VIEWPOINT

Report and Viewpoint on the Vaccine Safety Conference, Tryall Club, Jamaica, January 3–7, 2011: Cautionary Tales and Implications for the Caribbean

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ABSTRACT

This paper represents information obtained from a recent conference on vaccination safety and policy: Vaccine Safety: Evaluating the Science Conference, Tryall Club, Jamaica, January 3–7, 2011 and the author's viewpoint on the same. The first section represents a synopsis of recorded information and the second the author's view of Caribbean concerns related to the recorded information.

Keywords: Science and policy, vaccine safety

Reporte y Puntos de Vista sobre la Conferencia de Seguridad de las Vacunas Celebrada en Tryall Club, Jamaica, Enero 3–7, 2011: Narrativas Aleccionadoras e Implicaciones para el Caribe

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RESUMEN

El presente trabajo representa información obtenida de una reciente conferencia sobre seguridad y políticas de vacunación: evaluación de la Conferencia Científica en Tryall Club, Jamaica, del 3 al 7 de enero de 2011, y puntod de vista del autor sobre la misma. La primera sección ofrece una sinopsis de la información obtenida, y la segunda ofrece el punto de vista del autor sobre problemas del Caribe en relación con la información obtenida.

Palabras claves: Ciencia y políticas, seguridad de las vacunas

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OVERVIEW

Leading scientists, lawyers, journal editors, medical practitioners and public advocates from Israel, the United States of America (USA), United Kingdom, France and Canada came together to discuss current vaccine science, policy and safety at the Vaccine Safety: Evaluating the Science conference held January 3–7, 2011 at Tyral Club in Jamaica.

The conference suggests that for better or worse, vaccines have had a major impact on modern medicine and perhaps we should now address them with the same scientific and concerned eye that we are casting over such matters as antibiotics. It is also this author's opinion that as with the issue of antibiotics, a look at historical trends and data is warranted for vaccination.

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Cautionary Tales

1. The aluminium adjuvant (AA) is in fact highly reactive and affects the brain. It crosses the blood brain barrier and placenta *en route* to its preferred sequestration zones, the central nervous system and bone, after a pre-sequestration granuloma-like period in the dermal zone (1).
2. Brains of fetuses and babies up to two years old are susceptible to neurotoxins such as aluminium adju-

vants because the blood brain barrier is not complete until one year of age (note that AAs can also take advantage of several extracellular and cellular transport mechanisms that enable them to pass even the mature blood brain barrier), and because adjuvants can interfere with the action of neurotransmitters such as glutamate which is critical for normal brain development. In addition, adjuvants can activate microglia in the brain and thus create a state of persistent brain inflammation (2).

3. Otherwise healthy premature children, despite current teaching at medical schools, may not be appropriate subjects for a regular vaccination schedule on a date to date basis with term babies (3).
4. Aluminium injected does not behave as aluminium ingested and is less easily excreted because the sizes of most antigen-Al complexes (24–69 kDa) are higher than the molecular weight cut-off of the glomerulus of the kidney (2).
5. In the USA, vaccines are regulated *via* policy law, not regular food and drug law under which all other pharmaceuticals must be tested and regulated (4).
6. In vaccine trials and tests, the "placebo" is not an inert substance but the adjuvant or a different vaccine (5).
7. Vaccine pharmacokinetics have never been studied and no vaccine has ever been studied for long term effects because such studies are not considered relevant nor are they required for vaccines (6).
8. No vaccine has ever been rigorously tested for long term adverse effects. Most vaccine safety trials focus on acute events and subject follow-up is limited to several days to several weeks. Neurological disorders and autoimmune conditions can take years to develop (7).
9. Since the 1950s, the natural cycle of many diseases has been admitted as a major and inadequately addressed confounder of studies attempting to verify vaccine efficacy (8).
10. Susceptible groups (*eg* prematurely born babies, children with underlying autoimmune or neurological diseases, and the elderly) have never been adequately addressed or modelled in vaccine studies but these groups are often precisely the most vulnerable to adverse reactions to vaccines. In addition, the elderly are known to be more sensitive to the oxidative stress of aluminium in the brain. Most testing in vaccine trials is carried out on the healthy young, not including pregnant women and babies (1).
11. The flu vaccine in some studies is now showing that mothers receiving the shot during pregnancy are spiking interleukins with a possible connection to increased schizoid behaviour and autism in children (9).
12. Since the dramatic increase in the USA in the number of vaccinations deemed to be required prior to school entry (from 10 in the late 70s to 32 in 2010, 18 of which contain AA), the prevalence of neurological disorders in children in developed countries has increased by 2000–3000% [from less than 5 per 10 000 to 110–157 per 10 000] (2).
13. The Food and Drug Administration (FDA) is now fast-tracking much research *eg* the planned four-year study of a human papillomavirus (HPV) vaccine reduced to six months. The websites of the National Adverse Effects and Reactions and the National Vaccine Information Center can be checked for reports on the vaccine. There is still no proven long-term benefit from HPV vaccination, and vaccine safety concerns are significant, yet the companies are now recommending that boys be vaccinated as well (10).
14. In the USA, vaccine compounding is not as rigorously standardized as other drugs; one vaccine batch may be significantly biochemically different from the next batch and both batches are assumed under the same initial test and drug information insert. Quality control re-testing is not required nor is it state or federally legislated and is also admittedly difficult in Europe (11).
15. Possibly less noxious adjuvants than aluminium are not systematically pursued since aluminium remains a very inexpensive option (1).
16. The practice of increasing the amount of adjuvant in polyvalent vaccines has not been adequately addressed in light of evidence that this practice is likely unnecessary.

2010 Recommended USA Vaccines Containing Aluminum

Combo Comvax Merck 2001 Hib, Hepatitis B amorphous aluminum hydrox	225 mcg
DTaP Infanrix GlaxoSmithKline 2010 DTaP aluminum hydrox	625 mcg
Combo Pediarix GlaxoSmithKline 2008 DTaP, Hib, IPV aluminum hydrox, alum	850 mcg
DTaP Tripedia Sanofi Pasteur 2005 DTaP aluminum potassium sulfate	170 mcg
Combo Kinrix GlaxoSmithKline 2010 DTaP, IPV aluminum hydroxide	600 mcg
Combo Pentacel Sanofi Pasteur 2009 DTaP, IPV, Hib aluminum phosphate	333 mcg
Combo Twinrix GlaxoSmithKline Hepatitis A, Hepatitis B aluminum hydroxide, alum	450 mcg

(V Debold, FDA Vaccine and Related Biological Products Advisory Committee – personal communication; unreferenced public domain product inserts).

17. Research findings that delaying DTP/DTaP, with reference to the USA schedule, results in significant

decrease in childhood asthma have not been addressed by policy/schedule makers (12).

18. The fact that DTP is now considered unsafe for and is not used on the USA population has not prevented international marketing although childhood seizures are proven more frequent with it than if the more expensive acellular DTaP is used (13).
19. Despite the widely declaimed science behind the flu vaccine, the USA recommendation that everyone from aged six months till death receive a flu shot every year is still being recommended by the US Centres for Disease Control and Prevention (14).
20. Most states of the USA now obtain parents' consent for vaccinations and for those who now choose to opt out of vaccination programmes and are refused the service of the chosen paediatrician, depending on the circumstances, there may be legal redress (15).
21. The FDA admits it cannot keep up with the rate of formulation of new compounds slated for use as medicines either *via* testing or monitoring research and development and manufacturing sites *eg* dangerously contaminated anthrax vaccine facilities (4).
22. In reviewing tests and trials, the FDA can point out and reject material based on poor science and unethical practices but has no legal mandate to deal with later constructs used to re-submit material that is basically unchanged, it can only 'blackball'. There is also a 'revolving door' and conflicts of interest between staff of the FDA and pharmaceutical companies (16).
23. By 2013, the vaccine industry will be worth US$35 billion. In the 1980s, the USA population was given 23 doses of seven vaccines compared to the last decade in which the full schedule carries 69 doses of 16 vaccines from birth to 18 years. There are now approximately 200 additional vaccines in development (17).
24. The US government has now set up a billion dollar fund for payouts in cases of adverse reactions to medicaments and US$ 2 billion have already been paid out for vaccine injury (17).
25. The US drug lobby to Congress carries many times the weight and finance of the oil and military lobbies (18).

Implications for the Caribbean

1. We do well to maintain the vaccine load of our national schedules to an effective minimum.
2. Jamaica does well to keep the MMR schedule to two years old and four years old (booster) or the one dose at approximately 11 years of age.
3. In order to reduce toxin load and effects, it seems best to spread the schedule as widely as possible and administer vaccines as late as possible with due respect for any efficacy. Later administration of DTP/DTaP and lower asthma rates are a case in point.
4. The University of the West Indies might consider reviewing the teaching that healthy premature babies can be vaccinated on the same schedule as term babies. Premature babies may be especially at risk particularly during their known 'catch-up' phenomenon.
5. Cost may no longer be an appropriate argument for maintaining DTP in Jamaica's public sector.
6. Jamaica may be fortunate to have some practitioners who were immediately skeptical of 'vaccines' that covered only 2–4 of many HPV strains and a majority who are unlikely to be injecting males with them.
7. Jamaica may want to review BCG policy as we have heard at both the conference of the Caribbean College of Family Practitioners and the Vaccine Safety Conference that the immunity conferred wears off and is never boosted. Furthermore, many countries including the USA have never had this vaccine as part of their schedule and we may be putting newborns, especially premature babies, at risk.
8. Our governments may want to enforce stricter policy/further monitoring of vaccine sourcing and purchase policy as there are many issues about vaccines that remain unaddressed/ignored.
9. The Caribbean needs to enter, more fully, the effort to improve vaccine science and use.

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