The dynamics of biased controversies over drug safety is based upon a worrying perversion of two key-points of scientific legitimacy: the publication process on the one hand, and the game of refutation on the other. However, the secular rules of Hippocratic prudence still offer valuable guidance to prescribers that, in practice, can be used to manage today’s money-driven controversies that focus on promoting the “benefits” of drugs while downplaying or ignoring the often all-to-real “risks” associated with these same drugs.

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