Testimony of Mary Consoli, President
Danbury Nurses’ Union Unit #47, AFT Connecticut Local 5047

In Opposition to SB 1128
An Act Concerning Influenza Immunizations For Health Care Employees
Public Health
March 20, 2013

I am Mary Consoli, President of Danbury Nurses’ Union Unit #4, American Federation of Teachers Local 5047. On behalf of the 600 plus registered nurses I represent, I want to thank Representative Susan Johnson and Senator Terry Gerratana, Co-Chairs, and the entire Public Health Committee for the opportunity to testify in opposition to SB 1128, an Act Concerning Influenza Immunizations for Health Care Employees.

Neither the CDC nor the Joint Commission has determined that mandatory immunization is a useful policy. Unit #47 is in support of influenza immunization, but opposes the mandatory nature of this bill. Instead, a voluntary comprehensive employee influenza immunization campaign would be more effective, and will achieve the Healthy People 2020 Annual Goal of 90% influenza vaccine coverage for health care personnel. Through a collaborative effort between the Danbury Nurses’ Union, Unit #47, New Milford Hospital Nurses and Western Connecticut Health Network, such a voluntary program was put into place throughout the entire network. We were able to reach the desired 90% compliance.

The comprehensive employee education program included: educating all employees on the risks and benefits of flu vaccinations, addressing myths and misunderstandings about flu vaccinations and efficacy rates of the vaccine. The vaccinations were provided at work, while on duty for all shifts at no cost to the employees. All employees were offered one of three types of the vaccine; standard dose, preservative free and an inhaled method of administration. There was an informed declination for those employees who opted out of the program after receiving the education. They could opt out for medical, religious or personal reasons.

More and more hospitals throughout the country are using this approach with success. Some of them are:

- University of Iowa hospital, Iowa City
- Swedish Medical Center, Seattle
- Children’s Hospital of Philadelphia
- Harborview Medical Center, Seattle
- Finley Hospital, Dubuque, Iowa
Immunization alone will not prevent the spreading of the flu virus. It is a part, a tool, and may not be the most important part, of a comprehensive influenza plan. That includes the emphasis on hand washing, good respiratory hygiene (cover your cough), use of personal protective equipment and clothing (masks and gowns) and limiting the risk of exposure, i.e. not coming to work if you are symptomatic and limiting visiting to the hospital. A good model for this approach is the OSHA blood-borne pathogen standard which requires employers to assess potential exposures throughout a facility and then develop a plan to address those exposures.

Flu vaccination is only moderately effective in protecting against influenza. Recent research (2011) shows an efficacy rate of 59%. In a year in which the match between the vaccines and the circulating virus is low, the efficacy rate can be close to zero. Making vaccination mandatory unreasonably elevates its importance and provides a false sense of security for the public without greatly increasing their protection against infection. There is little evidence that vaccinating healthcare workers will prevent influenza among patients. A recent review published in the research journal Vaccine concludes, “The benefit of vaccinating health care workers to protect their patients remains highly questionable and should not be mandatory at present. A quote from OSHA:

“OSHA is strongly supportive of efforts to increase influenza vaccination rates. However, at this time, OSHA believes there is insufficient scientific evidence for the federal government to promote mandatory influenza vaccination programs that do not have an option for the health care employees to decline for medical, religious and/or personal philosophical reasons.”

Until there is more conclusive evidence, flu vaccination should not be mandatory in Connecticut.

Vaccination can be life threatening for some and increase certain health risks for others. One may have a chronic illness, and risk infection as a result of vaccination because their immune system’s inability to respond appropriately to the vaccine. We had one RN at Danbury Hospital have a severe allergic reaction. If it were not for the fact she was working in the Emergency Department, the consequences could have been more life threatening.

Forcing employees to be vaccinated is coercive and violates personal liberty. Employees should be educated and encouraged to receive vaccinations, not forced.

In conclusion I want to quote from, Aust Jour of Public Health, Jul 2012. “Given the poor evidence base and uncertainty about the degree of risk to patients from unvaccinated healthcare workers, it is difficult to justify the degree of emphasis currently placed on mandating universal healthcare worker vaccination.”
Unless and until, there is a greater body of scientific evidence, that influenza vaccination is the only way to protect patients from the flu epidemic, do not mandate flu vaccination for Connecticut health care workers. I ask you to oppose SB 1128. Thank you.

Mary Consoli
18 Great Plain Road
Danbury, CT 06811
January 16, 2012

National Vaccine Program Office
US Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination Subgroup
200 Independence Ave, SW
Room 733-G.3
Washington, DC 20201

Dear Subgroup Members:

On behalf of 1.5 million members of the American Federation of Teachers (AFT), I thank you for the opportunity to submit comments on the draft **Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel** (15 December 2011, V1.8). The AFT represents over 75,000 healthcare personnel in the AFT Healthcare division. Those healthcare workers include nurses in both acute care and long-term care facilities, school nurses, medical and radiological technologists and environmental service workers among others. We commend the sub-group in addressing both the interests of patient and healthcare personnel (HCP) in their recommendations to the National Vaccine Advisory Committee (NVAC).

The American Federation of Teachers submitted comments to the National Vaccine Program Office draft policy in January 2009. At the time we recommended that the NVP look to the comprehensive regulatory approach developed by OSHA on blood-borne pathogen exposure as a model to improve both healthcare personnel and patient safety. We are heartened that the Assistant Secretary of the Department of Health and Human Services (DHHS) acted upon some of our comments and constituted a working group to produce recommendations for the larger National Vaccine Plan and that DHHS reached out to the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) to participate in the process. As indicated by the Healthcare Personnel Influenza Vaccination Subgroup’s (HPIVS) report, consideration was given to a more comprehensive approach to reaching the goal of greater healthcare personnel influenza immunization.
It is our understanding that the sub-group was charged with focusing its recommendations on improving influenza immunization rates of healthcare personnel (HCP) to reach the Healthy People annual goal of 90% influenza vaccine coverage. We believe that the HCPIVS recommendations are more nuanced than those in the previous NVP drafts. The current draft recommendations acknowledge that data are lacking and that more surveillance of HCP immunization should be conducted before universal adoption of HCP mandatory immunization is recommended. However, the report indicates that the majority of the working group leans strongly in favor of mandatory immunization.

We remain unconvinced that mandatory influenza immunization is the most effective and sole approach for reaching the goal of 90% immunization of all healthcare workers. We concur with the first two recommendations of the working group. Comprehensive influenza infection prevention programs are essential for all healthcare facilities and settings; HCP immunization goals should be a part of those programs. However, the AFT believes that the subgroup has not given due consideration to a comprehensive occupational safety and health regulatory approach as an equally effective approach to achieving the 90% goal. Currently, there has been a patch-work of adoption of sound infection control and healthcare worker occupational safety and health programs on the part of healthcare employers. Granted, one may find exemplary models of these programs among larger healthcare employers. Others – especially smaller healthcare employers - however have been slow to take a comprehensive approach to protecting patients and healthcare workers. For instance, too many have neglected the training and information that are promoted in the sub-group report. They have not developed programs to encourage or create incentives for workers with influenza-like illnesses (ILI) to take sick leave and/or be evaluated by a healthcare provider. Others may have adopted the practice of mandatory influenza immunization but have passed on the costs to many low-wage healthcare workers who can ill-afford the economic burden.

We would recommend expanding recommendation three to include other key federal agencies in creating incentives and requirements – especially the Occupational Safety and Health Administration. A comprehensive OSHA standard is the most effective vehicle for bringing the healthcare personnel immunization to scale. The mandate should be the adoption of a comprehensive standard similar to OSHA blood-borne pathogen standard with requirements for training, voluntary immunization and declination after education. When healthcare personnel received training as part of the OSHA blood-borne pathogen standard, they readily accepted hepatitis vaccine as part of a broad program with the result of improved both worker and patient safety.

The AFT believes that the subgroup can strengthen its recommendations in other areas as well – especially in the arena of research. The subgroup acknowledges the gaps in surveillance and research evidence as well as the lack of standard measures healthcare employers can use to gauge HP immunization. AFT believes that the sub-group should expand the recommendation
for research to include vaccine efficacy among healthcare workers. Universal healthcare personnel influenza immunization may be an imperfect solution for protecting both patients and workers. What little research we have to date\(^1\) indicates that the effectiveness in target populations varies considerably. Those persons with co-morbidities such as diabetes, cardiovascular disease and other chronic illnesses do not readily mount an adequate immune response after vaccination and hence constitute a population at risk for infection after immunization. There is some indication that healthcare workers as a group are less healthy than the general population\(^7\). A review of healthcare insurance costs for healthcare personnel revealed that HP were more likely to be diagnosed with serious chronic diseases such as asthma, diabetes and heart disease than the general population. HP may need to be considered a vulnerable population with a different set of assumptions made about immune response to seasonal influenza vaccines than those made for a healthy, young population. More research through long-term prospective studies on vaccine efficacy within HP is essential to inform policy recommendations.

Similarly the efficacy of influenza seasonal immunization appears to fluctuate significantly from year to year and no surveillance or research tools exist to gauge efficacy during an influenza season. One researcher estimates the seasonal influenza vaccine efficacy to hover around 59\%.\(^3\) And we may reasonably anticipate influenza seasons when the antigenic match of the vaccine and the circulating viruses is low. In such seasons, reliance on universal HP immunization may not prove to protect either healthcare workers or patients.

Clearly much more aggressive research is required to gauge vaccine efficacy and immunologic response among healthcare personnel before sweeping policy can be made.

The AFT believes that establishing a mandatory seasonal influenza program is a change to the terms and conditions of employment. Therefore those healthcare employers with unionized workforces cannot unilaterally implement mandatory influenza programs with the consequence of discipline or discharge for those unwilling to do so without negotiating with the union should the union wish to do so. The National Labor Relations Board (NLRB) recently upheld that right in its decision in the Virginia Mason Hospital and Washington State Nurses Association, Case 19-CA-30154, August 23, 2011. In our opinion, a far better seasonal influenza infection control program that includes HP seasonal influenza policies would also result when employers and worker representatives enter negotiations.

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\(^1\) Michiels B et al. A systematic review of the evidence on the effectiveness and risks of inactivated influenza vaccines in different target groups. Vaccine 29:9159-9170, 2011


\(^3\) Osterholm MT et al. Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis. The Lancet Infectious Disease. Published online October 26, 2011.
In closing, the AFT believes that HCP influenza immunization alone is an imperfect strategy to guarantee both patient and healthcare worker safety. A better approach in our view is a comprehensive occupational health and infection control plan that includes voluntary immunization, training and education. A regulatory approach is a far more efficient mechanism for reaching scale on healthcare personnel immunization. A regulatory approach will guarantee that many healthcare workers who do not work for large healthcare employers will be offered the vaccine at no cost, education, training and monitoring. Furthermore, we believe that focusing solely on mandatory influenza immunization may have a downside of neglect of other important strategies for reducing patient and worker exposure such as patient isolation, improved ventilation and personal protective equipment and clothing. At the same time, there is a striking need for broader research on vaccine efficacy especially among demographic sub-groups of healthcare personnel.

Again, thank you again for the opportunity to submit comments.

Sincerely,

Darryl Alexander
Program Director
AFT health and safety
Belief not science is behind flu jab promotion, new report says
Teen Lenzer
New York

An independent meta-analysis of vaccines against influenza has found that claims of benefit have been significantly exaggerated. The report, released last month by the University of Minnesota’s Center for Infectious Disease Research and Policy, was based on a comprehensive review of data published from 1967 to 2012.1

Evidence for “consistent high-level protection is elusive,” the researchers concluded. Although vaccination was found to provide modest protection from infection in young healthy adults who rarely have complications of flu, the authors found that “evidence for protection in adults 65 years of age and older [who represent over 90% of deaths from flu] . . . is lacking.”

The authors also analyzed recommendations issued by the federal Advisory Committee on Immunization Practices, which provides expert advice to the US Centers for Disease Control and Prevention and which are “often considered the standard of practice . . . around the globe.” The report cited 30 instances in which its advisory statements “did not apply current standards of scientific rigor . . . and did not cite relevant work.”

The report’s lead author, Michael Osterholm, a former CDC consultant and an internationally recognized expert on flu, told the BMJ that a Dutch study cited by the CDC as evidence of vaccine efficacy was seriously flawed and constituted a “sales job.” Nevertheless, Osterholm said, the current jab does offer some protection and should be used until a more effective vaccine can be developed.

Joseph Bresee, chief of the epidemiology and prevention branch in CDC’s Influenza Division, told the BMJ, “I do not agree that CDC has inflated the benefits of influenza vaccine.” He added that he agreed with Osterholm that until better vaccines were available the current ones should be recommended. That recommendation, however, has come under fire from the authors of a Cochrane analysis that also found little to no benefit from flu vaccination.2

Tom Jefferson, lead author of several Cochrane reviews, told the BMJ, “Based on more than a decade of Cochrane reviews in adults, children, [the] elderly,
and healthcare workers, there is no credible evidence that the inactivated vaccines have any effect other than saving on average half a working day in healthy adults and avoiding symptoms in those who least need it: healthy adults and adolescents. Depending on the season, you need to immunize 33 to 99 adults to avoid one set of symptoms."

Osterholm criticized the methods of the Cochrane analysis, saying that the reviewers’ inclusion of studies that used serology titers rather than reverse transcription polymerase chain reaction or cultures to diagnose flu meant that its results were highly inaccurate. However, he acknowledged that the direction of bias caused by use of serology titers would be to make a vaccine seem far more effective than it was, a surprising bias for a meta-analysis that found no benefit for flu vaccines. The Cochrane reviewers also stated in their meta-analysis that the studies reviewed were “at high risk of bias.”

A growing number of healthcare facilities and states now require healthcare workers to be vaccinated against flu or face being fired or forced to wear masks and identification tags stating that they may be infectious.

A recent editorial in the journal of the Canadian Medical Association, CMAJ, recommending mandatory flu jabs for healthcare staff triggered strong criticism, including a letter to the editor from Peter Doshi, a postdoctoral fellow at Johns Hopkins University, and several Cochrane reviewers, who said that the recommendation was based on a misrepresentation of Cochrane data.3 4

Doshi opposes compulsory vaccination. He told the BMJ that health officials “risk losing credibility by continuing to promote the fiction that mandatory influenza vaccination policies are based on solid evidence. They are not, and it is time for healthcare institutions to do their own rigorous assessment of the evidence rather than continuing this dangerous game of follow the leader.”

Osterholm agreed that scientific evidence, not professional opinions, should guide policy. He told the BMJ, “I don’t think the data warrant mandated vaccine. If it was up to me, there are a hundred other things I’d mandate first, like mandating that sick healthcare workers don’t come to work. That is far more likely to be effective.”

bmj.com News: Bias alone could account for benefit attributed to flu vaccine, study finds (2008;337:a1550, doi:10.1136/bmj.a1550); Observations: A jab in the dark (2012;345:e5313, doi:10.1136/bmj.e5313)


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Studies: Flu vaccine effectiveness waned over 2011-12 season

Robert Roos  News Editor

Jan 31, 2013 (CIDRAP News) – It's been more or less an article of faith that influenza vaccination in the fall will protect a person through the winter flu season, but three studies published today in *Euro surveillance* are challenging that view.

All three studies suggest that during the 2011-12 flu season, the vaccine provided modest protection at first, but its effectiveness dropped sharply after 3 or 4 months.

A multicenter study by researchers in eight European countries indicated that overall vaccine effectiveness (VE) against influenza A/H3N2 in the first months of the season was 38%, but after mid-February it dropped to -1%.

Similarly, British researchers report that the vaccine had an overall effectiveness of 43% against H3N2 viruses from October 2011 to January 2012, but it dropped to 17% for February through April. And a study from Navarre, Spain, yielded similar findings, with overall VE of 61% against all flu types for the first 100 days after vaccination but zero effectiveness seen after 119 days.

"The concept that vaccine protection can be so short-lived provides a challenge for public health policy," says the British report. The authors say the findings raise the question of whether a second dose of seasonal vaccine might be needed for late-season outbreaks, and also point up "the pressing need for the development of influenza vaccines which provide better and longer-lasting protection."

The researchers say it's unclear how much of the drop in estimated VE was due to waning immunity and how much was attributable to late-season viral mutations (antigenic drift) or changes in the mix of circulating viruses.

**Multicenter study**

All three studies used the test-negative case-control method, wherein patients with influenza-like illness (ILI) symptoms are tested for flu and asked whether or not they received a flu vaccine.

The multicenter study was part of the Influenza Monitoring Vaccine Effectiveness in Europe (I-MOVE) project, which has been assessing flu VE since 2008. It included 4,362 patients with ILI, of whom 2,084 tested positive for flu; about 85% had H3N2 infections.

After adjusting for various potential confounders, the researchers found that the whole-season, all-ages VE was 25% (95% confidence interval [CI], -6% to 47%),
with a much higher 63% for those ages 15 to 59, but only 15% for those 60 and older.

Further, the authors found that overall effectiveness in the early part of the season, up to week 6 of 2012, was 38% (95% CI, -8% to 65%). After week 6, VE dropped to -1% (95% CI, -60% to 37%).

The report says there was some evidence of a suboptimal match between the 2011-12 vaccine and the H3N2 strains that circulated, and the mismatch might have increased during the season, possibly contributing to the lower VE seen late in the season.

But the researchers also note that it was a late flu season, causing a long delay between vaccination and peak flu activity. They say their data suggest that waning immunity may also be a plausible explanation of the late-season decline in VE.

"It is difficult to disentangle the respective roles of changes in the circulating viruses, possible waning immunity, and otherwise imperfect vaccine," they comment.

**British and Spanish findings**

The British study included 3,869 patients, of whom 396 tested positive for H3N2 and 45 had influenza B. The researchers calculated that overall VE against H3N2 viruses was 23% (95% CI, 10% to 47%).

By time period, the estimated VE was 43% (95% CI, -34% to 75%) for the first 4 months of the season (October through January), but it dropped to 17% (95% CI, -24% to 45%) for the last 3 months.

When the researchers assessed VE according to the interval between vaccination and onset of ILI symptoms, they found it was 53% (95% CI, 0 to 78%) for those vaccinated less than 3 months and just 12% (95% CI, -31% to 41%) for those vaccinated more than 3 months.

The team also found that VE against influenza B was much higher than for H3N2: 92% (95% CI, 38% to 99%).

Besides suggesting that a second dose of vaccine might be needed in some cases, the British authors say their findings indicate that clinicians should suspect flu even in vaccinated patients and should have a lower threshold for prescribing antiviral drugs to prevent flu complications.

The Spanish study included 411 patients who tested positive for flu—93% for H3N2—and 346 controls who tested negative. The overall adjusted VE was 31%
(95% CI, -21% to 60%), with 44% for those younger than 65 and 19% for those 65 and older.

By time period, VE was 61% (95% CI, 5% to 84%) in the first 100 days after vaccination, 42% (95% CI, -39% to 75%) between 100 and 119 days after vaccination, and zero after that. The waning protection occurred primarily in the elderly patients, the authors report.

"This finding could be explained by an immunosenescence phenomenon, aggravated by the long time between vaccination and virus circulation, which was longer than in most other seasons, and the limited match between vaccine and circulating strains," they write.

**Breaking new ground**

Nicholas S. Kelley, PhD, a research associate at the University of Minnesota's Center for Infectious Disease Research and Policy (CIDRAP), which publishes CIDRAP News, said the three studies break new ground.

He said researchers have speculated about waning protection in one flu season, mainly on the basis of studies in seniors, adding, "This is the first real evidence that shows any reduction in how well the vaccine works over the duration of a season." Kelley is the co-author of a major report on flu vaccine effectiveness and related issues, released last October.

Kelley said the I-MOVE study suggests that the reported mismatch between the vaccine and circulating H3N2 strains "didn't really seem to have that much impact" and that the time between vaccination and ILI symptoms appeared to be more important. "Maybe the duration of immunity has a bigger role to play," he said.

He praised *Eurosurveillance* for publishing three studies that challenge the time-honored view that vaccine-induced protection lasts the whole flu season.

"It's still early data, but its commendable to publish something like that," he said. "It's never easy to publish something that doesn't fit with the things we like to say. It shows scientific integrity and a passion for the best data."

**Kissling E, Valenciano M, Larrauri A, et al.** Low and decreasing vaccine effectiveness against influenza A(H3) in 2011/12 among vaccination target groups in Europe: results from the I-MOVE multicentre case-control study. Eurosurveillance 2013 Jan 31:18(5) [Full text]


Second, we have evidence that flu virus is aerosolized not just a droplet transmitted virus. Health care workers were exposed to primarily small particles (respirable size) in one important study. Exposure decreased with increasing distance from the source but exposure sufficient to exceed the airborne 50% human infectious dose of the flu virus at 6 feet from the head of a flu patient. The study result “questions the current paradigm of localized droplet transmission during non-aerosolized generating procedures”. The study also found some “superemitters” of the flu virus indicating some patients may be more infectious than other patients. This study is another argument for a more comprehensive approach that guarantees healthcare workers should have respirators (a minimum of N-95’s) to protect them when caring for patients with any respiratory symptoms. Being vaccinated is never enough to guarantee their protection.

Third – These mandatory influenza laws don’t take into account risk of rare but serious adverse outcomes such as Guillain-Barre syndrome. GBS is an autoimmune disorder that causes CNS symptoms. 2009 H1N1 vaccine was associated with a small increased risk of GBS. The point is healthcare workers who are compelled to be vaccinated must have guarantees that they will not bear the burden of adverse outcomes. Adequate care and compensation must be available for those who experience adverse outcomes from mandatory vaccination.

Fourth – Healthcare facilities must take a more comprehensive, proactive approach to protect both workers and patients that goes beyond mandatory vaccination. The approach should include increasing general dilution ventilation in the facility during flu season to dilute the concentration of influenza viruses in patient care areas. There is evidence that high humidity leads to loss of infectious influenza virus. So along with increasing the ventilation rate, healthcare facilities should increase the humidity during the flu season to over 43% RH. That will reduce the infectivity of the virus and spare everyone. Healthcare workers who experience acute respiratory illnesses should be encouraged to stay at home. Workers should have adequate infection control training and the right type of personal protective equipment. All the things we have been saying for years

Perhaps you should recommend that a state-wide task force with adequate representation of healthcare unions be convened to review all the studies and come out with recommendations for a more comprehensive approach beyond the knee jerk approach of mandatory vaccination.