

Public hearing session on HPV safety.

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Helen Petousis-Harris. PhD
Director of Immunisation Research and Vaccinology
Immunisation Advisory Centre
The University of Auckland
Convenor, NZ Expert Advisory Group on Vaccine Safety

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Overview

- Dr Lee claims to have tested vials of Gardasil vaccine for the presence of vaccine derived HPV L1 gene DNA sequences and to have detected it.
- Dr Lee claims to have tested post mortem samples from a single person for the presence of HPV DNA. He claims they are positive for HPV DNA bound to the vaccine adjuvant
- Dr Lee supports that the HPV vaccine may have caused death due to a complex of vaccine constituents
- The Immunisation Advisory Centre at The University of Auckland **strongly question both his methods, interpretation and conclusions**

Testing of Gardasil samples - concerns

- The vaccine is be expected to contain traces of vaccine type HPV L1 gene DNA – consistent with manufacturing process.
- However:
 1. The tests used have never been validated – methods are not transparent
 2. DNA contamination can be tested by most laboratories – not ‘cutting edge’
 3. PCR extremely sensitive, nested PCR much more so. High risk of amplifying other DNA sequences
 4. Use of degenerate primers increases sensitivity but also increases risk of amplifying other DNA sequences (decreases specificity) wildcard. Given that the genetic code of the vaccine L1 gene is known this is a strange thing to do.

Testing of post mortem samples - concerns

- **There are no controls used (unvaccinated). This is a vital part of the scientific process**
- Inclusion of degenerate primers again
 - Over sensitive, increased risk of amplifying other irrelevant DNA (junk)
+ reduced specificity for vaccine type HPV L1 gene
- Why did Lee not include primers for the plasmid and promoter sequences which would provide more robust evidence for the presence of vaccine HPV DNA.
- Has not proven that the DNA is of vaccine origin (no plasmid, no yeast)
- The amount of residual DNA in the vaccine is miniscule
 - How can such a small amount of DNA detected dispersed through out body tissues?
- It is not biologically possible for the HPV DNA to integrate into the host genome (does not have the necessary sequences)

Extraordinary hypotheses

- Dr Lee supports hypotheses whereby HPV DNA has bound irreversibly to aluminium adjuvant (theory), been taken up by macrophage (theory) and caused an inflammatory response (theory) leading to death (theory).
- He contends that these complexes can be detected in post mortem tissue samples and that they were carried there by the macrophage
- He has little if any evidence for this hypothesis, which, if it were true, needs to be tested using rigorous scientific methods.
 1. Convincing proof of binding of vaccine DNA to the adjuvant
 2. Convincing proof of carriage by macrophage
 3. Convincing proof of deposition in tissues (especially brain)
 4. Convincing proof of inflammatory immune cascade including TNF
- No one else has replicated the findings
- The findings are not supported by existing extensive research on the immunology or epidemiology of HPV vaccine safety.

Immune response following vaccination with protein-based vaccine

- After injection immune cells such as macrophage take up vaccine (adjuvant and antigen) **at injection site**
- The cells become activated and migrate via the lymph to **local lymph node** (not spleen)
- Half life of a macrophage ~6 days
- These facts do not support the potential for presence of adjuvant/HPV DNA in either blood or spleen
- In addition, the immune activation on uptake of HPV vaccine does not include an increase in inflammatory factors (incl TNF) even in vaccinees with large injection site reactions at time of local inflammation.

The NZ case

- This type of death is often caused by underlying cardiac abnormalities.
 - Testing was refused by the family
- There was no evidence of inflammation in the autopsy results for the NZ case
 - including either the brain or the heart

Key question and answer

- Does Gardasil trigger death?
 - **No**
 - Large epidemiological studies and routine surveillance systems conducted globally directly investigating this find no difference between vaccinated and unvaccinated population (refs provided)
 - If it did then we would see a higher rate of cases in vaccinated people, and this has not been observed.
 - Data for over 100 million doses to date

Extraordinary claims require extraordinary evidence

Carl Sagan 1934-1996

Selected references on safety of Quadrivalent Human Papillomavirus Vaccine

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