Influenza Vaccine and Health Care Workers: Why Not?

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Public health mandates for vaccines

"Boards of health, if in their opinion it is necessary for public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants of their towns, and shall provide them with the means of free vaccination. Whoever refuses or neglects to comply with such requirement shall forfeit five dollars."

—Text of the first US mandatory vaccination law, implemented in Massachusetts in 1809 and the subject of the US Supreme Court's landmark *Jacobsen decision* (Jacobsen 1905)

Mandates for vaccines

- Entry into countries
  - Yellow fever vaccine
  - Meningococcal vaccine – Saudi Arabia for the Hajj
- School entry
  - Childhood vaccines and public schools
  - HepB, MMR, Varicella, TdaP - medical and nursing schools
- Occupational licensure
  - Paramedics, some physicians

What do we mean by mandatory in public health?

- A mandate requires that
  - Opting out requires more than just saying "no"
  - There is an enforcement method, and a consequence

Wynia Am J Bioethics 2007;7:2-6

Enforcement of "mandates"

- None
- Moral suasion
- Signed declination
- Stated philosophical or religious objection
  - bureaucratic complexity
  - requirement for notarization
  - restrictions on religion/philosophy
- Medical contraindications only

Percent of states with >1% of school entrants claiming exemptions, by complexity of exemption process, 1998

Complexity level	Description of process	Percent of states with >1% exemptions
Low	Exemption form available at school, must be signed by parent	5/15 (33%)
Med	Exemption form available only at local health department and/or written statement required from parent which must meet specified criteria.	2/14 (14%)
High	Both exemption form and letter from patient required and/or notarization of signature, and/or additional letter from church or state authority	0/19

Rota JS AJPH 2001;91:645

When should a public health intervention be mandatory ?

- When the burden of disease is significant
- When there is clear medical value of the intervention to the individual
- When there is clear medical value of the intervention to public health
- When there is no other means to obtain the public health benefit

Wynia Am J Bioethics 2007;7:2-6

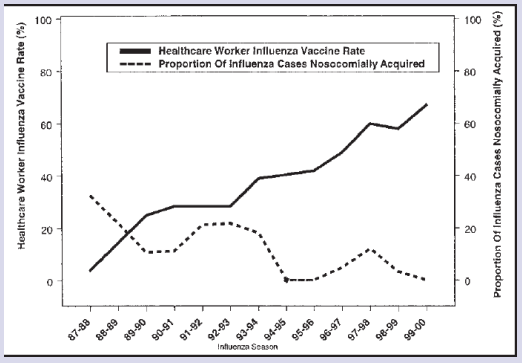
Estimates of Canadian influenza mortality burden

	Mortality rate per 100,000 pop/yr	# Deaths per year, Canada	Methods
CDC – P&I 1976-2007	2.4	700	Serfling model, adjusted for influenza and other viral activity
CDC – all 1976-2007	9.0	2600	Serfling model, adjusted for influenza and other viral activity
Canada 1990-1999	13	4000	Poisson regression, adjusting for season, viral activity
ONBOIDS 2006	2.2	700	Epidemiologic studies to estimate contribution of influenza to respiratory infection syndromes
TIBDN 2005-2011	1.1	370	Laboratory confirmed, hospitalized cases; in-hospital mortality

Thompson, MG MMWR 2010;59:1058-62; Schanzer D Epidemiol Infect 2007;135:1109-16
Kwong J [illegible] ; unpublished information TIBDN

Influenza mortality rates compared to common causes of mortality in Canada

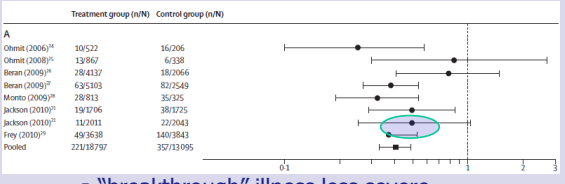
Disease	Mortality rate (/100,000/year)	Deaths per year, Canada
Lung cancer	48	20,500
Breast cancer	12	5,000
Heart attacks	37	16,000
Stroke	32	14,000
Road accidents	5	2,000
Influenza	2.2-4.4	700-2,500



Salgado ICHE 2005;11:923

Efficacy of influenza vaccine healthy adults

- 59% reduction in PCR confirmed, symptomatic influenza infection



- "breakthrough" illness less severe

Osterholm Lancet ID 2012;12:36

Common adverse effects after TIV in healthy adults

Symptom	Placebo	Vaccine
Fever	6.1	6.2
Tiredness	19.4	18.9
Malaise	17.5	16.0
Muscle aches	5.7	6.2
Headaches	14.4	10.8
Sore arm	24.1	63.8

Nichols et al. Arch Int Med, 1996;156:1546

Risks of influenza vaccine: healthy adults

- Common
  - Sore arm (40%): in 2 missed work days/100 vaccinees
- Less common
  - ORS (~1/10,000): ~15% with a MD visit
  - Allergic reaction (~1/20,000)
- Uncommon
  - Anaphylaxis (1/500,000)
  - Guillain Barré Syndrome (1/1,000,000)

Nichol NEJM 1995;333:889-93; Saxen PIDJ 1999;18:779; Wilde JAMA 1999;281:908; Nichol JAMA 1999;282:137; Smith Cochrane 2004, CD000245; Aroll,Keally Cochrane 2005, CD000247; De Serres, personal communication; Skowronski CID 2003;36:705; Price BMJ 2009;339:b3577

Reduction in illness associated with influenza vaccination, healthy adults

- Episodes of ILI: 3-10 per 100 vaccinated
- Sick days: 21-52 per 100 vaccinated
- Antibiotic scripts: ~0.7 per 100 vaccinated
  - (with associated adverse events, allergies, CDAD)
- Hospitalization: 1 per 100,000
- ICU admission: 1.2 per 1,00,000
- Death due to influenza: 1 per 3 M annually
- Guillian-Barré syndrome:

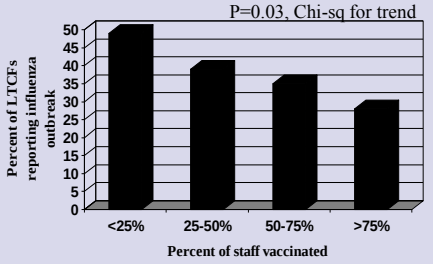
Nichol NEJM 1995;333: 889-93. Saxen PIDJ 1999;18:779. Wilde JAMA 1999;281:908. Nichol JAMA 1999;282:137.

Comparison of risks

Vaccine	No vaccine
9 minutes missed work	135 minutes missed work
40% chance of sore arm	33% chance of acute resp illness
1 in 5000 chance of allergic reaction	2 in 100 chance of illness needing antibiotics
1 in 1,000,000 risk of hospitalization (allergy/GBS)	1 in 100,000 risk of hospitalization due to influenza
1 in 50 million risk of death	1 in 3 million risk of death

Nichol et al. JAMA 1999;282:137; Smith et al. Cochrane 2004, CD000245; Aroll,Keally Cochrane 2005, CD000247; McGeer CID 2007; TIBDN unpublished information Neuzil JAMA 1999;281:907

Annual risk of influenza outbreaks by percentage of staff vaccinated



Stevenson CMAJ 2001;164:1413-9.

The Scope of the problem

- Influenza causes by far the highest number of deaths among vaccine-preventable diseases.
- Hospitalized patients are more vulnerable to influenza than members of the general population.
- The impact of infection on the frail can lead to failure to return to self care – the 3rd commonest cause of catastrophic disability behind only stroke and CCF. Wait for long term care bed rather than going home

The Scope of the problem

- Vaccination of healthcare workers reduces the risk to patients - frequently implicated as the source of influenza in healthcare settings and patient mortality and morbidity goes down when HCWs are vaccinated.
- Health care workers and health care systems have an ethical and moral responsibility to protect vulnerable patients from transmissible diseases.
- Transmission occurs before symptoms are obvious

HCW Vaccine – Ethical Issues

- Must put patients first
- Must do no harm
- Must protect those who can't protect themselves

EXPERT BODIES

NACI

- HCWs who have direct patient contact should consider it their responsibility to provide the highest standard of care which includes influenza vaccination.
- In the absence of contraindications, refusal of HCWs who have direct patient contact to be immunized implies failure in their duty of care to patients.

..and other organisations

- American Hospital Association
- American College of Physicians
- American Academy of Pediatrics
- Infectious Diseases Society of America
- Society for HC Epid of America (SHEA)
- National Patient Safety Foundation
- Over 150 Organisations in 36 states
- Health Officers Council of BC

SHEA

- Therefore, for the safety of both patients and HCP, SHEA endorses a policy in which annual influenza vaccination is a condition of both initial and continued HCP employment and/or professional privileges

LANCET Editorial

- Vaccination is a duty one assumes in becoming a healthcare provider
- Mandating vaccination is consistent with professional ethics, benefits many, including those who must rely on HCW to protect them, maintains a stable workforce, and sets an example that permits honest engagement with others working in hospital settings and the general public in educating them about the right thing about vaccination

BMJ Editorial

- There is clear evidence that healthcare workers play an important role in transmitting infections to their patients.
- Nosocomial flu infections have a high case fatality rate of 27%, especially in patients with comorbidities.
- Trivalent inactivated vaccine is safe and has a vaccine effectiveness of 70-90% in the presence of a good strain match
- flu vaccination must be mandatory in all HCW workers who have direct contact with patients.

Strategies

- Baseline 40%
- Access increase 40%
- Messaging
  - Posters 40%
  - Badges 40%
- Inducements 40%
- HUGE Inducements 40%
- Product Champions 40%

Alternatives ?

- No other method, be it performance linking, marketing, or offering inducements works to raise coverage to acceptable levels.
- Conversely, no model of introduction in the variable US settings failed to achieve exceptional coverage

Consistent drivers

- Messaging patient safety – the right thing to do
- Senior leader priority – core competence for managers
- Responsibility shared across organisation
- Multi-disciplinary planning committee

Key Drivers Behind Program

- It is a **patient quality and safety** issue akin to handwashing, isolation of infected patients, the use of masks and so on .. this policy reinforces our core business
- We have other mandatory processes already such as requiring immunity to measles, mumps, rubella, requiring TB skin testing, and requiring proper attire in the OR.
- It is an "excellence of organisation and leading edge "issue.

Key Drivers Behind Program

- It is increasingly seen in North America as an accreditation issue
- In addition to being a quality and safety issue **it is cost saving**. One study in health care setting showed absenteeism related to respiratory disease reduced by 28%. Many studies in other industries showed cost savings with worker vaccination
- It protects staff and their families as well as patients
- It aids capacity for disaster preparedness – annual influenza vaccination of staff can be seen as a drill to be prepared for a disaster event involving communicable disease

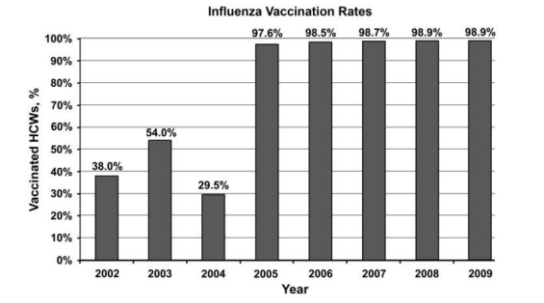
Messaging

- Marketing the patient safety in messaging and ignoring the savings – the right thing to do not the way to save some money
- Having it as a Senior Leader Priority - Every US organization told us it must come from the top down – Must be an organizational priority – a core competence for all managers and staff.
- Every organization developed strategies & practices to share responsibility. Most had very few OH nursing resources – their role was to coordinate rather than give thousands of immunizations themselves.
- Core Job Requirement – condition of employment rather than a fitness for duty program

Improving HCW vaccination rates

Hospital	Program	PCT vaccinated	
		Pre	Post
Cadena, 2011 Single hospital	QI methodology: PDSA cycle, with weekly meetings, force-field analysis, cause and effect diagrams, process flow charts, Gantt charts	59%	77%
Ribner, 2008 Single hospital	task force, senior management visible support, weekly feedback to managers, T-shirt given out to vaccinees, declination form required	43%	67%
Rakita, 2011 Single hospital	Task force, education, on-line modules, champions, incentives	38%	54%
Ajenjo, 2010 Multiple	Education, communication, incentives, feedback, leadership involvement, prizes, competitions, declination forms	45%	72%
Zimmerman, 2009 multiple	Education, communication, incentives, accessibility	32%	39%
Lopes, 2008 Single hospital	Education, communication, incentives, accessibility, leadership involvement	6%	49%

Virginia Mason Medical Center



Rakita ICHE 2010;31:881

US outcomes

- Mandation with Medical Exemptions 98%
  - But more pain
- Vaccine or masks 95%

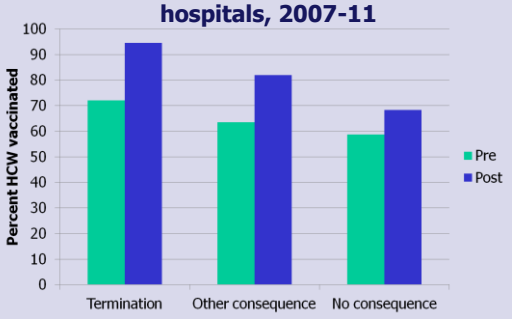
Summary of Employee Vaccination Status.

Vaccination status	No. (%) of employees
Vaccinated	25,561 (98.4)
Religious exemption granted	90 (0.35)
Medical exemption granted	321 (1.24)
Egg allergy	107
Prior reaction and/or allergy to other component	83
History of Guillan-Barré syndrome	15
Other	116
Policy compliant (vaccinated or exempt)	25,972 (99.96)
Noncompliant (neither vaccinated or exempt)	8 (0.03)
Total employees	25,980

Babcock H M et al. Clin Infect Dis. 2010;50:459-464

Clinical Infectious Diseases

Change in vaccination rate associated with institutional requirement, by consequences associated with refusal, US hospitals, 2007-11



What is happening in Canada?

- Mandatory programs in Ontario
  - North Bay General Hospital (2007)
  - ~10 of 38 local health units
  - at least one nursing home
- British Columbia
  - For 2012, all employees and physicians with privileges in regional health authorities will have to be vaccinated or mask during the winter season

Why Are Rates Low?

- HCW believe they:
  - Are not at risk of being infected
  - Will not transmit infection to patients
  - Influenza vaccine is not effective in preventing infection
  - Concerns about the safety of influenza vaccine and risks of side effects
- None of these supported by the science

Masks for Unvaccinated HCW: Rationale

- Masks can serve as method of source control of infected HCW who may have no symptoms
- Masks may protect unvaccinated HCW from as yet unrecognized infected patients or visitors with influenza
- Masks, in conjunction with hand hygiene, shown to have reduced rates of influenza-like illness in residents of college dormitories and households[1,2]
- Mask or respirator can filter influenza virus to undetectable levels when measured by real-time polymerase chain reaction (PCR) at a distance of 20 cm from an infected patient [3]

1. *JID* 2010; 201:491-498
2. *Ann Intern Med* 2009; 151:437-446
3. *CID* 2009; 49:275-277

How Did They Do It?

- Has to come from the top down – set as an organizational priority
- Core competence for managers and staff
- Senior leaders have to put in time, esp. in the first year of the policy
- Responsibility for immunizing shared across the organization, not just Occ Health

More on the How

- Multidisciplinary committee with varied leadership
  - MDs, RNs, OH, IC, HR, IT, comms, legal
- Planning varied; 6 weeks to several years
- The first year is the most difficult
  - "it takes less effort now to achieve 95% than it did to achieve 45%"
  - "it becomes the way you do business"

What Are the Policies?

- Policies apply equally to all – "if you go into a building where patient care is provided you are included"
- Must be immunized by a cut-off date
- A few allow medical and religious exemptions – but carefully screened and +++work
- Most allow masking as a substitute for immunization, but 24/7, Dec-April

Implementation Issues

- Questions about the science
- Where should the policy be applied?
- Why masks as an alternative?
- Questions, questions, questions…

Dealing with Issues

- I am the
  - Licensed practical nurse
  - ENT surgeon
  - Midwife.....
  - And I have looked at the internet, looked at the Cochrane review, reviewed the components of flu vaccine....
  - And I disagree with the decision, the science, the communication, the benefits, the safety, the process etc

Dealing with Issues

- I acknowledge your views but need to respect the expertise of groups like the 15 infectious disease, immunology, and vaccinology experts on NACI
- Flu vaccine is safe and works
- Please wear a mask during the designated winter months
- Do not answer the wrong questions

Cochrane plus effectiveness

- Cochrane most consistent reason given of those not vaccinating .. particularly used by physicians
- Combined with the Osterholm VE debate .. Only 60% effective
- Effectiveness in unvaccinated ??

Where Should Policy be Applied?

- Should policy just be applied to LTC?
- Should policy be introduced gradually?
- Lesson learned: All who work in patient care facilities are in from day one
- Anything else
  - Prolongs the pain
  - Is inequitable
  - Reduces herd immunity
  - Not supported by the science

Why Masks as an Alternative?

- Vaccination more effective than masking

- **BUT**:

- Masks can serve as source control for infected HCW who may have no symptoms
- Masks in conjunction with hand hygiene have been shown to reduce rates of ILI in dormitories (JID 2010)
- Masks filter virus to undetectable levels measured by PCR 20 cm from infected person (CID 2009)

LHSC 2013-14

- Medical Director of Infection Prevention and Control, in consultation with the Medical Officer of Health confirms influenza is widely circulating in our community:
- Staff and affiliates, who received an influenza vaccination for this influenza season, will be deemed fit to work and will continue to be scheduled and assigned work.
- All non-vaccinated staff and affiliates for that influenza season who enter a patient care area will be required to wear a procedure mask.
- Failure of staff to wear a procedure mask as required or directed will be sent home without pay and may be subject to discipline, which may result in termination.

Thanks to:

- Dr Allsion McGeer and Dr Paul Van Buynder, whose slides I have shamelessly copied and borrowed!


I need you here