
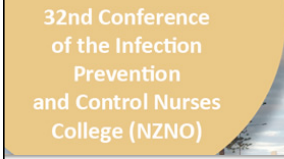



**Is mandatory influenza vaccination the best way to protect our patients?**  
**Dr. Michael Gardam, University Health Network, Toronto**  
**Broadcast live from the New Zealand Infection Prevention and Control Nurses College**



**Is mandatory influenza vaccination the best way to protect our patients?**

**Michael Gardam MSc, MD, CM, MSc FRCP**  
Division of Infectious Diseases  
Director, Infection Prevention and Control  
Chair, Medical Advisory Committee  
University Health Network  
University of Toronto  
Canada

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[www.webbertraining.com](http://www.webbertraining.com) September 3, 2015

## Overview

- Why this policy?
- Influenza
  - epidemiology
  - transmission
  - vaccine
- Vaccine or mask policies
  - development and implementation
- Other approaches
- Conclusion

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## Influenza or mask policy

Receive the influenza vaccine by the start of  
influenza season

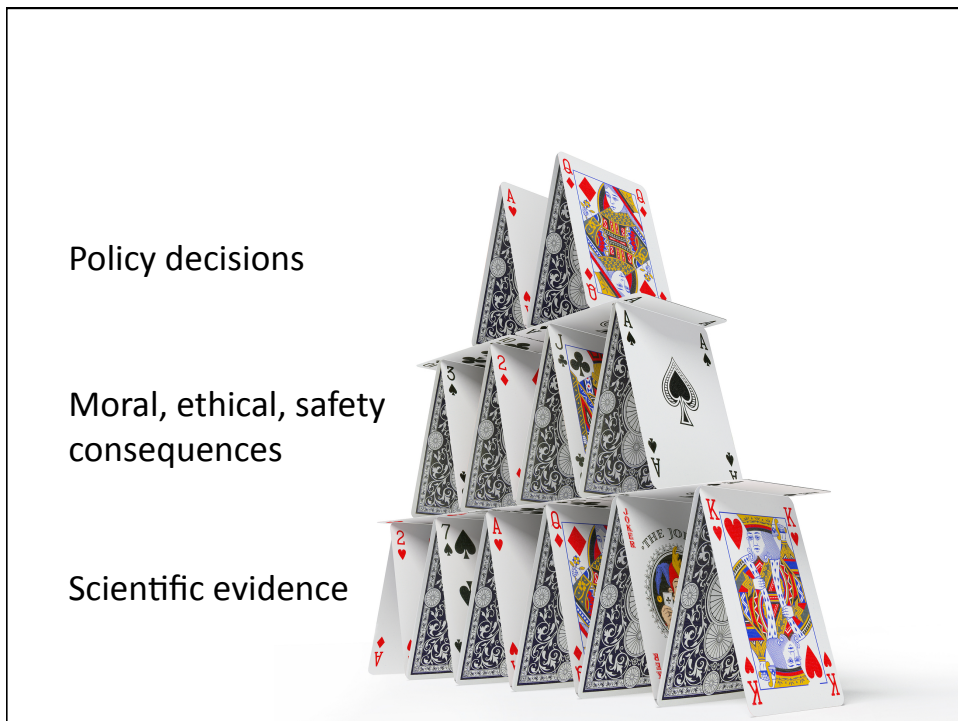
*OR*

Wear a surgical mask in clinical areas for the  
duration of the season

## Arguments in support

- Influenza kills the elderly and infirm
- We cannot wait for better studies
  - Precautionary approach
  - It would be unethical to do further studies
  - Randomized controlled trials are gold standard
- Patient safety comes first
- The policy is better than nothing
- Moral/ethical obligation
- Nothing else works to increase vaccination rates
- Patients support it
- Others countries are doing it

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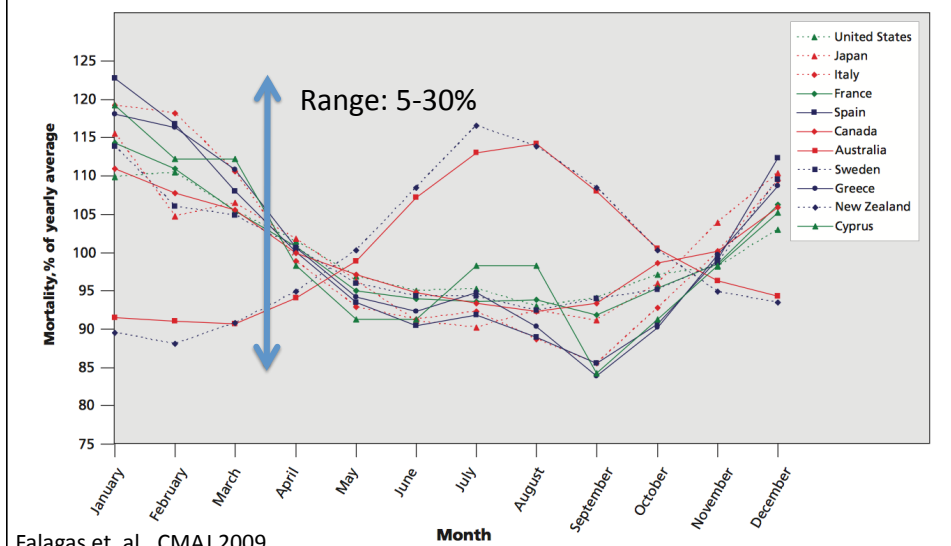
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**How many people die from/with influenza each year (CDN data)?**

- 4000-8000?
  - mathematical models typically assign all/majority of excess winter mortality to influenza
  - clearly an overestimate
- <500?
  - actual number of deaths with influenza that are reported
  - Not all cases detected
  - clearly an under estimate

**Excess Winter Mortality**



Falagas et al. CMAJ 2009

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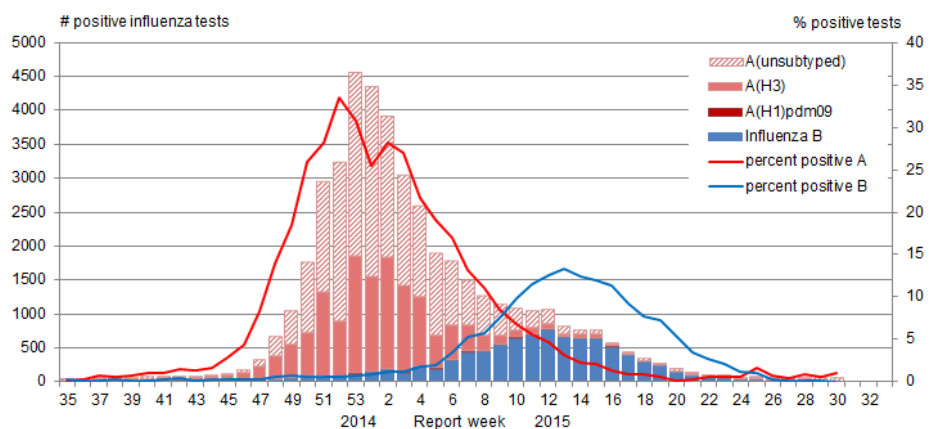


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**Is it fair to assign excess winter mortality to influenza?**

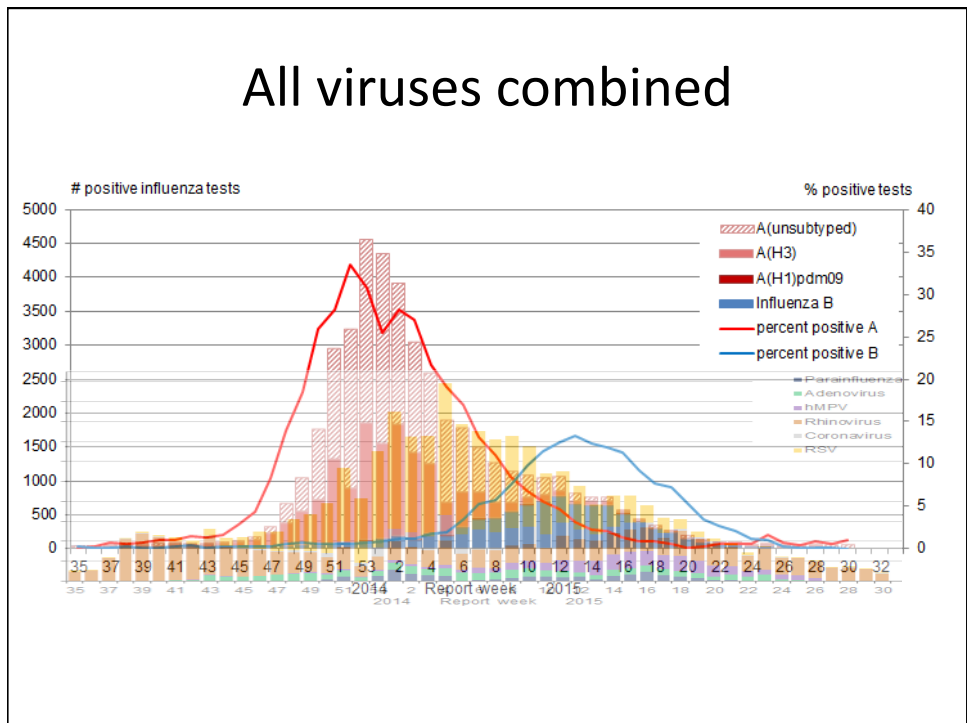
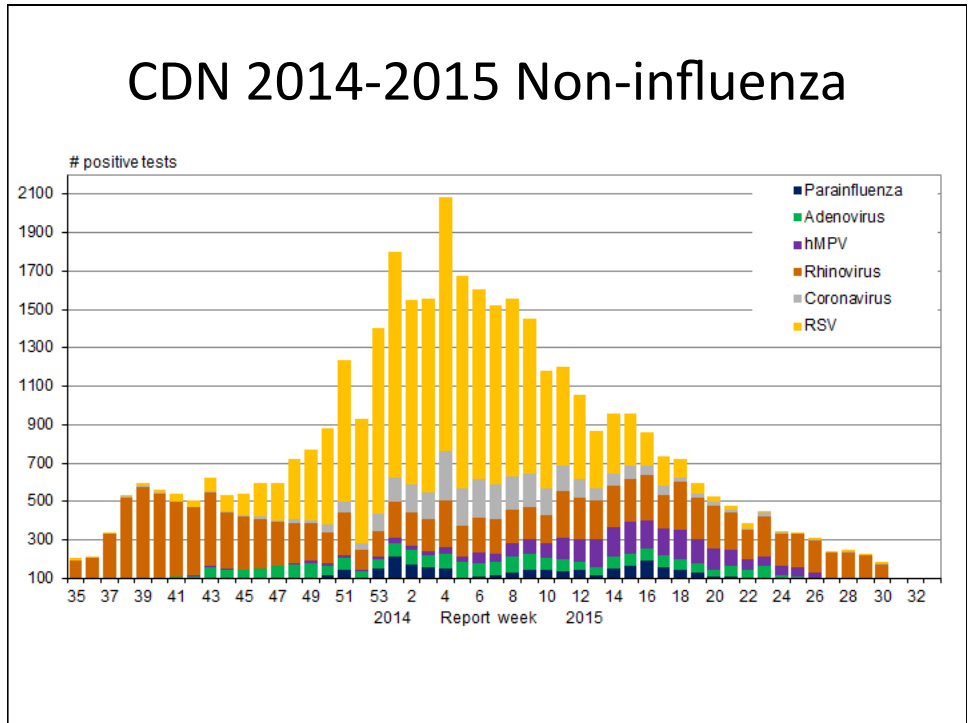
- Some, yes (estimated 10%)
- But average community attack rate is roughly 10-20%
- Influenza is a minority cause of influenza-like illness (ILI) so it should not be used as a surrogate

**CDN 2014-2015 influenza**



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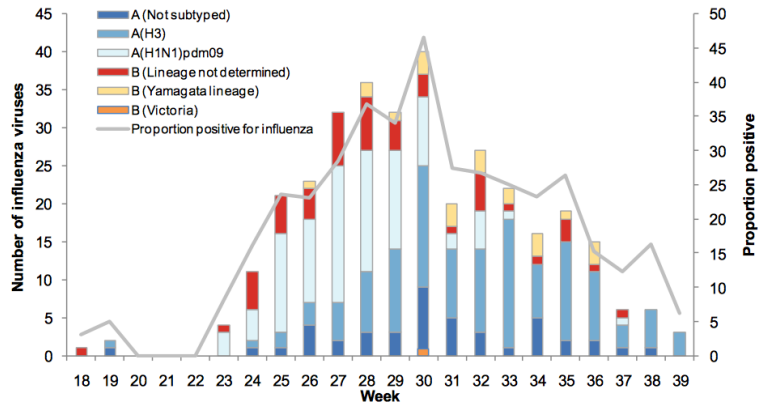


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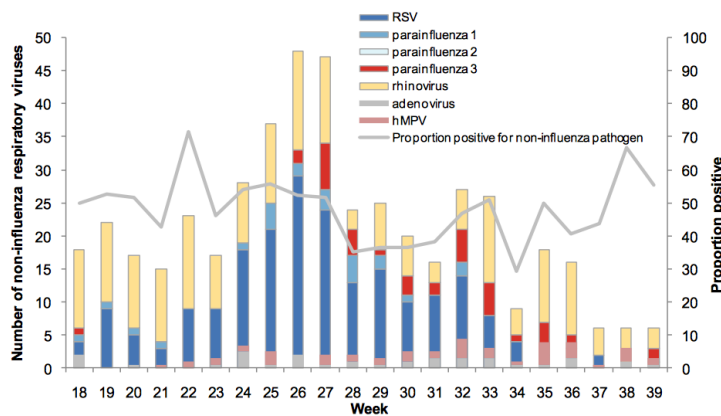
## NZ 2012 data influenza

**Figure 14. Temporal distribution of the number and proportion of influenza viruses from SARI specimens by type and week**



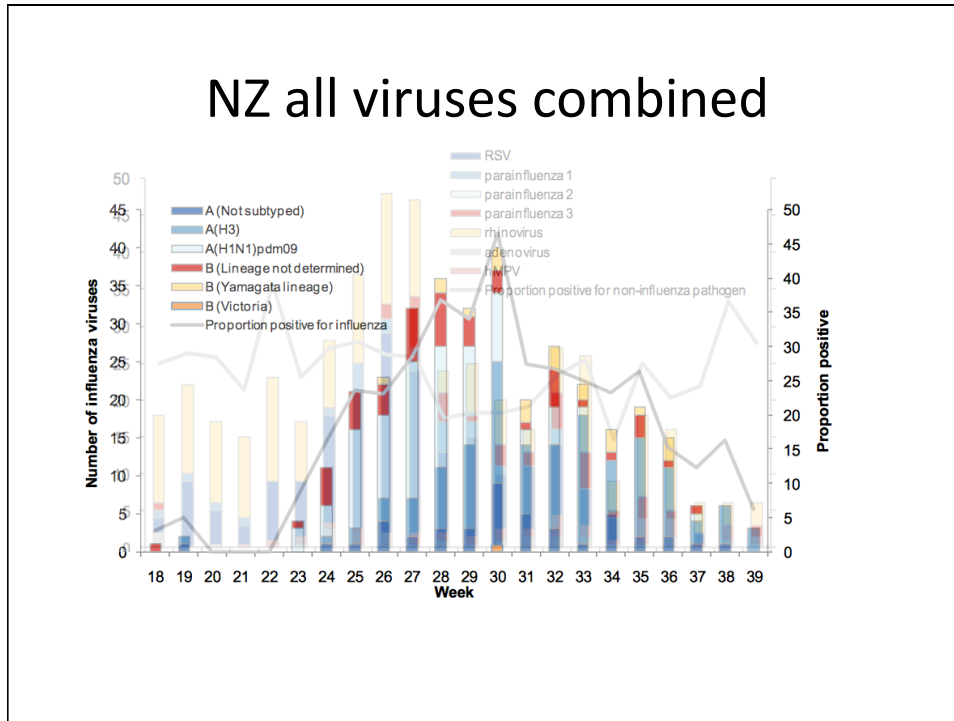
## NZ 2012 data Non-influenza

**Figure 15. Temporal distribution of the number and proportion of non-influenza viruses from SARI specimens by type and week**



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### How often do we catch influenza?

- Examined antibody levels to 9 influenza strains from 1968-2009 in China
- Roughly 2 infections per decade >age 40

**A**

Kucharski et. al. PLOS Biology 2015

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**3-8 patients/ 10 000 admissions develop  
nosocomial influenza**

What proportion comes from healthcare  
workers?

1. All of it
2. Some of it
3. We have no idea

(Answer: 3)

## Healthcare workers with influenza

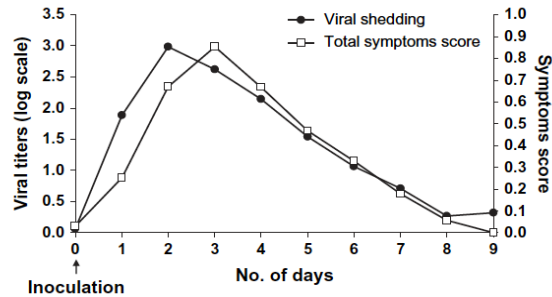
- Prospective study of ill healthcare workers
  - 54% had a viral pathogen
    - 8% had influenza
      - 51% of these were febrile
      - no difference in fever if vaccinated/unvaccinated (45% vs 61%,  
p=0.32)
- If using fever as a work exclusion criteria, will miss half of staff with influenza

Ridgway et. al. Clin Infect Dis 2015

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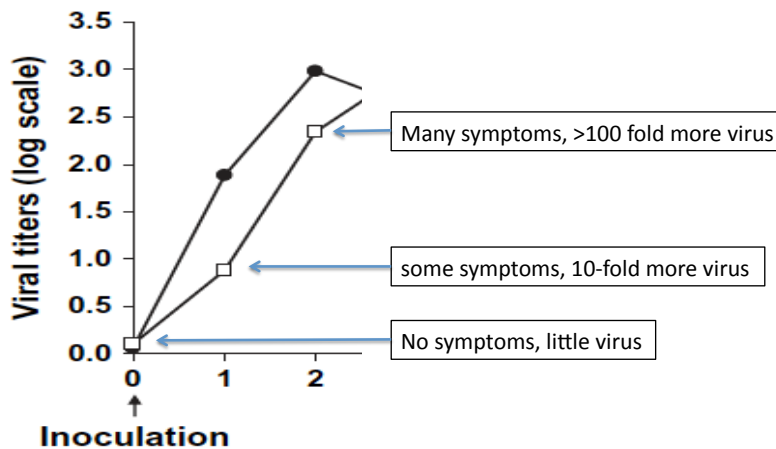
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**asymptomatic transmission?**



**FIGURE 5.** Summary curves of viral shedding and total symptoms scores in experimental influenza virus infection. Thirteen curves were used for viral shedding (refer to figure 2 legend), and 17 curves were used for total symptoms scores (refer to figure 3 legend).

Carrat et. al., 2008



Carrat et. al., 2008

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## Vaccine Effectiveness, 2005-2015

Table. Adjusted vaccine effectiveness estimates for influenza seasons from 2005-2015

| Influenza Season <sup>†</sup> | Reference     | Study Site(s)      | No. of Patients <sup>‡</sup> | Adjusted Overall VE (%) | 95% CI  |
|-------------------------------|---------------|--------------------|------------------------------|-------------------------|---------|
| 2004-05                       | Belongia 2009 | WI                 | 762                          | 10                      | -36, 40 |
| 2005-06                       | Belongia 2009 | WI                 | 346                          | 21                      | -52, 59 |
| 2006-07                       | Belongia 2009 | WI                 | 871                          | 52                      | 22, 70  |
| 2007-08                       | Belongia 2011 | WI                 | 1914                         | 37                      | 22, 49  |
| 2009-10                       | Griffin 2011  | WI, MI, NY, TN     | 6757                         | 56                      | 23, 75  |
| 2010-11                       | Treanor 2011  | WI, MI, NY, TN     | 4757                         | 60                      | 53, 66  |
| 2011-12                       | Ohmit 2014    | WI, MI, PA, TX, WA | 4771                         | 47                      | 36, 56  |
| 2012-13                       | McLean 2014   | WI, MI, PA, TX, WA | 6452                         | 49                      | 43, 55  |
| 2013-14                       | Unpublished   | WI, MI, PA, TX, WA | 5990                         | 51                      | 43, 58  |
| 2014-15                       | Flannery 2015 | WI, MI, PA, TX, WA | 2321                         | 23                      | 8, 36   |

CDC, 2015

mean=41%

### RESEARCH ARTICLES

## Interim estimates of 2014/15 vaccine effectiveness against influenza A(H3N2) from Canada's Sentinel Physician Surveillance Network, January 2015

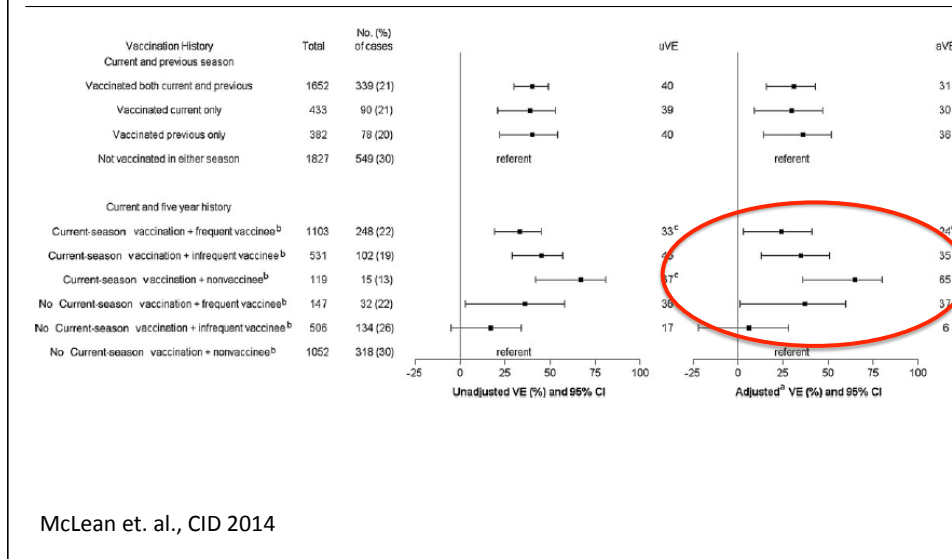
D M Skowronski (danuta.skowronski@bccdc.ca)<sup>1,2</sup>, C Chambers<sup>1</sup>, S Sabaiduc<sup>1</sup>, G De Serres<sup>3,4,5</sup>, J A Dickinson<sup>6</sup>, A L Winter<sup>7</sup>, S J Drews<sup>8,9</sup>, K Fonseca<sup>6,10</sup>, H Charest<sup>3</sup>, J B Gubbay<sup>7,11</sup>, M Petric<sup>2</sup>, M Krajden<sup>1,2</sup>, T L Kwindt<sup>1,2</sup>, C Martineau<sup>3</sup>, A Eshaghi<sup>1</sup>, N Bastien<sup>1,2</sup>, Y Li<sup>12,13</sup>

**-8% Vaccine Effectiveness (95% CI: -50 to 23%)**

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## Vaccination paradox



## Conclusions

- Influenza causes a minority of influenza-like illness
- <<1% of patients will get nosocomial influenza
- The risk of influenza transmission to patients from healthcare workers is unknown
- The vaccine is mediocre and repeat vaccination may make it more so
- Asymptomatic transmission is likely negligible

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## On to the Randomized Controlled Trials

### 4 RCTs in long term care

- Pooled data (3 studies) showed no significant impact on influenza-specific (or even influenza-related) outcomes
- Pooled data (3 studies) showed a significant reduction in all cause mortality
  - CDC RR=0.71 (0.59-0.85)—29% reduction
  - Cochrane RR=0.66 (0.55-0.79)—32% reduction

## How can this be?

- In two studies most of the differences in all cause mortality occurred **before the onset of influenza activity**
- The reduction in mortality is **greater than that for all excess winter mortality**
  - only 10% is believed to be due to influenza
- The vast majority of healthcare workers remained unprotected

## Hayward *et. al.*

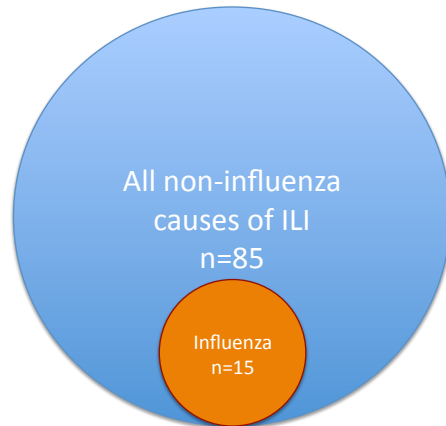
- 35% vaccination coverage
- 30% reduction in all-cause mortality

*“the number of staff needed to be vaccinated to prevent one death... was 8”*

*What?*

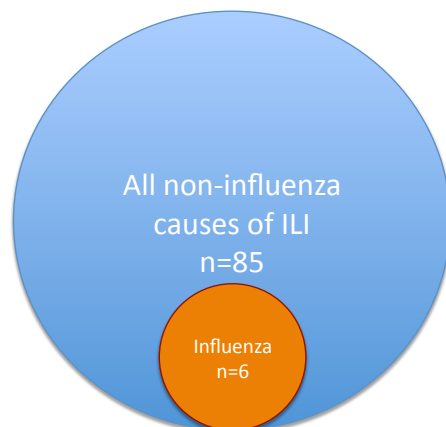
Hayward BMJ, 2006

## Why influenza-specific mortality matters



- Total cases of ILI=100  
 Influenza: 15/100 = 15%  
 Non-flu: 85/100 = 85%
- With placebo (effectiveness 0%)  
 % reduction in flu = 0  
 % reduction in non-flu = 0  
 % total reduction = 0

## 60% effectiveness (assuming 100% vaccine penetration)



- Total cases of ILI=91  
 Influenza: 6/91 = 7%  
 Non-flu: 85/91 = 93%
- % reduction in flu: 60%  
 % reduction in non-flu: 0%
- Total reduction:  
 $(100-91/100)*100=9\%$

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## Example: Pneumococcal vaccine

- decreased risk of invasive pneumococcal disease OR 0.26 (0.14-0.45)
- decreased all-cause pneumonia (low income population) OR 0.54 (0.43-0.67)
- no effect on all-cause mortality

Moberley *et. al.* Cochrane database 2013

## A decrease in all cause illness > specific illness is mathematically impossible

- The long term care RCTs must have inherent biases
  - Not-blinded
  - Other outbreaks
  - Changes in behaviour that affected flu rates
    - other infection control practices
    - biased case detection
  - note that inadequate influenza diagnosis is very unlikely in these trials

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The reason there is no reduction in influenza-specific mortality is because the vaccine has very little impact on this outcome

## The Acute care RCT

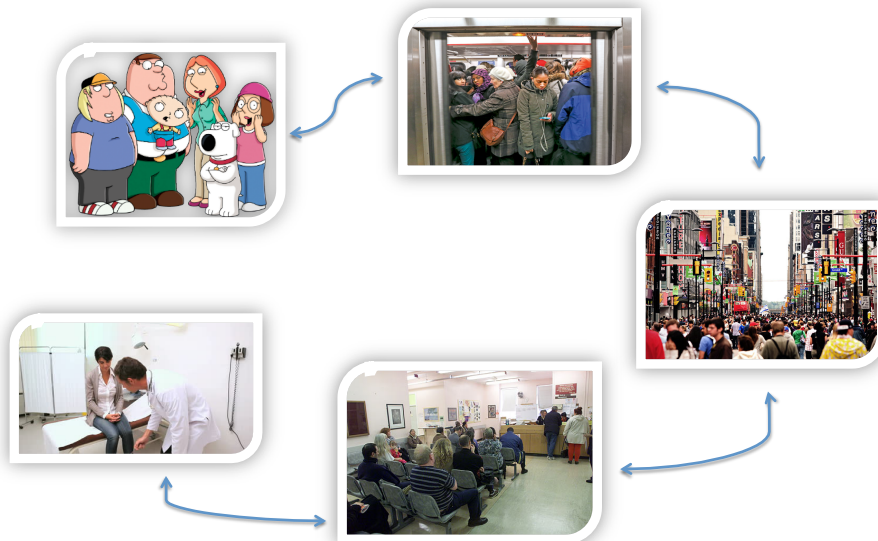
- Studied the impact of an educational intervention on vaccination rates
- Secondary outcomes:
  - nosocomial influenza + pneumonia
- 11% increase in vaccination rates resulted in a 50% decrease in influenza/pneumonia on one ward
- Researchers acknowledged many sources of potential bias

Riphagen-Dalhuisen et. al., Eurosurveillance 2013

## Are all clinical settings the same?

- Long term care
- Acute care
- Complex continuing care
- Home care
- Ambulatory care

## A trip to the family doctor



## Conclusions

- The available evidence is significantly flawed
- All-cause mortality decrease cannot be due to vaccinating healthcare workers
- To cite these studies as definitive (or even moderate) proof that healthcare worker vaccination saves lives is to mislead.
- Patient care settings are not the same

## What about this past CDN influenza season?

- Vaccine effectiveness is zero for H3N2
- Vaccinated staff do not need to mask, even when ill
  - not necessarily required to take prophylaxis during outbreaks
- Unvaccinated staff need to mask, even when not ill
  - must take prophylaxis during outbreaks

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## How not to develop policy



Policy decisions

Morale, ethical, safety  
consequences

Flawed scientific evidence

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## *“Misleading towards the truth”*

- *Misleading toward the truth is exceedingly common. It is well-intentioned – or at least it is grounded in a normal mix of self-serving and altruistic intentions.*
- *So what’s the problem? Misleading people, even toward the truth, is a very dangerous behavior. If and when people learn they have been misled, they have great trouble thereafter believing the truth they were misled toward. If and when they discover that the company or agency they have been listening to cannot be trusted, they jump to the conclusion that the facts it withheld or papered over must be damning. In our field, risk communication, this is predictable – as sound as Sound Science gets.*

Sandman and Lanard

The image shows a screenshot of a Vox Science & Health article. The Vox logo is in the top left, with 'SCIENCE & HEALTH' in a smaller font next to it. In the top right, there are social media icons for Facebook, Twitter, YouTube, and RSS. The article title is 'How anti-vaxxers have scared the media away from covering vaccine side effects'. Below the title, it says 'Updated by Julia Belluz on July 27, 2015, 2:01 p.m. ET' followed by Twitter and email icons and handles. At the bottom of the article preview, there are buttons for 'TWEET (457)', 'SHARE (1,166)', and a plus sign for more options.

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Is moral indignation a sound  
basis for policy?



### Consequences of this policy

- Negligible impact on patient safety
- Eroded medical and scientific credibility
- Ammunition for the anti-vaccination movement
- Disenfranchised and potentially disciplined staff
- Wrongful dismissal suits

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## Arguments in support of the policy

- Influenza kills the elderly and infirm
- We cannot wait for better studies
  - Precautionary approach
  - it would be unethical to do further studies
  - Randomized controlled trials are gold standard
- Patient safety comes first
- The policy is better than nothing
- Moral/ethical obligation
- Nothing else works to increase vaccination rates
- Patients support it
- Others in Canada and the USA are doing it

## Policy alternative

- Encourage influenza vaccination
- Avoid coming to the healthcare setting with influenza-like illness symptoms
- If you must attend work/visit, wear a mask while ill

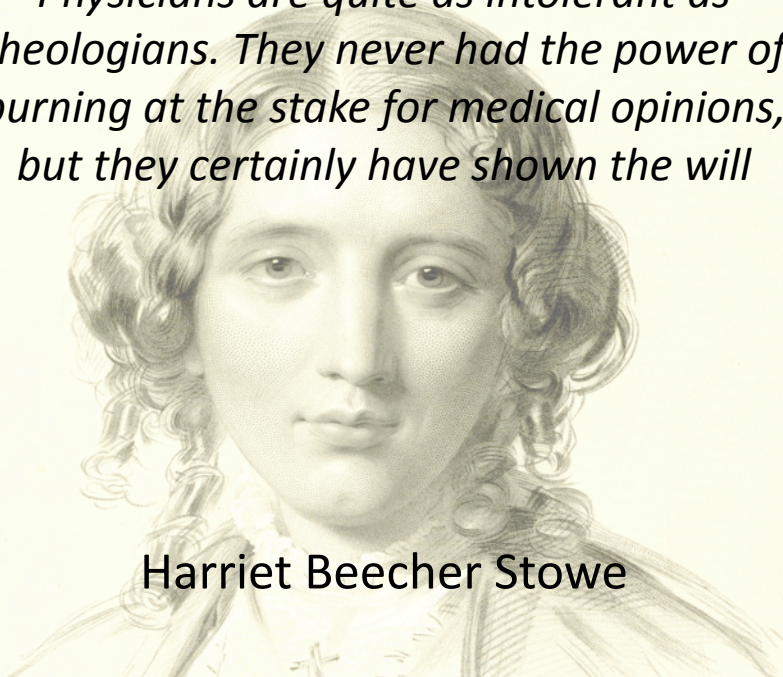
Sounds simple, but it isn't.

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## Final conclusions

- Vaccine or mask policies are fatally flawed
- They will not significantly improve patient safety
- They will potentially cause harm
- There is a better, more logical policy alternative

*Physicians are quite as intolerant as theologians. They never had the power of burning at the stake for medical opinions, but they certainly have shown the will*



Harriet Beecher Stowe

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# Questions



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**haere mai! haere mai! haere mai!**  
Nga manuhiri tuarangi, nga rangatira ma, tena koutou, haere mai  
Visitors from afar, respected guests, greetings to you all and welcome.  
he pu'ia taronui  
he ope tangata rau,  
e kara e ngara.

**NZ information on Middle East Respiratory Syndrome (MERS-CoV)**  
For NZ information on Middle East Respiratory Syndrome (MERS-CoV) please click here


**LATEST NEWS**

**Endoscope Contamination Thursday, 13 August 2015** -  
Cleaning of endoscopes has come under the radar again. Click here to find out more. **MORE**

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September 17 **CAN ENERGY MANAGEMENT BENEFIT INFECTION PREVENTION?**  
Andrew Streifel, University of Minnesota

September 24 (Free Teleclass)  
**EVIDENCE VS. TRADITION: EXAMINING THE EVIDENCE OF BATHING TO REDUCE HAI'S**  
Kathleen Vollman, Advanced Nursing LLC  
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September 28 (Free British Teleclass ... Broadcast live from the 2015 IPS conference)  
**WHAT DID THE ROMANS EVER DO FOR US?**  
Carole Fry, Healthcare Infection Society

September 29 (Free British Teleclass ... Broadcast live from the 2015 IPS conference)  
**FAECAL TRANSPLANT TO TREAT CLOSTRIDIUM DIFFICILE DISEASE**  
Carole Fry, Healthcare Infection Society

September 30 (Free British Teleclass ... Broadcast live from the 2015 IPS conference)  
**THE EMERGENCE OF MERS: FROM ANIMAL TO HUMAN TO HUMAN**

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