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What's New with Influenza Vaccine and Influenza Vaccination Policy

CHICA – Southwestern Ontario Meeting
West Haven Golf and Country Club
November 8, 2013

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Outline

- Last year's influenza season
- What's new with the influenza vaccine
- Mandatory influenza vaccine

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Epidemiology of Influenza 2012-2013

The Middlesex-London Health Unit Example

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Influenza Statistics Overview, Middlesex-London

	2009-2010	2010-2011	2011-2012	2012-2013*
Laboratory-confirmed cases	391	276	106	**477**
Hospitalizations	92	161	34	**301**
Deaths	8	17	3	**26**
Outbreaks	2	28	6	**40**

* Season to date as of August, 2013

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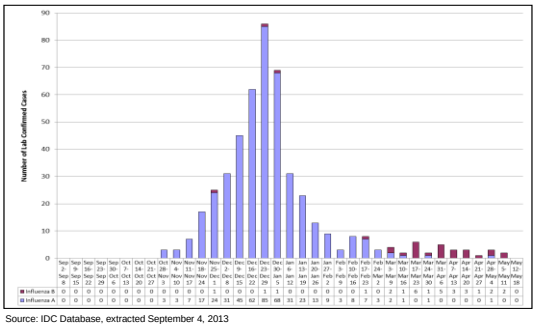
2012-2013 Influenza A & B Epi Curve (N=477)



Source: IDC Database, extracted September 4, 2013

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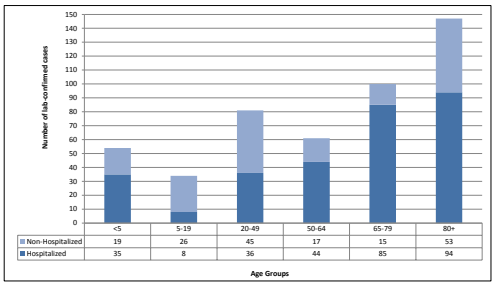
2012-13 Influenza Hospitalizations by age, n_h=302, Non-hospitalized, n_{nh}=175



	<5	5-19	20-49	50-64	65-79	80+
Non-Hospitalized	19	26	45	17	15	53
Hospitalized	35	8	36	44	85	94

Source: IDC Database, extracted June 21, 2013

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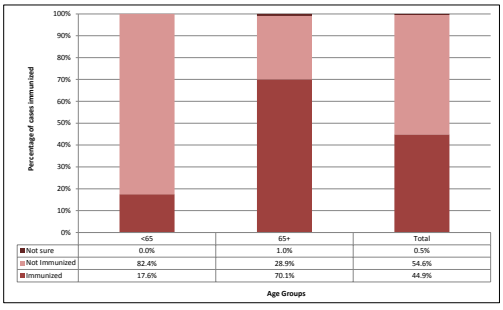
2012-13 Influenza Immunization Status, N=392



	<65	65+	Total
Not sure	0.0%	1.0%	0.5%
Not Immunized	82.4%	28.9%	54.6%
Immunized	17.6%	70.1%	44.9%

Source: IDC Database, extracted June 21, 2013

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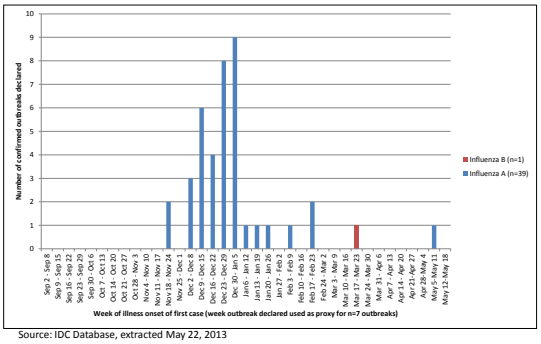
2012-2013 Confirmed Influenza Outbreaks (N=40)



Source: IDC Database, extracted May 22, 2013

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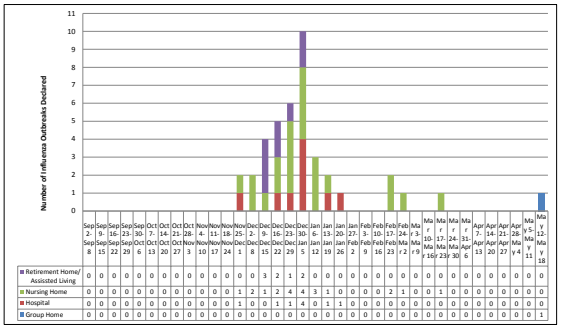
2012-2013 Confirmed Influenza Outbreaks (N=40), by setting



	Sep 2-Sep 8	Sep 9-Sep 15	Sep 16-Sep 22	Sep 23-Sep 29	Sep 30-Oct 6	Oct 7-Oct 13	Oct 14-Oct 20	Oct 21-Oct 27	Oct 28-Nov 3	Nov 4-Nov 10	Nov 11-Nov 17	Nov 18-Nov 24	Nov 25-Dec 1	Dec 2-Dec 8	Dec 9-Dec 15	Dec 16-Dec 22	Dec 23-Dec 29	Dec 30-Jan 5	Jan 6-Jan 12	Jan 13-Jan 19	Jan 20-Jan 26	Jan 27-Feb 2	Feb 3-Feb 9	Feb 10-Feb 16	Feb 17-Feb 23	Feb 24-Mar 2	Mar 3-Mar 9	Mar 10-Mar 16	Mar 17-Mar 23	Mar 24-Mar 30	Mar 31-Apr 6	Apr 7-Apr 13	Apr 14-Apr 20	Apr 21-Apr 27	Apr 28-May 4	May 5-May 11	May 12-May 18
Retirement Home/ Assisted Living	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nursing Home	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	1	2	4	4	3	1	0	0	0	0	2	1	0	0	1	0	0	0	0	0	0
Hospital	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	4	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Group Home	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1

Source: IDC Database, extracted May 22, 2013

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Nosocomial Influenza Infections

- Any lab confirmed influenza infections that were diagnosed **more than** 72 hours after admission to an acute care inpatient unit are considered to be nosocomial
  - 34 cases out of 477 met this definition (7%), all from London acute care settings
  - 21 of the 34 nosocomial cases (62%) were associated with the nine hospital outbreaks
  - 13 of the 34 nosocomial cases (38%) were not considered part of an outbreak

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What's New in Influenza Immunization

- Recent NACI changes
  - Egg allergy
  - Preferential intranasal vaccine for children
  - Upcoming reviews
- Quadrivalent vaccines
- Vaccine effectiveness
- Age specific vaccines
- New methodologies for making flu vaccine
- Narcolepsy and pandemic H1N1 vaccine
- H7N9 influenza

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Recent NACI Changes

Egg allergy

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Egg Allergy – 2011-2012

- No longer a contraindication for trivalent inactivated influenza vaccine based on several studies
  - Still is for FluMist
- Very small amount of egg protein in vaccine < 1.2 micrograms / ml

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Egg Allergy – 2011-2012

- Lower risk for severe allergic reactions
  - Localized hives, gastrointestinal symptoms
  - Vaccinate at usual; keep 30 minutes
- Higher risk of severe allergic reactions
  - Generalized hives or respiratory or cardiovascular reactions, or poorly controlled asthma with egg allergy
  - Graded vaccination
    - 10 % of the dose; wait 30 minutes; give remaining 90% of dose; keep 30-60 minutes

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NACI Changes – Egg Allergy

- Now recommending 0.5 ml for all
- Mild reactions such as hives
  - regular clinics
- Anaphylaxis with respiratory or cardiovascular symptoms
  - appropriate expertise and equipment to manage respiratory or cardiovascular compromise.
- Observe for 30 minutes

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Influenza Vaccine Allergy

- Previous discussion applies to egg allergy
- Influenza vaccine allergy still a contraindication

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Recent NACI Changes

Preferential Intranasal Vaccine for Children

Flumist – 2011-2012

- Live attenuated, intranasal vaccine
- 0.1 ml in each nostril (total 0.2 ml)
- Ages 2-59 years who are not immunocompromised
- NACI made preferential recommendations for children 2-17 years of age based on better efficacy in these children
- Re-looking at data regarding older children

FluMist Implementation

- Limited use so far
- Not publicly funded in Ontario
- Cost about $20.00 per dose
- Not available at our clinics

NACI Changes

Upcoming Reviews Based on Different Age Groups

Age expansion

- 2012-2013 – NACI recommended adding children 2 to < 5 years to high risk groups, as well as those who have close contact with them
- Based on elevated risk of hospitalization and outpatient visit and that source of community transmission
- Currently undertaking review of healthy:
  - 5 to 18 year olds
  - 19 to 64 year olds

Quadrivalent Vaccines

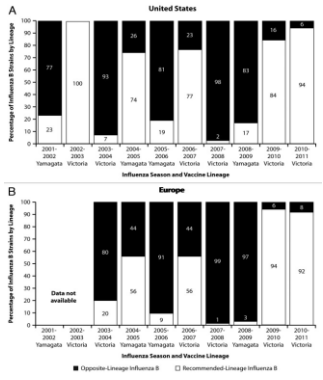
Quadrivalent Vaccines

- Contain H1N1, H3N2 and 2 B strains
- Live attenuated version and inactivated version available in the US
- Likely will be available in Canada next influenza season

Influenza B

- Affects all age groups, but mostly older children and adolescents
- Range from 1-44% of positive samples in 10 year period in US; average 24%
- 2 lineages have circulated globally:
  - B/Yamagata
  - B/Victoria
- 5 of 10 years, mismatch between vaccine and predominant circulating strain

Ambrose et al. Human Vaccines and Immunotherapeutics 8:1, 81-88; January 2012



Ambrose et al. Human Vaccines and Immunotherapeutics 8:1, 81-88; January 2012

This year's vaccine

- A/California/7/2009 (H1N1)-like virus,
- A/Victoria/361/2011 (A/Texas/50/2012)
- B/Massachusetts/2/2012–like (Yamagata lineage) virus.

- In US, Quadrivalent influenza:
  - B/Brisbane/60/2008–like (Victoria lineage) virus.

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Vaccine Effectiveness

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Vaccine Effectiveness Controversy

- Osterholm Review:
  - Assessed 31 studies
  - TIV pooled efficacy 59% (95 % CI - 51-67%) in 18-65 year olds
    - No TIV studies met inclusion criteria for other ages
  - LAIV pooled efficacy 83% (95% CI - 69-91%) for 6 months to 7 year olds
    - No LAIV studies met inclusion criteria for older ages

Osterholm MT et al. Lancet Infectious Disease 2012:12:36-44

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CDC Vaccine Effectiveness Estimates for Outpatient Visits

- Overall effectiveness 56% (CI = 47%-63%)
- A (H3N2) 47% (CI = 35%–58%)
  - 58% for persons aged 6 months–17 years;
  - 46% for persons aged 18–49 years;
  - 50% for persons aged 50–64 years, and
  - 9% for persons aged ≥65 years
- B 67% (CI = 51%–78%)
  - 64% to 75% across age groups.

CDC, MMWR February 22, 2013 / 62(07):119-123

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Age Specific Vaccines

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Trying to get better efficacy

- FluMist (live, intranasal)
  - Better in children, but to what age?
- Fluad (MF59 adjuvanted vaccine)
  - May have better immunogenicity, uncertain if better efficacy and effectiveness in elderly
  - Better efficacy in children
- Intanza (intradermal vaccine) and Fluzone (high dose - 60 micrograms)
  - May have better immunogenicity, uncertain if better efficacy and effectiveness

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New Methodologies for Making Flu Vaccine

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Flucelvax

- Cell-culture based vaccine (Novartis)
- Available in US for 18 years of age and over
- Not grown in egg; so very little egg protein

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FluBlock

- Recombinant hemagglutinin Vaccine (Protein Science)
- Available in US for 18 to 49 years
- Put hemagluttinin gene into baculovirus
- Highly specific to insect cells
- Infect insect cells with virus
- Incubate in ~48-72 hours
- Purify resulting protein

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FluBlock

- Uses larger amounts of hemagluttinin per strain (45 micrograms per strain)
- No egg
- From gene to production in 21 days
- Pandemic solution

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Narcolepsy and Pandemic H1N1 Vaccine

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Narcolepsy

- Excessive daytime sleepiness, disturbed nocturnal sleep, sleep paralysis, cataplexy, and hypnagogic or hypnopompic hallucinations
- Prevalence 20 to 50 / 100,000
- Incidence ~0.3–0.6 / 100,000 person-years
- Peak incidence is second decade
- Likely autoimmune and environmental triggers
- HLA-DQB1*0602 allele
- CSF hypocretin 1 low or undetectable

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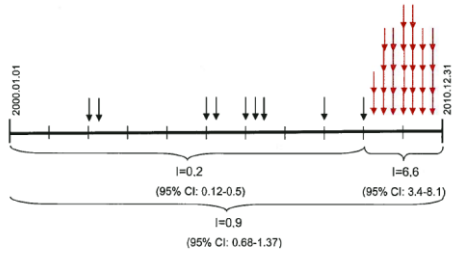
Narcolepsy and H1N1 Vaccine

- First reported in Finland and Sweden after ASO3 adjuvanted vaccine
- Canada, France, Ireland, UK, US? etc. have cases
- By January 2011 - 162 patients vaccinated with Pandemerix™ reported to GSK
- 4-25 fold increased risk of narcolepsy in children and adolescents
  - 25 fold increased risk is 1 / 16,000 vaccinated children

Figure 2 Incidence of narcolepsy in children in western Sweden between January 2000 and December 2010



Each arrow represents one patient. I = incidence figures in children aged 2-17 years/100,000/year before (black arrow) and after (red arrow) mass vaccination against H1N1 influenza in October 2009. The incidence in the period after vaccination compared with the period before was 25 times higher, giving a statistically significant difference ($p < 0.000001$).

Szakács A et al. Neurology 2013;80:1315-1321.

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Narcolepsy and H1N1 Vaccine

- Mechanism theories
  - H1N1 versus adjuvant
    - Increase in China related to influenza season, including post H1N1 influenza season
    - Not seen after MF59 adjuvanted vaccine
  - Molecular mimicry
  - Supercharged immune system
  - Is it just shifting people forward in time of onset?

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H7N9 Influenza

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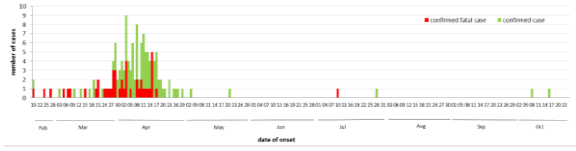
H7N9 Influenza

- 137 cases, 45 deaths since February 2013
  - 2 in October 2013
- All arose in Eastern China
- Middle aged and elderly men
- Believed to be attributed to contact with live bird markets; Limited person to person spread
- Under control due to culling birds in live bird markets and/or seasonal factors
- Candidate influenza vaccine viruses available

Epidemiological curve of confirmed cases of avian influenza A(H7N9) reported to WHO, by day, 2013



All dates refer to onset of illness

Data in WHO/HQ as of 25 October 2013, 08:00 GMT+1
Source: WHO/GIP

World Health Organization

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Mandatory Immunization Policies

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Staff Immunization Rates

- Despite multiple efforts, staff immunization rates have remained low particularly in hospitals
- Staff exclusion policies led to increase in long term care facilities but still suboptimal

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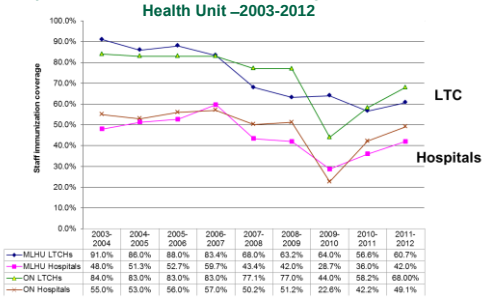
Local and provincial Staff immunization coverage for Middlesex-London Health Unit –2003-2012



	2003-2004	2004-2005	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012
MLHU LTCHs	91.0%	86.0%	88.0%	83.4%	68.0%	63.2%	64.0%	56.6%	60.7%
MLHU Hospitals	48.0%	51.3%	52.7%	59.7%	43.4%	42.0%	28.7%	36.0%	42.0%
ON LTCHs	84.0%	83.0%	83.0%	83.0%	77.1%	77.0%	44.0%	58.2%	68.00%
ON Hospitals	55.0%	53.0%	56.0%	57.0%	50.2%	51.2%	22.6%	42.2%	49.1%

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Serious Problem with No Excuses

- 400 – 4,000 deaths each year in Canada
- Hospitalized patients and long term care patients already significantly compromised
- Vaccination effective – 59%
- Vaccination safe
  - GBS study showed attributable risk of
    - 1.03 per million within 6 weeks of vaccination
    - 17.2 per million within 6 weeks of influenza health care encounter

Kwong et al. Lancet Infectious Disease (13)9, Sept 2013

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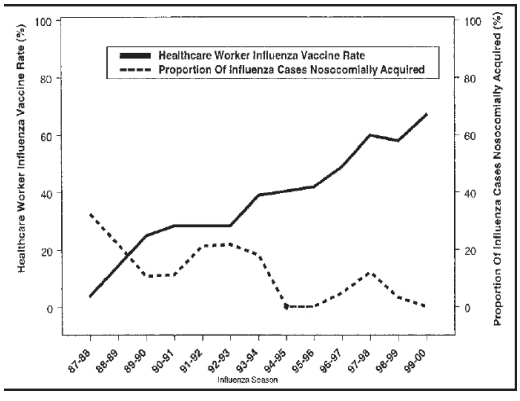
Vaccination of Health Care Providers Helps

Cluster randomized trials of the impact of HCW influenza immunization on patient mortality

Study	Journal/ Year	Setting	Crude mortality difference	Adjusted risk ratio
Potter *et al.*	JID 1997	1059 residents in 12 LTCFs in Glasgow	17% vs 12%	0.6 (0.4,0,8)
Carman *et al.*	Lancet 2000	1437 patients in 20 elderly-care hospitals in UK	22% vs 14%	0.6 (0.4,0.8)
Hayward *et al.*	BMJ 2006	2604 residents in 44 LTCFs in UK	15% vs 11%	0.6 (0.4, 1.0)
Lemaitre *et al.*	J Am Ger Soc 2009	3483 residents in 40 nursing homes in France	6.0% vs. 5.2%	0.8 (0.7,1.0)

Courtesy of Dr. Allison McGeer



Salgado et al. Infection Control And Hospital Epidemiology 2004;11:923

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Increasingly Taking More Aggressive Approach

- Ethical responsibility for patient care
- Need to sign a declination
- Mandatory on hire / for everyone
  - Some exemptions for medical / religious reason
- Non-compliance
  - Wear a mask or excluded from work
  - Excluded from work

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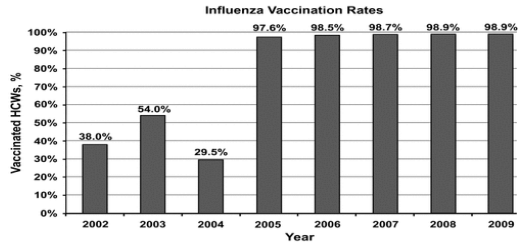
Virginia Mason Hospital - Seattle



Rakita RM et al. Infection Control and Hospital Epidemiology Vol 31, No. 9 Sept 2010

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CDC Survey

- 2011-2012 internet survey of 2,348 health care providers
- 66.9% vaccinated; 76.9% in hospitals
  - 95.2% if hospital required influenza vaccine
  - 68.2% if hospital did not require influenza vaccine

MMWR September 28, 2012 / 61(38);753-757
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6138a1.htm

National Advisory Committee on Immunization (NACI)

- NACI considers the provision of influenza vaccination to be an essential component of the standard of care for all HCWs for the protection of their patients. This includes any person, paid or unpaid, who provides services, works, volunteers or trains in a health care setting.

BC Policy

- Announced for 2012-2013
- Any health care provider with direct patient contact be vaccinated or wear a mask
- Applies to all health-care workers including health-authority staff, physicians and residents, volunteers, students, contractors and vendors who come into contact with patients.

BC Policy

- Challenged by some unions
- Enforcement put on hold by Health Ministry for one year
- Expected to be implemented in full in 2013-2014
- Recent grievance of the policy dismissed by an arbitor

Mask Policy

- Intended as source control
- May also prevent acquisition
- ?? Punitive

Acknowledgement

- Hilary Caldarelli and Alison Locker, MLHU Epidemiologists for epidemiology slides from 2012-2013 season
- Dr. Allison McGeer and Dr. Marina Salvadori for help with several slides regarding mandatory immunizations