Thursday October 10, 2019
MVI Boot Camp – Class discussion: Not Safe – Not Effective

Additional example of lack of safety:

1. Unsafe Manufacturing: Vaccine contaminants and cancer

Feb 2, 2018 – FDA: "Investigating Viruses in Cells Used to Make Vaccines; and Evaluating the Potential Threat Posed by Transmission of Viruses to Humans" (full text)

https://www.fda.gov/vaccines-blood-biologics/biologics-research-projects/investigating-viruses-cells-used-make-vaccines-and-evaluating-potential-threat-posed-transmission

"**The use of tumorigenic and tumor-derived cells is a major safety concern due to the potential presence of viruses such as retroviruses and oncogenic DNA viruses that could be associated with tumorigencity**. Therefore, detection of persistent, latent DNA viruses, and endogenous retroviruses in vaccine cell substrates is important for vaccine safety, **particularly in the development of live viral vaccines, where there are no or minimal virus inactivation and removal steps during vaccine manufacturing**."

2. Unsafe adjuvants: Aluminum toxicity
VaccineU – toxic ingredients 7 - module course

January 15, 2017 – Toxicology. Volume 375, 15 January 2017, Pages 48-57
"Non-linear dose-response of aluminum hydroxide adjuvant particles: Selective low dose neurotoxicity"
https://www.sciencedirect.com/science/article/pii/S0300483X16303043

"Aluminum oxyhydroxide (Alhydrogel®), the main adjuvant licensed for human and animal vaccines, consists of primary nanoparticles that spontaneously agglomerate.

Concerns about its safety emerged following recognition of its **unexpectedly long-lasting bio-persistence within immune cells in some individuals, with reports of chronic fatigue syndrome, cognitive dysfunction, myalgia, dysautonomia and autoimmune/inflammatory features temporally linked to multiple Al-containing vaccine administrations.**

Mouse experiments have documented slow transportation by monocytes cells from the injected muscle to lymphoid organs and eventually the brain. … We conclude that Alhydrogel injected at low dose in mouse muscle may selectively induce long-term Al **cerebral accumulation and neurotoxic effects."**

3. Unsafe Vaccine: Dtap

February 27, 2013: Vaccine – Pages 1447-1452

"VAERS evaluation of Tdap – Adacel and Boostrix – both approved in 2005. VAERS analysis: A total of 2090 reports (7% were serious; 55% listed Tdap alone) involving Tdap vaccines were submitted to VAERS May 2005–June 2007."
https://www.sciencedirect.com/science/article/pii/S0264410X12015708

AEs included:

- Myopericarditis,
- Demyelinating diseases of the central nervous system,
    - A 15 year old girl developed **bilateral optic neuritis** 18days after Tdap and HAV. Fundoscopic exam revealed bilateral disk edema with blurring of disk margins.
    - A 16 year old girl developed left **optic neuritis** 59 days after Tdap and HPV. Magnetic resonance imaging (MRI) of the brain showed some slight enlargement of the left optic nerve.
    - An 11 year old girl became **paraplegic** at the T10-T11 level 30 days after Tdap. During hospitalization she was diagnosed with idiopathic transverse myelitis.
    - A 16 year old boy developed headache, photophobia, progressive weakness, decreased sensation, and urinary retention 15 days after Tdap and MCV4, followed by **loss of consciousness** and lethargy.
- Guillain–Barré Syndrome,
- Syncope,
- Encephalopathy/encephalitis
- Seizure,
- Bell's palsy,
- Anaphylaxis, and
- Thrombocytopenia.

Conclusion?

"Because adolescents and adults were not routinely vaccinated against pertussis in the past, this surveillance summary provides important – ***and reassuring*** – information about the use of Tdap in these age groups.

Further example of lack of efficacy:

When is it effective? No endpoint…? Antibody ≠ PROTECTION.

FULL TEXT LINK: http://sci-hub.tw/10.1016/j.vaccine.2016.03.085

June 3, 2016 - Universal influenza vaccines: Shifting to better vaccines (FROM full text)

"For such UNIVERSAL immunizations to become a reality, a vaccine that induces broadly cross-protective and durable immunity would need to be developed. Licensed influenza vaccines and their limitations In general, influenza vaccines have an excellent safety record, **but their efficacy varies significantly in various age groups and against different strains**. **Rare exceptions to the safety profile have emerged in association to the use of specific adjuvants.**

Strain mismatch and pandemics are frequent causes for vaccine failure and, over the last few years, several mismatches and one pandemic have occurred."...

"**No consensus has been achieved on what primary clinical endpoint universal influenza vaccines should achieve to be considered successful.**

- **Whether or not they should completely prevent influenza infection or**
- **Reduce the severity of disease is still being debated.**

Despite the importance of **animal models** in the development of broadly reactive vaccines, carefully controlled human studies are essential. Field efficacy trials are costly and subject to a variety of confounding factors and biases. Human challenge studies allow for detailed measurements of the kinetics and magnitudes of a **range of immune responses**, which can help with the development of correlates of protection.

Wild-type influenza viruses have been used for challenge studies in adults while attenuated vaccine strains of influenza have been used to perform challenge studies in children.

In many instances, however, the results of these studies have been **difficult to interpret.** In some instances, volunteers have been protected from influenza illness **despite the lack of a measurable immune response to vaccination**, *although a possible explanation could be that disease was subclinical or not all non-vaccinated volunteers were reliably infected.*