Animal studies are mandatory to investigate the poorly understood fate and effects of aluminum adjuvants administered to billions of humans and animals worldwide

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Animal studies are mandatory to investigate the poorly understood fate and effects of aluminum adjuvants administered to billions of humans and animals worldwide.

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In a recent paper Ameratunga*;* Languth, and Hawkes. (1) raised "scientific and ethical concerns" pertaining to animal models of autoimmunity/autoinflammatory syndrome induced by adjuvants (ASIA) (1). The authors have previously questioned the existence of ASIA using arguments that were dismissed (2). Now, they try to convince the scientific community to forbid animal studies evaluating safety of aluminum adjuvants.

This is a shocking recommendation (i) because there has been only one reference experimental study on aluminum adjuvants toxico-kinetics (3) and it suffers major conceptual and methodological limitations (4); (ii) because aluminum adjuvants safety has never been epidemiologically evaluated on the long term, the Centers for Disease Control and Prevention stating "there have been no population-based studies specifically designed to evaluate associations between clinically meaningful outcomes and non-antigen vaccine ingredients, other than thimerosal" (5); and (iii) because these poorly understood compounds used in 60 per cent of current vaccines are intended to be administered to billions of individuals over the next years in the setting of a massive expansion of vaccine prevention strategies announced worldwide (6).

Ameratunga *et al* (1) reviewed a list of animal studies said to have been conducted to demonstrate ASIA (7-17). This selection is inadequate at least for the first study (7) which included no clinical evaluation because it was designed to explore and understand systemic translocation of aluminum and other biopersitent particles injected in muscle. In contrast, Ameratunga *et al* omitted a number of mouse studies documenting neurologic effects of aluminum adjuvant administration (18-20).

Ameratunga et al (1) listed several areas of concern in the evaluated studies.

1-Inappropriate dose and/or delivery of adjuvant used. Three studies, including the irrelevant one mentioned above, were criticized because they used doses considered "far in excess" of those used in humans (7, 9,10). Another one, that appropriately used a conversion factor to adjust the dose, was pointed out because it administered Gardasil® on 3 consecutive days instead of an over 6 months period used in humans (14). Extrapolating mouse to human dosage is a challenging issue since a firm scientific basis for allometric conversion is still lacking. To approximate human to mouse dosage for aluminum studies, a conversion factor of x30 is used by the Agency for Toxic Substances and Disease