

# New Quality-Control Investigations on Vaccines: Micro- and Nanocontamination

**Research Article**

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**Abstract**

Vaccines are being under investigation for the possible side effects they can cause. In order to supply new information, an electron-microscopy investigation method was applied to the study of vaccines, aimed at verifying the presence of solid contaminants by means of an Environmental Scanning Electron Microscope equipped with an X-ray microprobe. The results of this new investigation show the presence of micro- and nanosized particulate matter composed of inorganic elements in vaccines' samples which is not declared among the components and whose unduly presence is, for the time being, inexplicable. A considerable part of those particulate contaminants have already been verified in other matrices and reported in literature as non biodegradable and non biocompatible. The evidence collected is suggestive of some hypotheses correlated to diseases that are mentioned and briefly discussed.

**Keywords:** Vaccine; Disease; Contamination; Protein corona; Biocompatibility; Toxicity; Nanoparticle; Immunogenicity; Foreign body; Environment; Industrial process; Quality control

**Introduction**

Vaccines are one of the most notable inventions meant to protect people from infectious diseases. The practice of variolation is century-old and is mentioned in Chinese and Indian documents dated around 1000 A.D. Over time, variolation has been replaced by vaccination, vaccines have been enhanced as to technology, and the vaccination practice is now standardized worldwide.

Side effects have always been reported but in the latest years it seems that they have increased in number and seriousness, particularly in children as the American Academy of pediatrics reports [1,2]. For instance, the diphtheria-tetanus-pertussis (DTaP) vaccine was linked to cases of sudden infant death syndrome (SIDS) [3]; measles-mumps-rubella vaccine with autism [4,5]; multiple immunizations with immune disorders [6]; hepatitis B vaccines with multiple sclerosis, etc.

The notice of Tripedia DTaP by Sanofi Pasteur reports "Adverse events reported during post-approval use of Tripedia vaccine include idiopathic thrombocytopenic purpura, SIDS, anaphylactic reaction, cellulitis, autism, convulsion/grand mal convulsion, encephalopathy, hypotonia, neuropathy, somnolence and apnea". The epidemiological studies carried out did not show a clear evidence of those associations, even if in 2011 the National Academy of Medicine (formerly, IOM) admitted: "Vaccines are not free from side effects, or adverse effects"[7].

Specific researches on components of the vaccines like adjuvants (in most instances, Aluminum salts) are already indicated as possible responsible of neurological symptoms [8-10] and in some cases, in-vivo tests and epidemiological studies demonstrated a possible correlation with neurological

diseases [10,11]. Neurological damages induced in patients under hemodialysis treated with water containing Aluminum are reported in literature [12].

Recently, with the worldwide-adopted vaccines against Human Papillomavirus (HPV), the debate was reawaken due to some adverse effects reported by some young subjects.

Specific studies communicated the existence of symptoms related to never-described-before syndromes developed after the vaccine was administered. For instance, Complex Regional Pain Syndrome (CRPS), Postural Orthostatic Tachycardia Syndrome (POTS), and Chronic Fatigue Syndrome (CFS) [13]. The side-effects that can arise within a relatively short time can be local or systemic.

Pain at the site of injection, swelling and uncontrollable movement of the hands (though this last symptom can also be considered systemic) are described. Among the systemic effects, fever, headache, irritability, epileptic seizures, temporary speech loss, lower limbs dysaesthesia and paresis, hot flashes, sleep disorders, hypersensitivity reactions, muscle pain, recurrent syncope, constant hunger, significant gait impairment, incapacity to maintain the orthostatic posture are reported [14].

It is a matter of fact that every day millions of vaccine doses are administered and nothing notable happens, but it is also irrefutable that, regardless of the amount of side effects that are not recorded and the percentage of which remains in fact unknown, in a limited number cases something wrong occurs. No satisfactory explanation or, in many cases, no explanation at all has been given and it seems that those adverse effects happen on a random and stochastic basis.