

CIC 2014 CCI

December 2-4
2 - 4 décembre
OTTAWA

Canadian Immunization Conference
Conférence canadienne sur l'immunisation

Canadian National Vaccine Safety
(CANVAS) Network: Active Safety
Surveillance for Influenza Vaccine,
2013 and 2014

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Disclosure Statement

Disclosure of Relationship	Company/Organization
I am a member of an Advisory Board or equivalent with a commercial organization.	Medicago
I am a member of a Speaker Bureau.	N/A
I have received payment from a commercial organization (including gifts or other consideration or 'in kind' compensation).	N/A
I hold a patent for a product referred to in the CME/CPD program or that is marketing by a commercial organization	N/A
I hold a patent for a product referred to in the CME/CPD program or that is marketing by a commercial organization	N/A
I hold investments in a pharmaceutical organization, medical devices company or communications firms.	N/A
I am currently participating in or have participated in a clinical trial within the past two years.	N/A

CANVAS: Canadian National Vaccine Safety network

- Provides early safety data on the seasonal influenza vaccine in various age groups
- Surveillance in 5 provinces at 8 (2013) and 7 main sites (2014)
 - BC, AB, QC, ON and NS
 - 4 public health sub sites in Ontario and BC
 - Pharmacies in BC, ON and NS (2014)
- Online survey emailed 8-days after immunization
- Telephone follow up for severe events

CANVAS: Online Survey

- Online survey captures health events in first 7 days after vaccination
 - New events
 - Worsening of existing health conditions
- Reminder email sent to non-responders 3 days
- 2013 non-responders contacted by phone

CANVAS: Severe Event Definition

- Severe health events:
 - Cause work/school/daycare absenteeism
 - Prevent daily activities
 - Cause a health care visit

Adverse events after the vaccination this year

5. In the **first week (7days)** after your flu shot did you develop a new health problem or did an existing health problem get worse? *

- Yes
- No

5.1.1. Was this health problem severe enough to miss work/school or prevent/stop normal activities? *

- Yes
- No

5.1.2. Was this health problem severe enough to see a health care provider? *

- Yes
- No

CANVAS: Control Group

- Background rates/control survey
 - Participants from previous year emailed health event survey 2-weeks prior to start of influenza vaccination campaign
 - Online survey on health events with onset in past 7 days
 - Severe health events followed up by telephone
 - 2013 non-responders contacted by phone

Health Events

3. In the last week (7 days) did you develop a new health problem or did an existing health problem get worse? *

- Yes
- No

3.1.1. Was this health problem severe enough to miss work/school or prevent/stop normal activities? *

- Yes
- No

3.1.2 Was this health problem severe enough to see a health care provider? *

- Yes
- No

2013 Final Results

- Enrolled 21,669 vaccinees:
 - 58% online response rate
 - 61% including non-responder follow up (N=13,127)
 - 1459 (11%) parents of children 6 months-16 years
 - 11,668 adults
- Enrolled 13,622 controls:
 - 47% online response rate
 - 50% including non-responder follow up (N=6,763)
 - 855 (13%) parents of children 6 months-16 years
 - 5,908 adults

2014 Preliminary Results*

- Enrolled 19,700 vaccinees:
 - 6,760 completed health event survey
 - 1,002 (15%) parents of children 6 months-14 years
 - 5,758 adults
- Enrolled 21,669 controls (control data complete):
 - 39% online response rate (N=8,509)
 - 839 (10%) parents of children 6 months-14 years
 - 7,670 adults

*Data available as of November 13, 2014

Age Distribution of Children

	2013 Vaccinees (N=1459)	2014 Vaccinees (N=1002)	2013 Controls (N=855)	2014 Controls (N=839)
6-23 Mths	14%	9%	5%	8%
2-4 Yrs	25%	26%	21%	26%
5-9 Yrs	37%	46%	43%	38%
10-14 or 10-16 Yrs	23%	19%	31%	25%

- Most children vaccinated before (85%)
- 60% Flumist vs. 40% TIV

Age Distribution of Adults

Years	2013 Vaccinees (N=11668)	2014 Vaccinees (N=5758)	2013 Controls (N=5908)	2014 Controls (N=7670)
15-29	18%	18%	17%	13%
30-39	21%	24%	20%	18%
40-49	18%	22%	20%	16%
50-59	21%	22%	22%	23%
60+	22%	14%	10%	30%

- 66% vaccinated in a hospital campaign
- 98% previously vaccination

Vaccine Distribution

Adults

Children

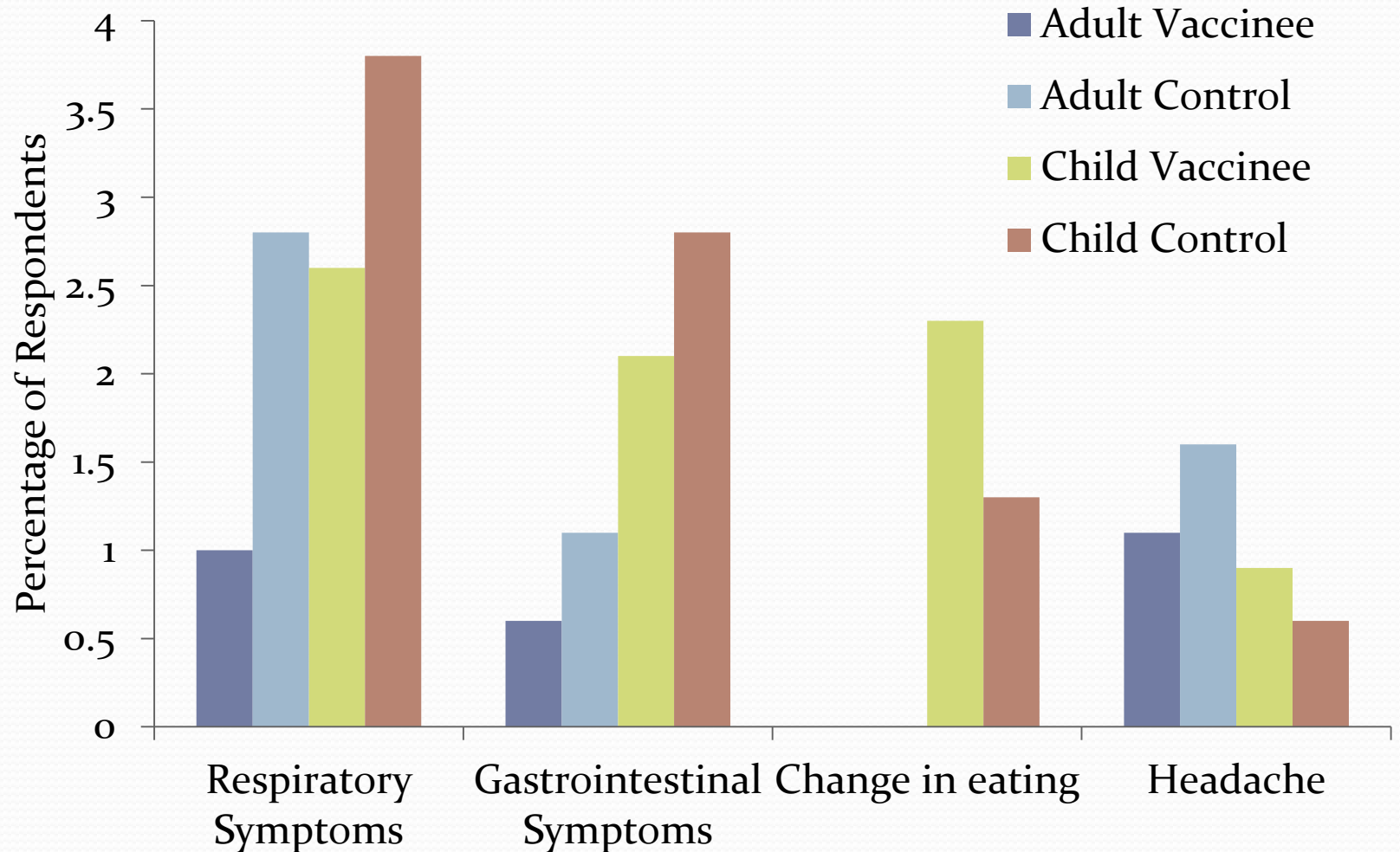
	2013	2014	2013	2014
Agriflu	29%	62%	3%	2%
Flumist	0.6%	1%	60%	69%
Fluviral	59%	31%	31%	24%
Vaxigrip	9%	6%	5%	4%
Fluad*	1%	0.3%	0	0
Unknown	2%	0.5%	1%	1%

*all recipients 50+ years

- Health Events Vaccinees:
 - 2013: 96% no reported adverse events vaccinees
 - 2014: 96% no reported adverse events vaccinees
- Health Events Controls:
 - 2013: 95% no reported health events controls
 - 2014: 95% no reported health events controls

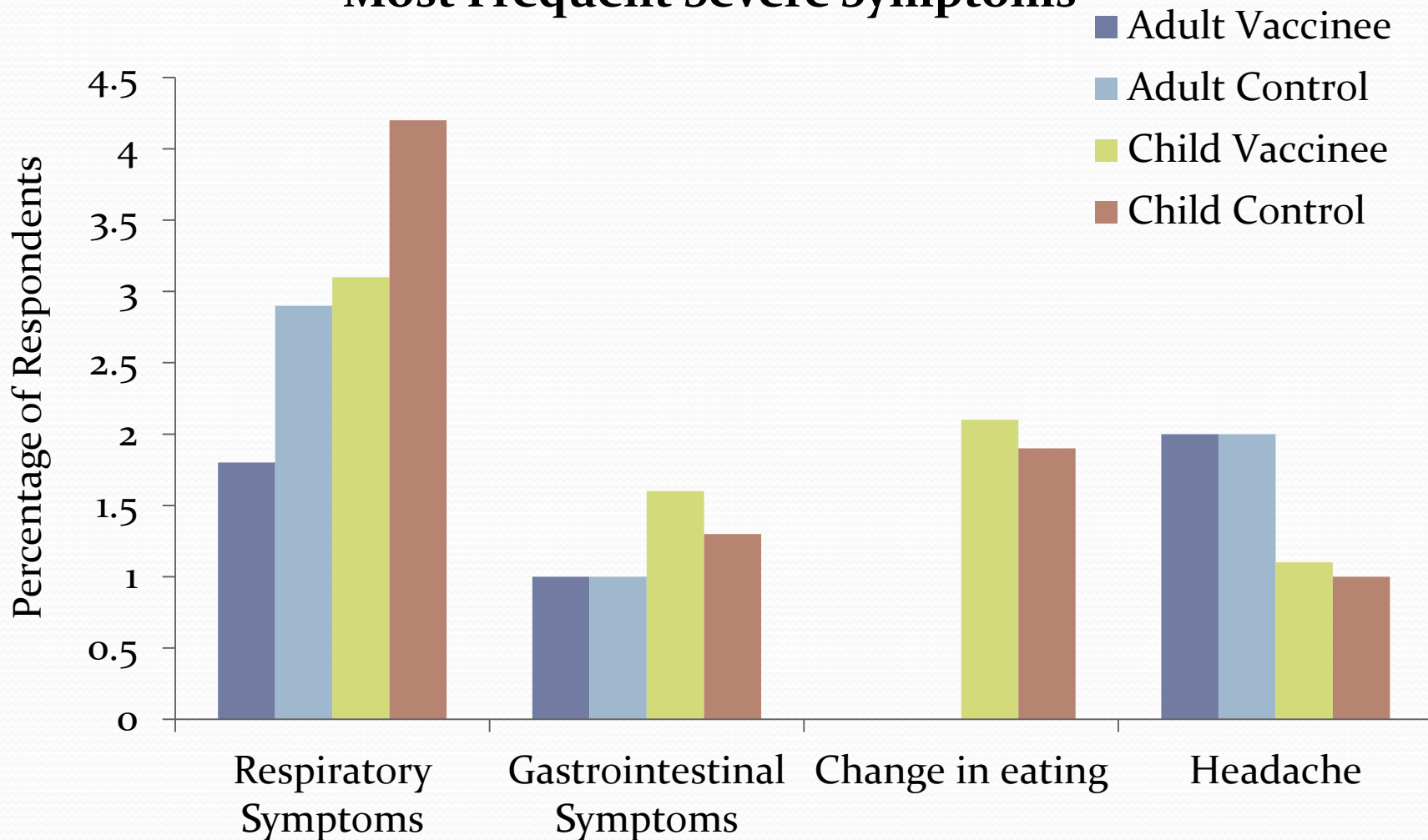
Events Reported 2013

Most Frequent Severe Symptoms



Events Reported 2014

Most Frequent Severe Symptoms



Infrequent Events Reported 2013, 2014

- Paresthesia, allergic-like reactions, severe local injection site reactions and ORS symptoms
 - Reported by <math><0.5\%</math> of adults and children
 - Reported rates similar in vaccinees and controls
 - Exceptions: ORS symptoms reported more frequently in control children in 2013 and allergic-like reactions reported more frequently in children vaccinees in 2014

Level of Care

- ED visits:
 - 7 vaccinees; 4 controls (2013)
 - 11 vaccinees; 26 controls (2014)
- Hospitalized
 - 0 vaccinees and controls (2013)
 - 0 vaccinees; 1 control (2014)
- Median duration 5 days (2013) 4.5 days (2014)

Outcome 2013

- At time of phone follow up
 - Resolved: 60% vaccinees 21% controls
 - Improving: 35% vaccinees 60% controls
 - No change: 4% vaccinees 17% controls
 - Worse: 2% vaccinees 2% controls

Conclusions

- No signals detected for 2013 or 2014 seasonal influenza vaccines
- Both years vaccines had good safety profiles
- Most health events in vaccinees similar to background event rates
 - Exception: change in eating reported more frequently in child vaccinees



CANVAS 2013-2014 Influenza Safety Surveillance Investigators and Collaborators

- **William Bowie** Vancouver General Hospital
- **Brenda Coleman** Mount Sinai Hospital
- **Meena Dawar** Vancouver Coastal Health
- **Gaston De Serres** Centre Hospitalier Uni. de Québec
- **Linn Holness** St. Mike's Hospital
- **Judy Macdonald** Calgary Public Health
- **Ann McCarthy** Ottawa Hospital
- **Shelly McNeil, Karina Top & Jennifer Isnor** Canadian Center for Vaccinology
- **William Osei** Northern Health
- **John Papastergiou** Save on Drug, Toronto
- **Anita Tsang-Sit** Peel Public Health
- **Louis Valiquette** Centre Hospitalier Uni. de Sherbrooke
- **Otto Vanderkooi & James Kellner** Alberta Children's Hospital
- **Paul Van Buynder** Fraser Health