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Commentary on Abnormal Menses Following COVID-19 Vaccines: A Toxicologic Consideration

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Commentary

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Research into tens of thousands of reports of abnormal uterine bleeding following COVID-19 nanoparticle m-RNA and DNA vaccines has identified a safety signal but not identified its cause. Suppositions have ranged from pandemic stress to an immune consequence impacting the hypothalamic-pituitary axis. No such hypotheses can explain the post-menopausal bleeding also occurring after COVID-19 vaccination. Both sequelae together suggest an oestrogenic effect. Preclinical studies of novel vaccines with novel excipients are critical resources to inform investigation of unexpected, widespread new adverse events.

They bear close scrutiny of the organs concerned. Since the newly injected nanoparticles contain components which have previously demonstrated ovarian and uterine vascular toxicity in rats, this focus is crucial. The sharply rising concentration of nanoparticles measured in the rat ovary at 48 hours post injection requires review of ovary microscopy. Unfortunately, no histology report is presented in COVID-19 vaccines' reproductive toxicity studies. Freedom of Information Request (no. 2565) for the ovary histology reports was refused by the Australian Regulator, the Therapeutic Goods Administration (TGA). Reasons given were histology reports were 'too voluminous' and the pharmaceutical companies had taken active steps to ensure the information contained within the documents is not disclosed to the general public. Unavailable ovary microscopy from these new vaccines directs attention to previous ovary histology following injected components of nanoparticles. Demonstrated the rat ovarian toxicity of injected polysorbate 80 at all doses tested over a tenfold range. No threshold dose is identified. Cystic changes and reduced ovary weights were observed and altered uterine arterioles described.

The effects of this nanoparticle constituent, polysorbate 80 (polyoxyethylene sorbitan monooleate), were the same as those of injected diethylstilboestrol in a positive control arm of the same study. Polysorbate 80 is present in the DNA COVID-19 vaccine (*Astra zeneca*). The closely related polyethylene glycol, which is polysorbate 80 minus the oleate, is present in mRNA vaccine nanoparticles. The effect of this oestrogenic-behaving, ovary-toxic chemical concentrating in ovaries is unknown. Subsequent microscopy of the ovary and uterus is unknown. The final concentration reached in ovaries following COVID-19 vaccination is unknown. The duration of high ovarian concentration is unknown.

Bayesian Confidence Propagation Neural Network and Multi-item Gamma Poisson Shrinker statistical valuation of reported Premature Ovarian Insufficiency (POI) and related events following HPV vaccination containing polysorbate 80 found stable and strong association with steady upward trend and 95% confidence interval. The number of signals were proportional to the total administered dose of polysorbate 80 therein. Four signals were observed for the quadrivalent vaccine injecting 3 doses polysorbate 80, one signal for the nonavalent vaccine injecting 2 doses polysorbate 80, and no signals for the bivalent HPV vaccine containing no polysorbate 80. Published POI and Human Papillomavirus Vaccine (HPV) case series contained biopsied teen ovary with peri-menopausal histology. Preclinical rat ovarian histology following quadrivalent HPV vaccine was also unavailable on Freedom of Information (FOI).

The histological resemblance of polysorbate 80 injected rat ovary and uterus to stilboestrol-injected ovary and uterus is of concern. Newborn Vitamin K injections with 10 mg polysorbate 80 also now raise concerns. New abnormal menses and post-menopausal bleeding following COVID-19 vaccines are consistent with an oestrogenic insult and require preclinical gonad histology review.