murdoch children's research institute

SAEFVIC

'Shingles' temporally associated with Zostavax® vaccine

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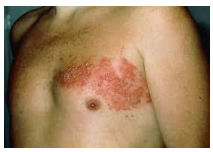
Nigel Crawford

'Shingles' background

- Zostavax®
- 'Shingles' cases in the clinical trials [product information]-
  - "temporal association"
  - 0-42 day window
  - **17** for Zostavax, **36** for placebo
  - p = 0.009; nil OKA strain
- Has been a 'shingles' vaccine strain case report- in an immunocompetent individual 9-months after immunisation[1]



1. Tseng et al: *Clinical Infectious Diseases*, Volume 58, 2014, Pages 1125-1128

'Shingles' vaccine on the NIP

- The National Zostavax® Immunisation program officially commenced on the 1st November 2016.
- In late November, SAEFVIC (Victorian vaccine safety service) nurses noted a number of reports of clinical 'shingles' cases, temporally associated with the vaccine……..
- Definition 'Shingles'- CDNA confirmed case[1]
- Laboratory definitive evidence
  - Isolation of varicella-zoster virus from a skin or lesion swab (culture or PCR)
- **and** Clinical evidence
  - A vesicular skin rash with a dermatomal distribution that may be associated with pain in skin areas supplied by sensory nerves of the dorsal root ganglia

1. http://www.health.gov.au/internet/main/publishing.nsf/Content/cdna-casedef-shingles.htm

Zostavax™ coverage Victoria

- In the 1st 12-months of the program, Victoria Zostavax distributed doses = **242,625**
- The Victorian target population (70-79 years) according to the ABS census = **435,143**
- Estimated coverage **~56 %**

Acknowledge: Rosie Morey DHHS Victoria

SAEFVIC 'Shingles' report

Methods

- SAEFVIC 'shingles' reports in 1st 12 months Zostavax® program
  - Nov 2016- October 2017

Results

- 46 'shingles' cases reported
  - SAEFVIC 31 (67%); DHHS 15 (33%)
- Lab testing was undertaken in 50%
  - all were zoster virus NAT positive
  - one case confirmed as wild-type strain, nil OKA strain to date.
- Detailed clinical (n=31; 67%)
- 52% male
- Median age 75 years (range 71-86 yrs)
- Time of 1st symptoms post vaccine
  - median 6 days (range 0- 120 days)
- 74% received an anti-viral medication
- Three cases had a past history of cancer, nil on active therapy

- Conclusion:
- Most cases being < 6-days post vaccine- makes….coincidental 'wild type' reactivation the likely diagnosis…..

Limitations

- Only have vaccine distributed dose data
  - Australian Immunisation Register (AIR) introduced 30th September 2016
- Relied on clinical diagnosis
  - Real-life study; not a clinical trial
- Limited samples sent to accredited laboratory
  - Developed a protocol for testing
- Limited duration of the study - only 12-months
  - Did capture the 'catch-up' part of the 'Zostavax program'- well promoted

Implications

- New flow chart for VZV testing (wild type *versus* vaccine strain)
  - http://www.mvec.vic.edu.au/immunisation-references/zoster-vaccine-zostavax-faqs/
- Important part of the TGA national review re- vaccine safety & 'Zostavax' program

- Shingrix®
  - Inactivated zoster vaccine- not expected to have a temporal association with a 'shingles' like rash, c/w live attenuated vaccine

Acknowledgements

Co-authors: Alafaci A, Harris A, Lewis G, Buttery J, Morey R, Strachan J
VIDRL & SAEFVIC vaccine safety staff