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# HPV Year 1 BC:

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Adverse events following immunization  
in passive surveillance

**Monika Naus, MD, FRCPC**  
**Director, Immunization Programs**  
**BC Centre for Disease Control**  
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## Syncope After Vaccination --- United States, January 2005--July 2007

# Anaphylaxis following quadrivalent human papillomavirus vaccination

Julia M.L. Brotherton MD MPH, Mike S. Gold MD, Andrew S. Kemp MD PhD,  
Peter B. McIntyre MD PhD, Margaret A. Burgess MD, Sue Campbell-Lloyd RN,  
on behalf of the New South Wales Health HPV Adverse Events Panel

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European Medicines Agency  
*Press office*

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### **PRESS RELEASE**

#### **European Medicines Agency recommends continued vaccination with Gardasil**

The European Medicines Agency (EMA) has reviewed the available information on the two cases of status epilepticus with myoclonus (repeated and prolonged seizures and loss of consciousness) reported in two girls vaccinated with the cervical cancer vaccine Gardasil in Spain.

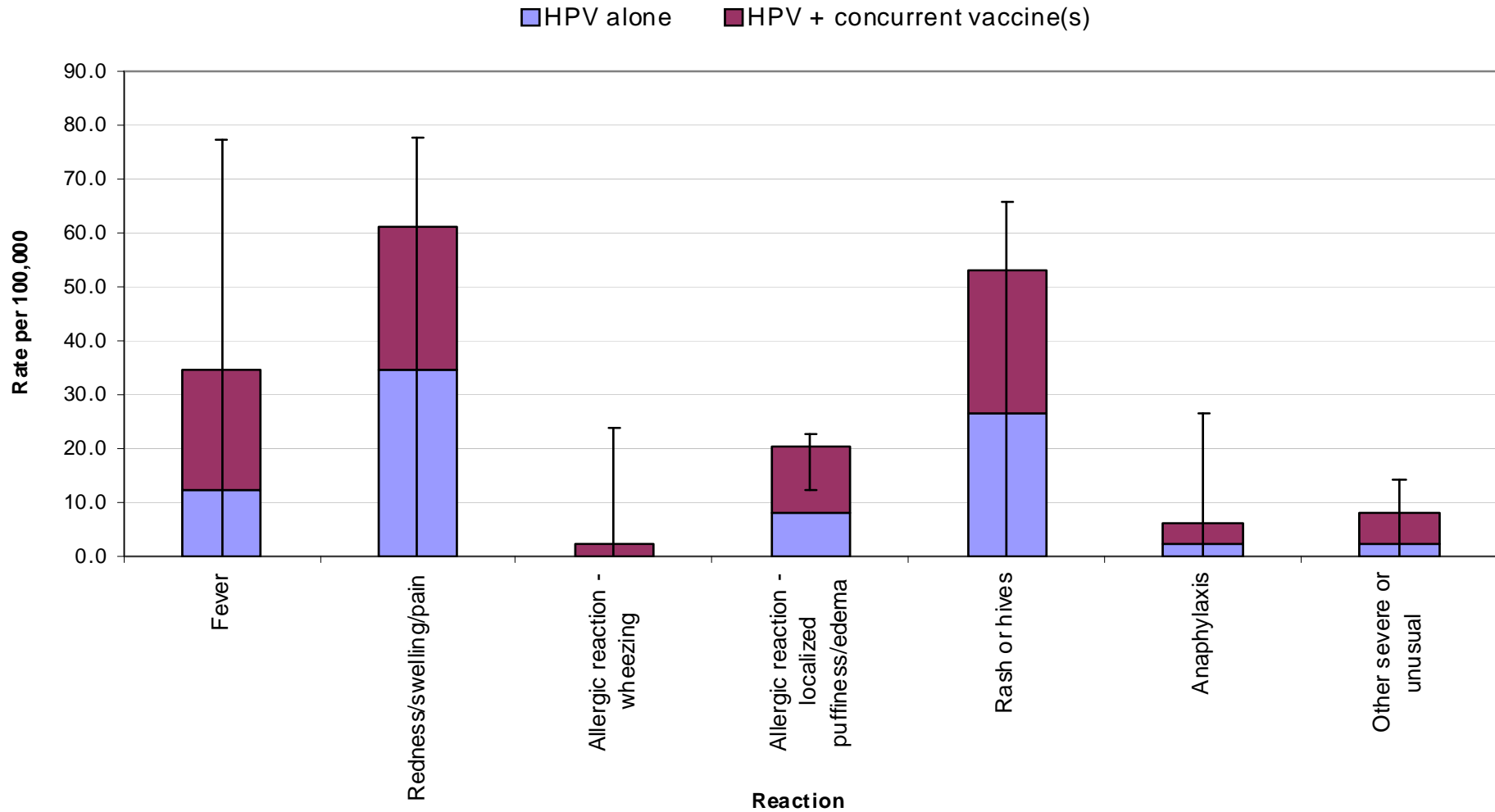
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## HPV vaccine: reported events from first season of grade 6 and 9 immunizations in BC

- Cohort: ~23,000 girls in each of grades 6 and 9, receipt of ~90,000 doses between September 1/08 and June 30/09
- AEFI: 114 events reported from 91 recipients (appointment dates from September 2008 to April 2009 inclusive)
  - 16 “serious” events among 15 individuals reported (selected if reported as: anaphylaxis, convulsion/seizure, encephalopathy, meningitis and/or encephalitis, anaesthesia/paresthesia , paralysis, Guillain-Barré syndrome, other severe or unusual events
  - 3 hospitalized (2 syncope with tonic/clonic episode, 1 ‘other severe/ unusual’ without details)

# Adverse events following HPV immunization reported through passive system, BC

Symptom reporting rate for HPV immunization, Sept 2008 to April 2009 N=91



# HPV vaccine: 16 reported “serious” events to April 09: grade 6 and 9 immunizations in BC

Reaction type	N
Anaphylaxis	3
Anaesth/ Paresth 24 hr+	3
Syncope with tonic/ clonic activity	6
Other severe or unusual event	4

## 4 “other severe or unusual”:

2 with no comments

1 blurred vision

1 autoimmune hemolytic anemia

## Recoded from “other severe or unusual”:

6 fever+

1 urinary incontinence

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## Canadian Adverse Events Following Immunization Surveillance System – to December 2008

- 310 reports to date since onset of marketing
  - 32 per 100,000 (cf. USA ~50)
  - 2 per 100,000 for serious (N=19)
    - 7 Paresthesias
    - 2 Appendicitis
    - 1 each of:
      - Anaphylaxis
      - Breast abscess
      - New onset DM
      - Febrile illness with persistent microhematuria
      - Conversion psychosis
      - ADEM presentation in 2006, now MS
  - 11 hospitalizations but only 1 definitely related (syncopal fall with head injury)
  - 1 GBS with 20 week interval post immunization