Quadrivalent Human Papillomavirus Vaccine (HPV4): Summary of Post-Licensure Safety Monitoring

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Summary of findings: HPV post-licensure safety monitoring

- Presentations summarize experience of 20 million doses under passive surveillance and > 375,000 doses under active surveillance
- Reporting to VAERS has been robust since licensure
  - Elevated reporting expected due to publicity and general increase in adverse event reporting
  - 94% of reports non-serious
  - Most commonly reported events consistent with pre-licensure trial data
- Controlled data from VSD does not support causal association between HPV vaccine and Guillain-Barrė syndrome, venous thromboembolism, or other target conditions
  - Findings subject to power limitations for GBS and anaphylaxis

Summary of findings

- VSD findings show no evidence of elevated risk for syncope following HPV vaccine, but do support increase in post-vaccination syncope across adolescent vaccines first identified through VAERS

- Published Australian case series of demyelinating diseases and anaphylaxis following HPV vaccine
  - Available data from U.S. surveillance does not support causal relationship with GBS or TM
  - No confirmed reports of anaphylaxis within VSD
  - Surveillance and study of outcomes ongoing in VAERS, CISA, and VSD