

Vaccination and auto-immunity : reassessing evidence

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Vaccination, infection & autoimmunity: Myth and reality.

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Although vaccine safety is a obviously major issue, even a rapid survey of medical journals is enough to observe that the word "myth" (or: "fiction") is a key word for any controversy on this topics. I am confident that this conference will be a landmark to go further than disqualifying any person concerned with vaccines hazards.

I am not here as an immunologist, but as a specialist in drug research and as a medical expert witness with an extensive experience in criminal inquiries on drug scandals and data distortion. Thus I would like to take vaccines to illustrate the effects of quite general vices such as negligence, poor methodology, selective assessment, disregarding or rejection of data – and to suggest that, as a consequence, the auto-immune potential of vaccination could be greatly underestimated.

Let's begin with negligence.

A number of mechanisms could account for autoimmune hazards of vaccines
(slide 2):

- ❖ an individual toxicity, if a vaccine antigen mimics host antigens;
- ❖ a statistical addition of each individual toxicity when several vaccines are given;
- ❖ a possible interaction, two vaccines given together producing one reaction that neither of them could have induced by itself.

Even theoretical, this multiple potential for auto-immune hazards should carry at its highest level the Hippocratic principle *first not to harm*. This should be all the more so since: 1) in developed countries, most vaccines are given to people in perfect health, 2) each of exposed subjects has a tiny risk of developing a severe form of infectious disease, 3) the probability of vaccine inefficiency is never zero (and sometimes fairly high).

Yet, strangely enough, caution is certainly not the rule with vaccination policy. In a country like France, and while epidemiological evidence is mainly lacking, up to 11 vaccines (including one heptavalent against *pneumococcus*) are recommended prior to the age of 1 year, some of them being even mandatory.

Data quality.

In addition, for a drug expert, the quality of the safety studies performed on vaccines is problematic:

- ❖ during development, their duration is abnormally short, whereas it is not easy to understand why products supposed to have beneficial effects in the long term could not also have detrimental effects within the same long term (slide 3);
- ❖ most of these trials are carried out in developing countries, where reliable systems of long term follow-up are not available;
- ❖ even in developed countries, post-marketing surveillance depends mainly on systems such as VAERS where almost every alert is discredited on the basis that spontaneous reporting does not permit reliable assessment.

So, each time a immunologist addresses the issue of the auto-immune hazards of vaccines, he begins with a dreadful list of potential mechanisms, prior to conclude that fortunately, no reliable evidence is available. To be sure, lack of evidence is an expected consequence of such a poor system of surveillance; but if reliable assessment of their hazards is out of reach, it remains to be re-assessed whether it is consistent with the Hippocratic principle to expose so many people in perfect health to such products.

Moreover and strangely enough, it seems that the reliability of vaccine surveillance is fluctuating, according to the trend of its results: very poor when suggesting a toxicity (slide 4), quite satisfactory when no hazard is detected¹ (slide 5).

This brings us to the issue of selective assessment.

In contrast with those of physics or chemistry, data of drug research is "soft": its significance requires an interpretation. But interpretation does not mean *selective* assessment of available evidence as illustrated by the preceding examples. On the contrary, our main requirement to claim a minimum of scientific validity should be a strict, I should say an obsessive regularity in giving the same weight to data of the same reliability. In fact, our concern is not to assess whether the causal relationship of severe toxicity is "certain": after all, this is not a real issue that the efficacy of vaccines is never certain either... In a job where no assessment can be more than statistical, our only concern should be to appreciate whether the level of evidence for such or such vaccine toxicity is the same, less or higher than the level of evidence normally considered as "sufficient" to take medical or regulatory measures.

Let's take one example (slide 6).

¹ Exactly the converse of what should be expected on purely methodological grounds: reporting represent an alert for the least, whereas non-reporting leaves completely open the issue of an undetected toxicity (as illustrated by a number of examples in the history of pharmacy).

Tolcapone (Tasmar®) is a drug that was licensed in some severe forms of Parkinson's disease. In Sept 1998, further to a safety alert, all international reports of liver injury were reviewed by the European agency (CPMP).

Apparently, in an indication where severely disabled patients may have been willing to accept a high level of risk in the hope of even a modest benefit, a total of ten serious cases worldwide, generally of questionable causality and of which only 3 were published, was sufficient to justify drug withdrawal: it would be interesting to compare this level of "significance" with that requested by governmental agencies to admit that there might be a problem with, for example, sudden infant death syndrome, for which thousands of cases have been reported after vaccination...

So, let us take as a unit of measure the level of evidence normally deemed as "sufficient" even for drugs aimed at curing severe diseases. **My point is to show that with such a natural unit of measure, evidence of toxicity for some vaccines is already far higher than usually claimed by experts or agencies.**

Consider, amongst others, the case of hepatitis B vaccine (HBV). It has been repeated that no significant problem was ever reported outside France and that the French problem was an artefact due to media coverage.

This is not true (slide 7).

Besides the overwhelming predominance of reports with HBV, it is clear from the slide that: 1) this predominance was obvious before any media coverage, which began in 1996; 2) it was blatant as compared to other vaccines of far larger exposure. I let you compare the activism of governmental agencies *versus* that induced by only 3 publications on tolcapone: at the end of 1994, when dozens of publications were already available, the French minister launched an universal campaign of hepatitis B vaccination. And 10 years later, universal vaccination in other countries is still an issue...

Now, let us consider the data of the French health system (slide 8), which shows a clear increase of neurological or auto-immune diseases after the mass campaign was launched. As differences in the absolute frequencies make it difficult to maintain a vivid representation, it may be instructive to make a change in scale and to focus on the evolution of MS as compared to the number of units sold (slide 9).

But returning to the original graph (slide 8) reveals another interesting trend, namely the time lag of about 1 year between the increase in MS and the subsequent increase in unspecified "neuro-muscular disorders" which is not prior to 1996. In fact the first increase had an important impact on media coverage and from this time, according to the stubborn denials of agencies as well as of experts, it became scientifically incorrect to make a formal diagnosis of MS in a person exposed to hepatitis B vaccine: this reluctance is clearly illustrated by the time lag and the dramatic increase after. An addition of both curves (slide 10) gives a clearer picture of the effects of the mass campaign on the prevalence of severe neuro-muscular diseases. It should be reminded that this dramatic evolution, which concerns thousands of citizens in perfect health prior to their exposure, is only that of the *severe* cases.

Data rejection or dissimulation.

The last point I would like to get onto is illustrated by two slides. This paper (slide 11), obviously excellent since I was the author, was accepted and you can see here the proof already corrected. Unfortunately, you will never read it (slide 12): even at my modest linguistic level, I wonder whether the final letter of rejection complies with the basic rules of international politeness...

This should be a matter of concern for every scientist that an unidentified "advice" is sufficient to justify the rejection of a paper at this step of the publication process. This should be all the more so since, apparently, the editor responsible for this unusual shift claims to be in charge of teaching scientific ethics...

To sum up and conclude (slide 13):

- ❖ other examples of poor methodology, selective assessment or dissimulation of data could easily be multiplied, suggesting that research and development on vaccines is still **at the zero-level of evidence-based medicine** (EBM);
- ❖ as assessed with units of measure normally in use with other drugs, some vaccines, such as HBV, appear to have **an unacceptable benefit/risk ratio**, esp. in countries of low-endemia;
- ❖ for obvious reasons of profit, the threats to the scientific and medical ethics of our job have reached a worrying level: it is **the personal responsibility of each** of us to resist – and to support those who are the most under pressure.