

OSHA is also concerned that minority comments describing insufficient evidence of a link between worker vaccination against influenza and patient safety have not been adequately addressed in the draft report. In order to prevent any allegations concerning the scientific integrity of this report, OSHA requests that the final report include appropriate minority comments.

While OSHA has serious policy concerns about promoting mandatory influenza vaccination programs, and does not believe that there is sufficient evidence to support such programs, we nonetheless are convinced that influenza vaccination is generally beneficial for worker health and are supportive of efforts to promote vaccination. Accordingly, we support an approach of mandating off-employment of vaccination by employers, mandatory education of workers, and the option for employee declination statements.

OSHA is strongly supportive of efforts to increase influenza vaccination rates among healthcare personnel in accordance with the Healthy People 2020 goals. However, OSHA believes that there must be a very high burden of proof that mandatory taking programs are not just desirable, but also necessary to protect the public health before the government promotes such a controversial policy that may result in employment termination. At this time, OSHA believes there is insufficient evidence for the federal government to promote mandatory influenza vaccination programs that may result in employment termination.

The Occupational Safety and Health Administration (OSHA) offers these comments on the Health Care Personnel Influenza Vaccination Subgroup (HCPVSG) draft report.

Reference: Solicitation of Written Comments on the Draft Report and Draft Recommendations of the Healthcare Personnel Influenza Vaccination Subgroup for Consideration by the National Vaccine Advisory Committee on Achieving the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel (FR Doc. 2011-32308)

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JAN 13 2012

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The scientific literature clearly supports offering the influenza vaccine to workers for the protection of the workers themselves, however OSHA does not believe that at this time the scientific literature adequately supports the notion that vaccinating HCP also provides a significant measure of protection for the patients for whom they care. While we support the Healthy People 2020 goal of 90% HCP vaccination as an aspirational goal, we are troubled that some have tried to convert the goal into a mandate. High HCP influenza vaccination rates are generally desirable, but we are unaware of any evidence to support the notion that such a high influenza vaccination rate is also *essential* to protect patients, and should thus be *mandatory*.

We offer three recent and highly influential studies as support for our concerns:

- Jefferson et al. (Cochrane Database Syst Rev, 2010) states “There is no evidence that they [influenza vaccinations] affect complications, such as pneumonia, or transmission.” The evidence-based review also concluded that “At best, vaccines might be effective against only influenza A and B, which represent about 10% of all circulating viruses [that cause influenza or ILI symptoms].”
- Michiels et al. (Vaccine, 2011) concluded “There is a striking lack of sound evidence for the effect of vaccination on influenza complications such as pneumonia, hospitalization and mortality among individuals with co-morbidities.”
- Thomas et al. (Vaccine, 2010) determined that “there is no evidence that vaccinating HCPs prevents influenza in elderly residents in LTCFs.”

OSHA believes that these recent studies must be substantively addressed in the body of the final report. Furthermore, we are concerned that the subgroup has obscured the issue of insufficient evidence of a link between worker vaccination against influenza and patient safety, by addressing the issue at the end of the section on mandatory vaccination and just before the conclusion (Page 21, lines 4-12). The strength of association (or lack thereof) between worker vaccination and patient safety is a central and necessary element before contemplating whether mandatory influenza vaccination is an appropriate remedy. Additionally, the ethical and legal arguments associated with mandatory influenza vaccination also rely upon the integrity of the scientific evidence. OSHA asks the subgroup to reconsider the ethical and legal arguments in the context of an updated scientific analysis. Accordingly, OSHA believes that these important scientific concerns must be addressed in order to avoid any data quality concerns.

Furthermore, it is well-recognized that there is great variability in the effectiveness of the influenza vaccine in preventing infection, as well as preventing life-threatening illnesses. (Osterholm et al., *Lancet Infect Dis.*, 2012) The vaccine also requires annual reformulation and revaccination. Every year there are numerous circulating strains of influenza that are not included in the vaccine. In years where the antigenic match is good, the vaccine only provides protection against the 3 strains in the formulation. In years when the antigenic match is poor, the vaccine may provide limited or no protection at all. The limits of current influenza vaccine technology are especially problematic in

the context of a mandatory influenza vaccination program that results in job loss. OSHA believes that the report should specifically address the implications of the limitations of current influenza vaccine technology on HCP mandatory vaccination [e.g., that in some cases, a worker could be fired for refusing the influenza vaccine that provides little protection].


Given the current state of the science surrounding influenza vaccination, OSHA disagrees with HCP/AS Recommendation #4 that states that if a healthcare employer (HCE) can not achieve Healthy People's 2020 goal of 90% HCP influenza vaccination rate, the HCE should "strongly consider an employer requirement for influenza immunization." OSHA believes the report should clearly state that HCP should not be terminated from employment for refusing the influenza vaccine. Consequently, we ask that the recommendation be deleted.

OSHA is a strong supporter of appropriate education, ready access and signed declaration statements for HCP vaccinations. OSHA's bloodborne pathogen standard regarding Hepatitis B education and vaccination is a best-practice model. Influenza vaccination exemptions should be allowed for HCP with valid medical contraindications to vaccinations, or religious and/or personal objections. In addition, a signed declaration statement should indicate that the HCP has been educated regarding influenza; is aware of the risk and benefits of influenza vaccination; has been given the opportunity to be vaccinated at no charge, and can receive the influenza vaccine in the future, at no cost, should they change their mind. We believe declaration statements are an appropriate way that healthcare settings can document employee refusal and employer actions to encourage vaccine acceptance.

OSHA is encouraged by and supportive of HCP/AS DRAFT report recommendations 1, 2, 3, and 5 that state healthcare employers (HCE) establish a comprehensive influenza infection prevention program (HCP/AS Recommendation 1), influenza vaccination programs be integrated with HCE's existing infection prevention programs (HCP/AS Recommendation 2), the Centers for Medicare and Medicaid Services standardize the methodology used to measure HCP influenza vaccination rates (HCP/AS Recommendation 3), and improved and longer lasting influenza vaccines be developed (HCP/AS Recommendation 5).

We thank the subgroup for their work on improving the health and safety of healthcare personnel and will work with you and our colleagues at the Department of Health and Human Services to support efforts to increase influenza vaccination rates.

Sincerely,



Jordan Barab
Deputy Assistant Secretary for Occupational Safety and Health

Supporting Scientific References

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- Michiels B, Govaerts F, Remmen R, Vermeire E, Coenen S. A systematic review of the evidence on the effectiveness and risks of inactivated influenza vaccines in different target groups. *Vaccine*. 2011;29(49):9159-9170. doi: 10.1016/j.vaccine.2011.08.008.
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American Federation of Labor and Congress of Industrial Organizations



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January 12, 2012

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Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

RE: Draft Report and Recommendations of HCPIVS to the NVAC Adult Immunization Working Group on Influenza Coverage for Health Care Personnel

Dear Sir or Madam:

The AFL-CIO is a federation of 57 national and international labor unions representing more than 9 million workers in their workplaces, including workers employed in the healthcare industry. We appreciate the opportunity to submit comments on the draft report and recommendations of the Health Care Personnel Influenza Vaccination Subgroup of the NVAC Adult Immunization Working Group concerned with increasing the rate of influenza vaccination among healthcare workers.

As a representative of healthcare workers, the AFL-CIO believes that all healthcare workers are entitled to a workplace where they are fully protected from exposure to infectious agents such as influenza. In order to achieve this objective, employers must implement a comprehensive infection control program. That program would include an infectious agent hazard analysis; exposure control plan using engineering and workpractice controls along with personal protective equipment; procedures to identify and isolate infected patients; medical surveillance and vaccination of healthcare workers; information and training of healthcare workers; appropriate signage and labeling; housekeeping; and periodic evaluation/revision of the exposure control plan. Such a comprehensive infection control program will protect both healthcare workers and



patients from becoming infected in the workplace with influenza or other infectious agents.

In our view, influenza vaccination of healthcare workers represents an important component of the overall infection control program to protect workers. However, vaccination is only one component and it will not by itself, in the absence of implementing all of the other elements of an infection control program, provide the full degree of protection that workers need. The AFL-CIO supports influenza vaccination of healthcare workers and we encourage healthcare employers to establish effective voluntary programs to achieve high rates of vaccination among its workforce. We do not support, however, mandatory required influenza vaccination programs that compel healthcare workers to become vaccinated under threat of disciplinary action, including discharge, as a means to achieve a vaccination influenza rate target. Mandatory vaccination programs are not necessary in order to achieve high rates of vaccination among healthcare workers.

Recommendation 4 in the draft report from HCPIVS to NVAC states that if healthcare employers cannot achieve the Healthy People 2020 goal of 90% influenza vaccination coverage for healthcare workers, then those employers should "strongly consider an employer requirement for influenza immunization". We urge NVAC to reject this recommendation requirement outright for the set of reasons that we outline below. Should NVAC not reject this recommendation outright, then we would suggest that it be modified to remove the language requiring healthcare employers to establish mandatory flu vaccination and to add language that stresses the importance of establishing training and information programs on the importance and value of becoming vaccinated. This revised recommendation will assist employers and employees in the healthcare sector in achieving high rates of vaccination without the use of discipline or discharge.

Our opposition to *Recommendation 4* and rationale for urging NVAC to reject it is based on the following arguments:

The Healthy People 2020 Objective Of 90 Percent Seasonal Influenza Vaccination Among Health Care Personnel Is A Goal Rather Than A Mandatory Requirement

The Healthy People 2020 has established goals and objectives for improving the health in the United States, including the setting of a "target" of 90% of health care personnel becoming vaccinated against seasonal influenza. While this target of 90% is laudable, there is no evidence to substantiate that this level of vaccination among health care workers is necessary in order to protect them or patients from becoming infected with the seasonal flu. That said, the 90% target represents an arbitrary, but voluntary, objective that health care employers should seek to achieve. This objective under Healthy People 2020 is not

however, a requirement or mandate. Thus, *Recommendation 4*, which calls for an employer requirement to achieve this goal, violates the spirit and intent of the Healthy People 2020 initiative and as a consequence, should be rejected by NVAC.

The Influenza Vaccine Is Not Very Effective And Mandating Its Use Can Provide Employers And Workers With A False Sense Of Protection From Workplace Influenza Exposures In The Absence Of A Complete Infection Control Program

The influenza vaccine varies widely from year to year in its efficacy and effectiveness depending upon the antigenic match with the influenza strains that are in circulation in any given year. And the effectiveness is determined only after the influenza season is over. As a result, the overall effectiveness of the seasonal influenza virus has recently been estimated to be around 59% (1). Thus, on average, the effectiveness of the seasonal influenza vaccine is far less effective than one would desire in a vaccine. Regardless of the proportion of health care workers who receive the vaccine, many of the recipients are likely to have no effective immunological response – particularly in those flu seasons where the antigenic match is poor and the vaccine effectiveness is low. Mandating the seasonal influenza vaccine that is often not very effective creates an illusion that healthcare workers are being adequately protected when they are not – which further heightens the necessity of implementing comprehensive infection control programs (including seasonal flu vaccination as one of its components). And there appears to be no scientific justification to mandate flu vaccination for healthcare workers in order to protect patients (2). The NVAC should not adopt a recommendation for mandating seasonal flu vaccination when its effectiveness is so poor – and one which requires humans to receive a new vaccination every year.

It is well established that there are serious problems with the effectiveness of the seasonal flu vaccine. In our view, NVAC would be far more effective in addressing this issue by advocating for additional research to generate a more consistently effective seasonal flu vaccine – and one that did not need to be given so frequently – rather than to advocate for required use of an ineffective vaccine that could result in healthcare workers losing their jobs.

Voluntary Programs Alone Can Achieve Sufficiently High Influenza Vaccination Rates That Obviate The Need For Mandatory Requirements

Programs and policies that require seasonal flu vaccination for healthcare workers under threat of discipline or even discharge are not necessary in order to achieve high rates of vaccination within a healthcare sector workforce. It is possible for healthcare employers to achieve seasonal flu vaccination rates in

excess of 90% which can achieve the Healthy People 2020 "target" of 90% without resorting to mandatory programs which places the livelihoods of healthcare workers on the line (3). NVAC would do well to take the high road here by strongly supporting research and case studies that identify the impediments and constructive features of programs that will enhance the rate of flu vaccination among health care workers – rather than to encourage employers to adopt policies that terminate workers.

Unilateral Implementation Of Mandatory Seasonal Influenza Vaccination Programs In Unionized Healthcare Facilities Is A Violation Of The National Labor Relations Act – NVAC Should Not Endorse Illegal Acts By Employers

The establishment of mandatory seasonal influenza programs that require, as a condition of employment, healthcare workers to become vaccinated or suffer discipline or discharge for failing to do so is a term and condition of employment under the National Labor Relations Act. As such, employers with unionized workforces cannot unilaterally implement these mandatory programs without negotiating with the union over the program should the union demand negotiations. This legal requirement in unionized healthcare settings was recently upheld in a decision by the full National Labor Relations Board in *Virginia Mason Hospital and Washington State Nurses Association*, Case 19-CA-30154, August 23, 2011 (4). In our view, NVAC should abandon a recommendation for requiring mandatory programs – and leave that issue, should it arise, to be addressed between the employer and the employee's representative.

Healthcare Workers Must Be Provided With Medical, Religious And/Or Personal Reasons To Decline Vaccination So That Their Continued Employment Status Is Not Jeopardized

Healthcare workers must be permitted to refuse the annual seasonal influenza vaccination without fear of reprisal for medical, religious, or personal reasons. Such a declination is fully appropriate as part of a comprehensive employer program that is designed to enhance the likelihood of health care workers voluntarily choosing to receive the vaccination. The experience with OSHA's Bloodborne pathogens standard, which requires employers to provide, but not mandate its use, the hepatitis B vaccine is instructive. The number of cases of hepatitis B among healthcare workers has decreased dramatically despite the fact that workers can decline the vaccine with no reprisals. We think NVAC should adopt a similar posture regarding the seasonal flu vaccine for health care workers.

In closing, we hope that NVAC will adopt our perspective and reject *Recommendation 4* in the report.

Sincerely,

A handwritten signature in black ink that reads "Bill Kojola". The signature is written in a cursive, flowing style.

Bill Kojola -
Industrial Hygienist
Safety and Health Department
202-637-5003

REFERENCES

- (1) Osterholm MT, Kelly NS, Sommer A and Belongia EA. Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis. *The Lancet Infectious Disease*. Published online October 26, 2011.
- (2) Michiels B, Govaerts F, Remmen R, Vermeire E, and Coenen S. 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) Hakim H, Gaur AH, and McCullers JA. Motivating factors for high rates of influenza vaccination among healthcare workers. *Vaccine*. In press, 2011.
- (4) National Labor Relations Board. *Virginia Mason Hospital (a Division of Virginia Mason Hospital Center) and Washington State Nurses Association*. Case 19-CA-30154. August 23, 2011.



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January 13, 2012

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Dear Sir or Madam:

On behalf of our 1.6 million members, including healthcare workers in hospital, nursing home and home care settings, the American Federation of State, County and Municipal Employees (AFSCME) thanks you for the opportunity to comment on the draft developed by the Healthcare Personnel Influenza Vaccination Subgroup (HCPIVS) of the National Vaccine Advisory Committee (NVAC), charged with increasing influenza vaccination rates among healthcare workers.

While we support the bulk of the *Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel*, AFSCME cannot endorse Recommendation # 4 urging that employers require influenza vaccination without allowance for medical, religious and philosophical exemptions, where they are unable to achieve to 90 % compliance. Issues of concern are:

- The use of mandatory vaccination is contrary to the collective bargaining process in union-represented facilities. A new mandatory vaccination policy would be considered a subject of bargaining.
- Efficacy of vaccines for influenza can vary greatly from year to year, and can be as low as 40%. The Centers for Disease Control recently updated its information on vaccine efficacy to be only about 59% in a typical year. Since influenza is an annual vaccination, it should not be compared to the MMR vaccination or even Hepatitis B or pertussis. Individuals, along with the physicians, should have some say if they would want an annual vaccine that may or may not be very effective.
- Although it is generally a very safe vaccine, workers may have a negative outcome from an influenza vaccination even if it isn't as serious as Guillain-Barre syndrome or an allergic reaction. This can be a part of the normal immune response. Many employers use punitive practices such as point systems and discipline for using leave, making it unlikely that employees would be excused for feeling ill after receiving a vaccination. In fact, the HCPIVS does not consider the effects that punitive employer leave policies may have on the rate of influenza transmission or the vaccination rate for healthcare personnel.
- Immunization by itself is not infection control. Good infection control is based on a multi-faceted, systems based approach. Workers' personal actions (getting a shot, hand washing) should not alone be the thrust of any health care organization's policy. AFSCME fears that mandatory vaccination would lead some health care employers to become complacent in other aspects of influenza infection control.

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National Vaccine Program Office

January 13, 2012


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- The Occupational Safety and Health Administration (OSHA) has stated it does not believe that there is sufficient evidence to meet the bar necessary to support mandatory vaccination programs.
- There are still shortages of skilled healthcare personnel in many areas of the country. A requirement for an annual vaccination may drive some out of the profession, or make it unattractive to prospective students

Finally, although an admirable goal, a vaccination rate of 90% for healthcare personnel is not necessary to achieve herd immunity within a facility. As an alternative, AFSCME suggests that the NVAC amend Recommendation #4 to incorporate an employer requirement to provide education, modeled after the highly successful OSHA Bloodborne Pathogens Standard's education requirements for the Hepatitis B vaccine. While the HCPIVS frequently cites the importance of healthcare worker education, none of the recommendations actually encourage, or even mention education.

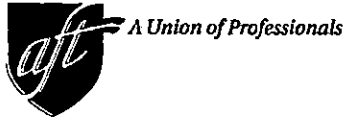
Thank you for considering our comments and concerns as you finalize the recommendations of the Health Care Personnel Influenza Vaccination Subgroup.

Sincerely,



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January 16, 2012

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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 HPIVS recommendations are more nuanced than those in the previous NVP drafts. The current draft recommendations acknowledge that data are lacking and

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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 date¹ 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 population². 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.

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

² Thomas Reuters Research Brief. August 2011. *Sicker and Costlier: Healthcare Utilization among US Hospital Employees*.

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.

National Vaccine Program Office
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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

Healthcare Personnel Influenza Immunization
FR Doc 2011-32308 Filed 12-16-11

The Association of American Physicians and Surgeons (AAPS), a national organization of physicians in all specialties founded in 1943 to preserve the sanctity of the patient-physician relationship, objects strenuously to any coercion of healthcare personnel to receive influenza immunization.

It is a fundamental human right not to be subjected to medical interventions without fully informed consent.

Like all medical interventions, influenza vaccination has risks as well as benefits. Safety testing has been limited, especially concerning long-term health effects of repeated vaccination. It is known that serious adverse effects sometimes occur, and may lead to death or chronic disability. Benefits have been difficult to demonstrate. Benefits to patient populations linked to vaccination rates of personnel, if demonstrable at all, are small. Outside of study populations such as long-term care facilities, benefits are largely hypothetical.

The majority of healthcare workers decline annual influenza vaccination. The government has no constitutional authority to impose medical interventions on individuals, even if put to a majority vote. In the case of influenza vaccination, a majority vote of the affected individuals would apparently be negative. With what justification do "stakeholders" of Healthy People 2020, which is apparently a public-private partnership without specific statutory authorization or oversight, advocate overruling Americans' decision about their own health, even Americans who are medical professionals?

The draft document itself reveals the poor quality of the evidence backing this recommendation. Estimates of annual "influenza-associated deaths" vary 13 fold, from 3,000 to 49,000. This likely reflects annual variation in influenza prevalence as well as uncertain diagnostic criteria. Whatever causes this wide variation will vastly outweigh any effect of higher immunization rates, since efficacy under the best conditions is likely no better than 70%. Of the alleged 200,000 hospitalizations "for respiratory illnesses and heart conditions associated with seasonal influenza infections," we have no idea how many involve vaccine-preventable influenza. The proportion that resulted from contact with unimmunized medical workers is also unknown but probably very small.

The statement that "immunization is the most effective method for preventing infection from influenza and possible hospitalization or death" is an assertion unsupported by evidence. Better handwashing and respiratory hygiene, vitamin D supplementation, use of ultraviolet lights to decontaminate air in enclosed areas, or other methods have not been tested in comparison with immunization.

Notably, recommendations do not include better safety testing of vaccine. This would include measures of health in vaccinated and unvaccinated populations, including prevalence of

allergies and autoimmune conditions. It might also include measures of mercury levels in tissues, since influenza vaccine contains mercury in thimerosal, a known neurotoxin that accumulates in the body. Quantitative comparisons of mercury exposure from medical treatments with environmental exposures that are of concern to the Environmental Protection Agency (EPA) should be part of informed consent. All vaccine components should be tested for potential allergy-inducing adjuvant effects, whether or not they are intended as adjuvants.

Respectfully submitted,
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ASSOCIATION OF FLIGHT ATTENDANTS - CWA, AFL-CIO

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PHONE 202-434-1300 FAX 202-434-1310

Submitted via email to nvpo@hhs.gov

January 16, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue SW
Room 733G.3
Washington, DC 20201
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

RE: Draft Report and Draft Recommendations of the Healthcare Personnel Influenza Vaccination Subgroup for Consideration by the National Vaccine Advisory Committee [NVAC] on Achieving the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel [76 FR 78659]

The Association of Flight Attendants – Communications Workers of America, AFL-CIO (AFA) represents nearly 60,000 flight attendants at 23 airlines. AFA welcomes this opportunity to comment on the draft report and recommendations of the NVAC subgroup.

Flight attendants are trained in many healthcare-related tasks and frequently called upon to provide or support patient care giving activities in the performance of their duties as first responders on board commercial air transport airplanes. As such, the flight attendant profession is clearly a component of the broader healthcare community, and AFA members may therefore be affected should the NVAC subgroup draft recommendations drive substantive changes to government and private employer vaccination and illness prevention policies. Regarding the subject NVAC subgroup report, AFA supports in particular the following draft recommendations:

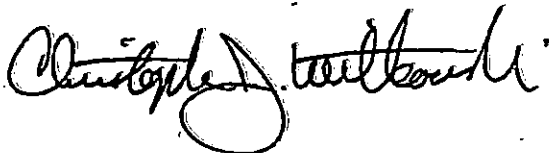
- Recommendation 1, that “facilities establish comprehensive influenza infection prevention programs as recommended by the CDC [Centers for Disease Control and Prevention] ...” AFA agrees with the need for effective vaccines and prevention programs to protect the health of workers. This is especially important for flight attendants, who are in continual and close contact with the public while working and passing through various densely-populated locations that include airplane cabins, airports, shuttle buses / people movers and hotels.
- Recommendation 2, that “facilities integrate influenza vaccination programs into their existing infection prevention programs or occupational health programs...” This is a common sense proposal.
- Recommendation 3, that efforts be continued to “standardize the methodology used to measure HCP [health care personnel] influenza vaccination rates...” AFA agrees that measuring and reporting rates improve vaccination levels.
- Recommendation 5, which encourages “ongoing efforts to develop new and improved influenza vaccines and vaccine technologies...” AFA is aware that studies (particularly in the aftermath of the H1N1 pandemic) have generated uncertainty as to whether influenza vaccines are as effective as they should be. This recommendation if followed should help to improve the effectiveness of vaccines and further limit the spread of influenza within worker populations.

INFLIGHT SAFETY PROFESSIONALS

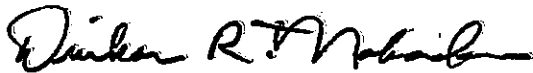
However, regarding Recommendation 4, AFA does not support making influenza vaccination a condition of employment for HCP. As stated in the draft report, this is a controversial and hotly debated recommendation. It is also one that if adopted will have significant, career-altering consequences for workers who object strongly (for whatever reason) to influenza vaccination. AFA argues that there are numerous reasons not to *require* influenza vaccination of employees, including: 1) The Healthy People 2020 goal of 90% coverage of HCP cited in the NVAC subgroup draft report is simply a goal, not a requirement, and scientific evidence supporting the stated value of 90% is apparently lacking; 2) Influenza vaccines are generally less effective than desirable, given the numerous strains of influenza in circulation; and 3) Comprehensive illness prevention programs that incorporate employee training and information, hazard analysis, exposure controls, medical surveillance and *voluntary* vaccination (paid for by the employer) are sufficient to minimize the risks to worker and public health posed by circulating strains of influenza.

In conclusion, AFA supports Recommendations 1, 2, 3 and 5 of the NVAC subgroup draft report, but urges rejection of Recommendation 4 (or, at the very least, deletion of that part of the recommendation that influenza vaccination be a condition of employment for HCP.) Thank you for considering AFA's comments regarding these issues of importance to flight attendants.

Sincerely,



Christopher J. Witkowski
Director
Air Safety, Health and Security Department



Dinkar R. Mokadam, CIH
OSHA Specialist
Air Safety, Health and Security Department



**CALIFORNIA
NURSES
ASSOCIATION**



**NATIONAL NURSES
ORGANIZING COMMITTEE**

January 13, 2012

A Voice for Nurses. A Vision for Healthcare.
www.calnurses.org / www.nnoc.net

National Vaccine Program Office
US Dept. of Health and Human Services
Att: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon
200 Independence Avenue, SW
Room 733-G3
Washington, DC 20201

Dear Sir or Madam:

On behalf of the National Nurses United (NNU), we thank you for this opportunity to offer our comments on the draft, "Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel", developed by the National Vaccine Advisory Committee (NVAC):

National Nurses United (NNU) represents 170,000 members in every state, the largest professional association and labor organization of direct care registered nurses (RNs) in the United States. Our members represent direct care RNS working in every state in the country including Advance Practiced Registered Nurses (APRN) in selected states. Nearly 95% of our membership works in hospitals and/or Critical Access Hospitals. Our mission is to provide safe, therapeutic and effective care in the exclusive interest of our patients and to expand the voice of the direct care RN and patients in the planning, development, implementation and evaluation of public policy as it relates to the health care needs of our patients.

NNU objects NVAC's Recommendation #4, "Healthy People 2020". We appreciate the concern of the Health and Human Services Department Secretary's over increasing influenza vaccination rates among health care providers, and as frontline caregivers, registered nurses (RN) care deeply about health policies regarding the transmission of the influenza virus in health care setting. Further, our organization maintains the position that every RN should be vaccinated against the flu. Despite this, we advise caution against placing an over-reliance upon vaccination as a means to fully stem transmission. Doing so may put RNs, other health care workers, and patients at an increased risk of infection. Issues such as vaccination supply and efficacy make it such that the vaccine cannot be relied upon to exclusively provide adequate protection from the flu virus. As recently as October 2011, the Center for Infectious Disease, Research and Policy, at the University of Minnesota published, "Efficacy effectiveness of influenza vaccines: a systematic review and meta-analysis". The study concludes that the efficacy rate for the influenza vaccine is 59% for working age adults, leaving a significant number of vaccinated individuals unprotected from the virus.

We believe that employer-sponsored voluntary vaccination programs can be effective if the program includes extensive education on the risks and benefits of vaccination, and if vaccines are conveniently accessible to employees. This is one reason we cannot support mandatory vaccination policies, because, rather than being educated on the importance of vaccination, employees are instead coerced into accepting the vaccine, or risk being punished, retaliated against, and, in some cases, fired by their

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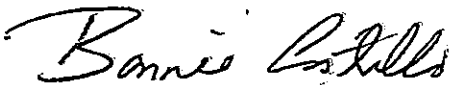
employer. Mandatory flu vaccination programs engender distrust and resistance among employees; offer a disincentive to providing vaccination education to employees, and raise ethical and legal questions about the personal employment rights of employees. This is not the way to protect public health.

Additionally, we'd like to point out that requiring health care workers who decline vaccination to wear a mask will not properly stem the transmission of influenza, and will create a false sense of protection for employees and patients, particularly with regarding to the influenza virus which is know to be airborne transmissible. An abundance of research has shown that masks do not effectively protect health care workers from airborne transmission of disease. They are simply not designed to provide such protection. Mask are not a sufficient substitute for vaccination, and policies that require masks be worn by those who are not vaccinated do not appear to be borne out of science.

We remind NVAC the California Department of Industrial Relations, Division of Occupational Safety & Health, in Title 8, Section 5199, and Aerosol Transmissible Disease (ATD) provides for a declination statement that permits employees to decline the influenza vaccinationⁱ. We believe this is a responsible policy. It states that education is mandatory, but allows for the civil right to decline the vaccination. NNU will vehemently oppose any erosion of this standard and civil right for health care workers.

Rather than imposing an employer requirement to vaccinate, we believe it is safer to require hospitals to offer accessible vaccinations to employees, with extensive education as one part of a comprehensive influenza transmission prevention program that also includes important protective measures such as the provision of safe and appropriate respiratory and personal protection equipment, hygienic improvements, and thoughtful isolation procedures. We hope NVAC will adopt our perspective and reject Recommendation #4 in the report.

Sincerely,



Bonnie Castillo
Director, Government Relations

ⁱ Osterholm, MT, Kelly NS, Sommer A and Belongia EA. Efficacy and effectiveness of influenza vaccines; a systematic review and meta-analysis. The Lancet Infectious disease. Published online October 26, 2011.

ⁱⁱ California Department of Industrial Relations, Division of Occupational Safety & Health:
<http://www.dir.ca.gov/Title8/5199.html>.

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January 13, 2012,

National Vaccine Program Office

U.S. Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination, c/o Jennifer Gordon
200 Independence Avenue SW
Room 733G.3
Washington, DC 20201

Dear Sir/Madam:

The Civil Service Employees Association (CSEA) is writing to comment on the National Vaccine Advisory Committee (NVAC) Health Care Personnel Influenza Vaccination Subgroup's (HCPiVS) draft report; Recommendation on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel.

Our first concern is the basis for the goal of the 90% vaccination rate for health care workers. Our understanding is that there is currently no scientific basis for this goal and that the needed rate of vaccination to obtain a "herd protection" is not generally agreed upon.

CSEA represents approximately 300,000 government employees across New York State many of whom are or directly assist healthcare workers. We strongly support the need for healthcare employers to develop and implement comprehensive infection control programs to prevent the spread of influenza and other infectious diseases among health care workers and their patients. While there is much that we support in the report, we feel that there is a serious element omitted in Recommendations #1 and #2 – the direct involvement of workers and their representatives (if unionized), in the development and implementation of these programs.

Frontline workers and their representatives are in a unique position to understand the scenarios that can lead to disease transmission in their workplace and to evaluate the efficacy, feasibility, and unintended consequences of infection control measures that are prescribed. This involvement, coupled with education and training about all aspects of the program, is critical. Only then will employees understand the role that vaccination plays in a comprehensive program. If the vaccine is then offered by the employer at no cost,

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www.csealocal1000.org



on-site, and during work time, the likelihood of high vaccination rates is great. Several studies have shown that the 90% goal can be easily achieved under these circumstances.

There will likely be scenarios where the vaccination rate is below the Healthy People 2020 goal of 90%. When this occurs, the employer should be encouraged to sit down again with the employees and their representatives to identify the barriers and to collectively address the shortcomings in the infection control and vaccination program.

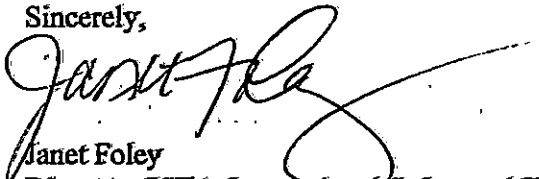
Encouraging employers to mandate vaccination, as the HCPIVS report does in Recommendation #4, is misguided in a few ways. First, it would likely be unnecessary if the employer takes the cooperative approach offered in our previous recommendation. Second, mandating that individuals be vaccinated potentially violates individuals' rights, for those who are unwilling, for reasons of religious or conscious objection, to be vaccinated.

Our experience has been that some employers will rely on this mandatory vaccination program as a panacea, and will pay scant attention to other infection control measures. As the NVAC itself recognizes, the efficacy of the flu vaccine is sub-optimal, and varies annually. Thus, anything that leads to employers' diminished commitment to a comprehensive infection control program should be avoided.

For these reasons, CSEA requests that the U.S. Department of Health and Human Services modify the HCPIVS' recommendations in the manner outlined above, adding a requirement that employers directly involve their workers and their representatives, and eliminate Recommendation #4 of the report.

Thank you for considering CSEA's concerns.

Sincerely,



Janet Foley

Director, CSEA Occupational Safety and Health Department

**COALITION OF
KAISER PERMANENTE
UNIONS**

January 16, 2012

National Vaccine Program Office
US Dept. of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon
200 Independence Avenue, SW
Room 733-G:3
Washington, DC 20201

Re: HCPIVS Draft Recommendations to the NVAC Adult Immunization Working Group on Influenza Vaccine Coverage for Health Care Personnel

Dear Sir or Madam:

The Coalition of Kaiser Permanente Unions is composed of 28 local unions representing 95,000 frontline employees of the Kaiser Permanente health system. Our members work primarily in hospitals, medical offices, and other supporting facilities, and have roles ranging from direct care providers such as nurses, therapists, and technicians, to support workers in environmental and food service, and reception and administration.

The HCPIVS report has progressed in the direction of more a balanced tone, through a clearer recognition that vaccination is just one component of a comprehensive infection prevention program, and by referring often to the importance of worker education and information about flu prevention. However the recommendations remain quite unbalanced, in particular recommendation 4 suggesting employers consider a requirement for healthcare worker vaccination as a condition of employment, and leaves open that this requirement could not allow workers to decline for personal or philosophical reasons. We are also disappointed the recommendations do not address the need for improved, consistent, appropriate education of health care workers about flu prevention.

We encourage NVAC to amend Recommendation #4 to call for an employer requirement to provide education, modeled after the highly successful OSHA Bloodborne Pathogens Standard's education requirements for the Hepatitis B vaccine.

The vaccine is not good enough to mandate

We agree with the broad consensus that it is a worthwhile goal to increase the flu vaccination rates of healthcare workers. We believe it is worth the effort to have more workers and their families vaccinated to reduce their risk of getting the flu. It is encouraging that rates are increasing in the past few years as more effort has been put

into education and outreach around vaccination, and to make vaccination more easily available.

However, we don't understand where the Healthy People 2020 goal of 90% vaccination rate for healthcare workers came from and what evidence it was based upon. The HCPIVS, and their allies in the health industry, are trying to turn this figure from a broad population-wide goal, into a mandatory standard of performance. Yet we are not told why such a high rate is needed. And we particularly question why we should push so hard for a vaccine that is now acknowledged to be only moderately effective, and in some years has little effectiveness at all.

The most recent review, from the fall of 2011, concludes the flu vaccine is only 59% effective in working age adults in a typical year.¹ CDC and others had prior to this been claiming the vaccine was 70 to 90% effective. The evidence has been mounting against this claim, and finally the CDC has, as of last fall, adjusted its claim to a lower range of 50-70%. Unfortunately, this has not led to a pause in the push by some individuals and institutions to make vaccination a condition of employment for healthcare workers.

The assumption that vaccinating health workers is necessary to protect patients, seems logical, but this is not the same as having evidence that it is true to any significant degree. A 2007 review found the leading studies conducted in nursing homes showed no statistical evidence of increased infections among residents from transmission from healthcare workers to patients.² A more recent review published November last year in the research journal *Vaccine* concludes, "The benefit of vaccinating healthcare workers to protect their patients remains highly questionable and should not be mandatory at present."³

Vaccinate-or-mask policies

The 'vaccinate or mask' option some hospitals and county health departments (including San Francisco, Sacramento and Yolo counties in California) are requiring is also not based on evidence of effectiveness. There is no scientific evidence that the routine wearing of surgical masks by unvaccinated healthcare workers protects either patients or the wear of the mask from getting the flu. We believe this practice is intended to coerce and intimidate workers into getting vaccinated, and is not grounded in thoughtful analysis of whether the practice of daily mask wearing protects anyone. Since the flu vaccine is typically only 59% effective in a given flu season (and can be substantially less effective in a bad-match year), and since there are many influenza-like illnesses (ILI) that cannot be prevented by the flu vaccine (about 15% of ILI are caused by influenza) then many workers who are vaccinated can and will get the flu

¹ Osterholm, M., et al., *Efficacy and effectiveness of influenza vaccines: a systematic and meta-analysis. Lancet Infect Dis, 2011.*

² Jefferson, T., et al., *Vaccines for preventing influenza in healthy adults. Cochrane Database Syst Rev, 2007, 7: p. CD001269.*

³ Michiels, B., et al., *A systematic review of the evidence on the effectiveness and risks of inactivated influenza vaccines in different target groups. Vaccine, 2011, 29(49): p. 9159-9170.*

and they can also get another ILI. The logic of the situation tells us that it is not just unvaccinated workers who are at risk of being a pre-symptomatic case of ILI (one of the justification we've been given for such policies). Both vaccinated and unvaccinated HCW could be a pre-symptomatic ILI case. By this logic every healthcare worker should be masked every day during flu season? We are not claiming this is a path that should be followed, but this is the direction logic leads us if we accept that the vaccinate-or-mask policy makes sense. However we do believe this situation makes it clearer still the need for beefing up infection prevention practices (standard; contact and aerosol precautions) as a key to preventing the spread of flu and other ILI.

We are also concerned that all-day mask wearing in the current environment (where masks are not consistently being replaced during the day) would increase exposure to flu virus (and other pathogens) by health workers and their patients due to the frequent mouth/nose/eyes contact that will happen when a worker uses their hands to don, duff and adjust a (possibly re-used) surgical mask throughout the day.

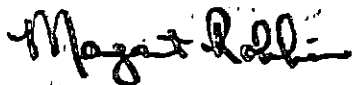
We wish the report and recommendations had reviewed and commented upon the safety and appropriateness of this type of requirement for vaccine refusal.

Workers should not be encouraged, not coerced

We recognize that public health departments have long used police powers to mandate aggressive policies to protect the public from major health threats. However, we don't believe the threat to patients of health workers who are unvaccinated for flu constitutes a major threat to the public health, compared to vaccinated workers. Is it an overall good idea to get more Americans vaccinated? Yes, it is. But that is not the same as saying the government should roll out the police powers to mandate vaccination, or by recommending employers do the same by making flu vaccination a condition of employment. We believe the government and employers should strive to be more effective when they educate and encourage health workers and the public to undertake health protective efforts, including flu vaccination. We can learn from our past, such as the Bloodborne Pathogens Standard, for ways to reach employees with vaccine and other infection prevention information. Employee relations and public health are not well served by the use of coercion to achieve flu vaccination ends. And it is not consistent with our national values openness, respect, and informed consent around medical treatments we receive.

Thanks you for the opportunity to comment on the draft document.

Sincerely,



Margaret Robbins, MPH
National Director, Occupational Safety and Health
Coalition of Kaiser Permanente Unions

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New York State
NURSES
ASSOCIATION

January 13, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination, c/o Jennifer Gordon
200 Independence Avenue SW
Room 733G.3
Washington, DC 20201
nvpo@hhs.gov

Dear Sir / Madam;

The New York State Nurses Association, representing more than 37,000 nurses in New York State, fully recognizes the importance of a goal to protect their colleagues and the patients they care for from the effects the seasonal influenza. The creation and implementation of an integrated fully comprehensive infection control program is the best means to achieve that goal. Vaccination is but a single component of that program and to elevate a single component to a mandatory status, as is suggested in recommendation number 4 of the report, can serve to diminish the importance of the other, equally important components.

Furthermore, the flu begins in the community (200,00 infections) and is brought into the healthcare facility. The report fails to address the efforts healthcare facilities should be taking in the public health arena to stop the spread of the influenza at its source. Rather, after the fact, the report recommends taking healthcare providers away from direct patient care, even considering their termination, if they do not get the vaccine. It is counterintuitive to diminish an already understaffed healthcare work force unilaterally during the peak of the flu season. These tactics, while they may increase the uptake of vaccinations within the healthcare facility, do nothing to impact the root cause of the 200,000 pre-hospital infections.

In the report, NVAC admits that the efficacy of the flu vaccine is sub-optimal for particular populations and during those seasons when the vaccine is poorly matched with the circulating virus or when the strain shifts significantly during the season. Additionally, the vaccine efficacy varies annually. Mandating such a vaccine as the most effective means to stop the spread of the flu is misguided and NYSNA respectfully requests that the U.S. Department of Health and Human Services modify the HCPIVS' recommendations to eliminate the mandatory option for employees. A better alternative, patterned after the Hepatitis B vaccine, would be to mandate healthcare facilities to offer the flu vaccine free of charge and at a time and place convenient for all employees. The use of a standard declination form has also demonstrated positive results for increasing the uptake of the vaccine.

New York State
NURSES
ASSOCIATION

Additionally, NYSNA recommends that the employer be required to directly involve front line workers and their representatives in the development and implementation of a comprehensive infection prevention program.

If the goal is truly intended to reduce the spread of the influenza virus, then a recommendation should also include a mandate for the healthcare employer to participate in the development and offering of community outreach programs in cooperation with the local departments of health to educate the general population on prevention strategies.

Thank you for the opportunity to offer comments to help improve the efforts to stop the spread of influenza, not only in the hospital setting, but in the community on whole.

Respectfully,

Renee Geccedi

Renee Geccedi, MS, RN
Director, Education, Practice & Research
New York State Nurses Association
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Latham, NY 12110
518 782 9400 ext 282

New York State **NURSES** ASSOCIATION

The New York State Nurses Association is the voice for nursing in the Empire State. With more than 37,000 members, it is New York's largest professional association and union for registered nurses. The association represents registered nurses, and some all-professional bargaining units, in New York and New Jersey. It supports nurses and nursing practice through education, research, legislative advocacy, and collective bargaining.



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January 13, 2012

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National Vaccine Program Office
U.S. Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination, c/o Jennifer Gordon
200 Independence Avenue SW
Room 733G.3
Washington, DC 20201.

Dear Sir/Madam:

The New York State Public Employees Federation (PEF) is writing to comment on the National Vaccine Advisory Committee (NVAC) Health Care Personnel Influenza Vaccination Subgroup's (HCPiVS) draft report; Recommendation on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel.

PEF represents 56,000 state government employees in a myriad of New York agencies, including 15,000 healthcare workers. We strongly support the need for healthcare employers to develop and implement comprehensive programs to prevent the spread of influenza and other infectious diseases among employees and patients. While there is much that we support in the report, we feel that there is a serious element omitted in Recommendations #1 and #2 – the direct involvement of workers and their representatives (if unionized), in the development and implementation of the program.

Frontline workers and their representatives are in a unique position to understand the scenarios that can lead to disease transmission in their workplace and to evaluate the efficacy, feasibility, and unintended consequences of infection control measures that are prescribed. This involvement, coupled with education and training about all aspects of the program, is critical. Only then will employees understand the role that vaccination plays in a comprehensive program. If the vaccine is then offered by the employer at no cost, onsite, and during work time, the likelihood of high vaccination rates is great.

There will likely be scenarios where the vaccination rate is below the Healthy People 2020 goal of 90%. When this occurs, the employer should be encouraged to sit down again with the employees and their representatives to identify the barriers and to collectively address the shortcomings in the infection control and vaccination program.

Encouraging employers to *mandate* vaccination, as the HCPiVS report does in Recommendation #4, is misguided in a few ways. First, it will often be rendered moot if the employer complies with our recommendation above. Second, mandating that individuals be vaccinated potentially violates individuals' rights, for the small minority who are unable for medical or religious reasons to be vaccinated. Third, our experience has been that some employers will rely on this mandatory vaccination program as a panacea, and will pay scant attention to other infection control measures. As the NVAC itself recognizes, the efficacy of the flu vaccine is sub-optimal, and varies annually. Thus, anything that leads to employers' diminished commitment to a robust infection control program should be avoided.

For these reasons, PEF requests that the U.S. Department of Health and Human Services modify the HCPiVS' Recommendations in the manner outlined above, adding a requirement that employers directly involve their workers and their representatives, and eliminating Recommendation #4.

Thank you for considering PEF's comments.

Sincerely,

Kenneth Brynien
Kenneth Brynien
President

nurse alliance PA of SEIU

January 16, 2012

National Vaccine Program Office

U.S. Department of Health & Human Services

Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

200 Independence Avenue, SW

Room 733- G.3

Washington, DC 20201

Dear Sir or Madam

On behalf of the Nurse Alliance of Pennsylvania, a subsidiary of Service Employees International Union (SEIU) Healthcare Pennsylvania, thank you for the opportunity to present our comments on the draft, "Strategies to Achieve the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel."

The Nurse Alliance of Pennsylvania is the voice of 10,000 registered nurses and licensed practical nurses in the Commonwealth of Pennsylvania. Our nurses can be found throughout healthcare facilities- working on the frontline in hospitals, long-term care facilities, clinics, and prisons.

As nurses we know the importance for a well-rounded infection control program to combat the influenza virus. We strongly support *employer-sponsored voluntary vaccination programs*.

Employers who provide a well-developed mandated educational program that provides support and answers to the individual concerns of personnel will be rewarded with a strong compliance. Vaccinations should be provided free of charge

and easily assessable on work units to further promote compliance. As such, we would like to declare our support for HCPIVS recommendations #1 and 2.

However, we do not and cannot support HCPIVS recommendation #4 that allows employers to mandate the influenza vaccine for healthcare personnel. We see this as a basic disregard of the civil liberties of individuals based on a supposition that has little or no scientific foundation.

We feel that such a change will promote a false sense of security within the healthcare environment and in the general public. Instead the recommendation should be to promote an increase in those environmental practices that prevent the spread and transmission of the virus within facilities. This would be of more benefit and would provide an effective protection against the spread of influenza.

The annual vaccinations that have been developed provide a limited effectiveness against the influenza virus. When a vaccine can claim only an effectiveness of 38-59%, how can there be a justification that the vaccine is so relevant as to recommend mandating it?

In conclusion, the Nurse Alliance of Pennsylvania supports a *Mandatory-Offering of Vaccination by Employers* as well as a mandatory, well-developed educational program with the option for employee declination statements allowing for medical contraindication, or religious and/or personal objections. Instead, we believe that more progress would be made towards the *Healthy People 2020* goals by focusing efforts and resources on developing a more-effective, longer-lasting influenza vaccine as suggested in HVPICS recommendation #5.

Sincerely,

Deborah Bonn

Director, Pennsylvania Nurse Alliance

SEIU Healthcare Pennsylvania



January 16, 2012

National Vaccine Program Office
US Dept. of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon
200 Independence Avenue, SW, Room 733-G.3
Washington, DC 20201

"The benefit of vaccinating healthcare workers to protect their patients remains highly questionable and should not be mandatory at present." Vaccine, Nov 2011 (1)

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199506-0001-01

Dear Sir or Madam:

On behalf of the Service Employees International Union (SEIU), thank you for this opportunity to present our comments on the draft document developed by the Healthcare Personnel Influenza Vaccination Subgroup (HCPIVS), of the National Vaccine Advisory Committee (NVAC), charged with increasing influenza vaccination rates among healthcare workers. I have also appreciated representing SEIU on the HCPIVS.

Introduction

SEIU is the nation's largest organization of healthcare workers representing more than 1.1 million doctors, nurses and other allied health workers from a broad range of occupations employed in hospitals, nursing homes, home care and other healthcare settings.

We are proud of our track record in promoting immunization of healthcare workers against influenza and other vaccine preventable illnesses. In 1986, when healthcare employees were denied education about, and free access to the hepatitis B vaccine, SEIU appealed to HHS and petitioned OSHA, which led to the promulgation of the OSHA Bloodborne Pathogens Standard of 1991. As a result of this standard, which requires employers to provide annual comprehensive education about the benefits of receiving the hepatitis B vaccine without charge within the framework of a comprehensive bloodborne diseases infection control program, hepatitis B cases among healthcare workers have plummeted from 17,000 to less than 400 per year. (2)

Summary Conclusion/Alternative Recommendation

Based on a number of scientific reviews that have found a lack of statistically significant epidemiological evidence of healthcare worker to patient flu transmission (1,3,4), a relatively low rate of flu vaccine effectiveness compared to other vaccines (5), unresolved legal and civil rights issues (6, 7, 8) and ethical considerations (9,10,11) including financial conflicts with flu vaccine manufacturers (12), there is insufficient justification at this time for the HHS National Vaccine Advisory Committee to vote to adopt Recommendation #4 that will lead to discriminatory and disciplinary action against healthcare workers who refuse to be vaccinated against their will. Such a premature action would undermine the public's trust in federal vaccine policy. (17)

In a straw poll of HCPIVS members conducted in August 2011, there was deep a division on this question of an employer requirement. Only a minority of HCPIVS members (12 of 27) voted for an employer requirement that lacked an exemption for personal and/or philosophic reasons. (13,14) Thus we urge NVAC to reject Recommendation #4 as currently written.

As an alternative, a more measured and appropriate response by NVAC based on the sentiment expressed by this vote of the HCPIVS members would be for NVAC to amend Recommendation #4 to instead incorporate an employer requirement to provide education about the benefits of the flu vaccine vs. forced vaccination. Modeled after the highly successful OSHA Bloodborne Pathogens Standard's education requirements for the Hepatitis B vaccine, this change would also address an apparent oversight. The HCPIVS members and the report itself frequently cites the importance of healthcare worker education in promoting vaccination, yet none of the Recommendations actually include the word "education."

The breath of organizations that strongly support flu vaccination, but are on record concurring with SEIU in opposing a flu vaccine employer requirement in the absence a basic philosophic or personal exemption for healthcare workers include: OSHA, CDC's NIOSH, the EEOC, the AFL-CIO, the AMA (15), the ANA, ACOEM (the largest organization of occupational health physicians), and the Association of Occupational Health Professionals in Healthcare (AOHP), the California Nurses Association (CNA), Leading Edge (the trade association for the non-profit long term care industry), National Nurses United (NNU), the New York State Public Employees Federation (PEF), and the New York State Chapter of the American Civil Liberties Union (ACLU). OSHA asked that their particularly thoughtful statement be included in this final draft HCPIVS report. It is now included as an attachment to this letter for the benefit of, and review by the NVAC membership.

The Science.

Lack of Evidence to Essentially "Legislate" a 90% Goal

While there is broad consensus that increasing flu vaccination rates among healthcare workers is a worthy goal, the HCPIVS was asked to accept the annual Healthy People 2020 goal without reservation and without any supporting documentation to provide a scientific basis to support the imperative of reaching this 90% figure. As this goal was inserted in the Immunization chapter of Healthy People 2020 instead of the Occupational Health chapter, few if any individuals or organizations within the occupational health community or groups representing the interests of healthcare workers, or healthcare workers themselves, were aware of, or consulted about this goal and thus did not have an opportunity to comment. And while this figure has been described as "achievable," none of the eight adult immunization Healthy People 2010 goals have yet been achieved.

Finally while it is fine to aspire to achieve a 90% vaccination rate, it is an entirely different exercise for NVAC to now suggest that this should be an employer requirement. By adopting Recommendation #4, HHS through NVAC will essentially be giving "license" to healthcare employers to do whatever is necessary to achieve this goal with the result that many healthcare workers will be discriminated against and disciplined, forced to wear unproven surgical masks and/or fired if they refuse to get vaccinated.

Vaccine Lacks Sufficient Effectiveness to be Mandated

The most recent review this past fall, which also finally lead to CDC updating their outdated website information, is that the flu vaccine is at best only 59% effective in working age adults in a typical year.(5) It is hard to justify the imperative of achieving such a high vaccination rate with such a marginally effective vaccine. A greater emphasis on achieving Recommendation #5 (a better vaccine), perhaps with its own Healthy People 2020 goal, would automatically lead to increased vaccination rates voluntarily.

Lack of Evidence that Vaccinating Healthcare Workers Protects Patients

While it is reasonable to assume that vaccinating healthcare workers will protect patients, the three most comprehensive reviews of all available epidemiological studies has concluded that unfortunately such information is not available. Remarkably these studies have found no statistically significant evidence that higher rates of vaccination of healthcare workers result in fewer cases of influenza and its complications among their patients. (1,3,4) In the most recently published study in the November 2011 issue of the journal *Vaccine*, the authors concluded that: "The benefit of vaccinating healthcare workers to protect their patients remains highly questionable and should not be mandatory at present." (1) This of course does not mean that healthcare workers cannot transmit the flu to their patients. However more research is clearly needed to document the extent of this potential threat and the efficacy of the current flu formulations in stemming this threat before justifying an employer vaccine requirement. We suggest that strong consideration be given to including a new sixth Recommendation in the final HCPIVS report calling for such additional research.

Lack of Basis to Recommend Surgical Masks

While many employers require unvaccinated healthcare workers to wear surgical masks, it is important to acknowledge that there is no scientific evidence that the wearing of surgical masks by unvaccinated healthcare workers is protective for patients. Instead there is evidence that this practice has been used as a modern day "Scarlett Letter" to label, coerce and intimidate workers into getting vaccinated. Otherwise with a vaccine that is only 59% effective in a given flu season, why wouldn't employers logically require ALL healthcare workers to wear surgical masks, as 4 out of 10 vaccinated workers would also pose a risk? Research has also shown that the more frequent mouth/ nose/eyes contact necessitated when workers use their hands to don, duff and adjust their surgical mask can actually lead to more contamination and potential for infection; not less. (16) Finally as currently practiced, the requirement to wear a surgical mask by unvaccinated workers could rightly be considered a potential HIPAA violation that essentially "broadcasts" the health status of unvaccinated healthcare workers.

The Law

Legally there are a number of barriers to implementing mandatory influenza vaccination programs. While the HCPIVS report relies on a case from 1905 involving the smallpox vaccine, more recent legal actions involving influenza is likely more instructive. In 2009 when New York State became the first state to mandate flu vaccination for healthcare workers, a judge considered the available evidence—including ACLU arguments that such a mandate would violate well established principles of personal autonomy including the right of competent adults to refuse medical care—and issued a stay. (6,7) This is not to suggest that a state never can require vaccination, but this case illustrates that a balance must be struck between the rights of the individual and public health. Comparing influenza with smallpox—a significantly more virulent disease with a much more effective vaccine—obviously makes for a poor comparison. Perhaps this is why, contrary to statements by the New York Department of Health officials that a mandate would be back by 2010, it has never been reintroduced.

Regarding the application of labor law and the ability of an employer to unilaterally impose a workplace based mandate, a recent decision by the full National Labor Relations Board concluded that the employer could not require vaccination nor the wearing of surgical masks without first providing employees with denied requested information, and bargaining over this change in working conditions.

Finally the Equal Employment Opportunity Commission has stated that flu vaccination should be voluntary. (8) Requests to include the ACLU (7) and EEOC (8) information and citations in the final HCPIVS draft report to portray a more balanced legal perspective have repeatedly been denied.

The Ethics

From an ethical standpoint, bioethicists and others have looked at these questions. Professor George Annas, Chair, Health Law, Bioethics & Human Rights, of Boston University School of Public Health reminds us that the practice of medicine is a voluntary pursuit based on informed choice. Forcing nurses and other healthcare workers to become unconsenting patients - even for a flu shot - undermines the consensual nature of the health care relationship. Dr. Annas also believes that the requirement that healthcare workers be vaccinated as a condition of employment will predictably confuse the public who will ask that if healthcare workers won't voluntarily take the swine flu vaccine, why should I? (9) The NY Chapter of the ACLU believes that a mandate will undermine trust in the public health system. (7) On the issue of mandating a vaccine with such limited effectiveness, Peter Sandman, perhaps the leading authority on matters concerning risk communication, argues that overselling flu vaccine effectiveness risks undermining public health credibility; that you will not build public trust. (17)

Additional articles were provided to the HCPIVS leadership team to provide a more balanced viewpoint on this particularly controversial topic. The first article argues that we first need more experience in implementing and evaluating flu vaccine programs, that requirements are premature, counter-productive and foment an adversarial relationship that can weaken trust. (10) The second article suggests we focus our energies on maximizing current best practices and education prior to supporting a mandatory approach. The article argues that while the desire to fulfill national patient safety goals requires our attention, "the ethical justification is not solid." (11)

Requests to include this information and citations in the final HCPIVS draft report to portray a more balanced legal perspective have been denied.

Lack of Financial Disclosure

In recent years, the inspector general of HHS has raised concerns that advisors involved in federal vaccine policy have potential conflicts of interest that are not identified or left unresolved. (12) The issue of the disclosure of financial conflicts of HCPIVS members was raised within our group. It was suggested that such disclosure was important for transparency and could add to the credibility of the report's recommendations. It is known that some HCPIVS members either work directly for, or the organizations that they are affiliated with, or their associated foundations, receive funds from flu vaccine manufacturers. With such concerns in mind, HCPIVS members agreed to divulge such conflicts and include this information in the final HCPIVS report. However Dr. Grabowski, the government official staffing the HCPIVS, stated that after consulting with HHS counsel, a decision was made to not ask HCPIVS members to reveal this information.

In conclusion, SEIU stands ready to continue to work with the government, employers and other organizations to promote the vaccination of healthcare workers against influenza as part of a comprehensive infection control effort.

However based on the lack of a firm scientific basis to support a vaccination rate of 90% along with a lack of epidemiological evidence documenting statistically significant transmission from healthcare workers to patients (1,3,4), as well as significant unresolved legal (6,7,8) and ethical issues (7,9,10,11), it would be premature for NVAC to vote to adopt Recommendation #4.

The practical effect of voting to adopt Recommendation #4 would in essence be to make flu vaccination a mandate for millions of healthcare workers, without NVAC or HHS ever having to go through the typical rulemaking procedures as stipulated under the Administrative Procedures Act. However this divisive action is unnecessary as comprehensive voluntary efforts have been proven to achieve vaccination rates in excess of 90%.

Finally a sound evidentiary base must precede the promulgation any public health policy, especially one that will lead to discrimination and unwarranted disciplinary actions against our nation's healthcare workers. Issuing such policies without such evidence also threatens to jeopardize the public's trust and support for flu vaccination. (17)

Sincerely,



William K. Borwegen, MPH
Director, Occupational Health and Safety
Service Employees International Union, CTW, CLC

cc Dr. Howard Koh, Assistant Secretary for Health, Health and Human Services
Dr. David Michaels, Assistant Secretary of Labor for Occupational Safety and Health

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Attachment

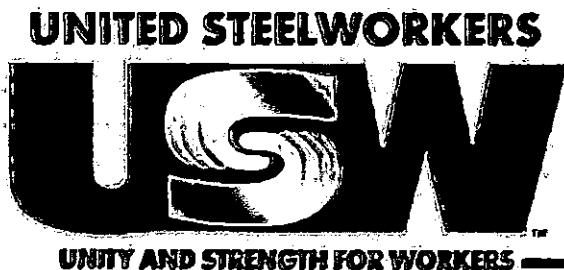
Position of OSHA on Flu Vaccination

September 2012

The Occupational Safety and Health Administration (OSHA) is strongly supportive of efforts to increase influenza vaccination rates among healthcare workers in accordance with the Healthy People 2020 goals. 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 HCP to decline for medical, religious and/or personal philosophical reasons.

While we are supportive of the Healthy People 2020 goal of a 90% vaccination rate, we have seen no evidence that demonstrates that such a high rate is in fact necessary. Furthermore, the current influenza vaccine is no magic bullet. The current state of influenza vaccine technology requires annual reformulation and revaccination and the efficacy is quite variable. Every year there are numerous circulating strains of influenza that are not included in the vaccine. In years where the antigenic match is good, the vaccine only provides protection against the 3 strains in the formulation. In years when the antigenic match is poor, the vaccine may provide no protection at all. The limits of current influenza vaccine technology are especially problematic in the context of a mandatory influenza vaccination program that results in job loss. Lastly, reliance on a mandatory influenza vaccination policy may provide healthcare workers, health care facility management and patients with an unwarranted sense of security and result in poor adherence to other infection control practices that prevent all types of infections, not just influenza. Influenza vaccination has always been just one part of a comprehensive multi-layered infection control program.

While OSHA does not believe that there is sufficient evidence to meet the bar necessary to support mandatory vaccination programs, we nonetheless are convinced that influenza vaccination is generally beneficial and are supportive of efforts to promote vaccination. Influenza vaccination exemptions should be for HCP with valid medical contraindications to vaccinations, or religious and/or personal objections and a signed declination statement that indicates the HCP has been educated regarding influenza, is aware of the risk and benefits of influenza vaccination, has been given the opportunity to be vaccinated with the influenza vaccine at no charge, and can receive the influenza vaccine in the future at no charge to the HCP.



January 16, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 733G.3
Washington, DC 20210
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

Dear Sir or Madam:

On behalf of the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (hereafter United Steelworkers or USW), thank you for this opportunity to provide comments on the draft report and recommendations "Strategies to Achieve the Healthy People 2010 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel," developed by the National Vaccine Advisory Committee (NVAC) Adult Influenza Working Group's Health Care Personnel Influenza Vaccination Subgroup (HCPV).

Among the first unions in the United States to organize health care workers, the United Steelworkers and our Health Care Workers Council represent 30,000 members throughout the health care sector. We care for our communities by working in hospitals, nursing homes, doctors' offices, rural clinics, dialysis centers, dental offices, pharmacies, and on ambulances. We utilize our collective voice to ensure that collective bargaining agreements and public policy remain patient focused and that they empower all health care workers to provide the highest quality patient care possible.

We strongly support policies and practices that promote safe and healthful environments for the benefit of patients, the workforce, visitors and others in health care settings. A multi-faceted and comprehensive infection control program that protects these personnel from exposure to agents including the influenza virus is important for patients and healthcare workers alike. Among the features of such a program are appropriate personal protective equipment (including respiratory protection that is protective for aerosolized viral transmission); procedures to identify and isolate infected patients; vaccination of healthcare workers; effective sick leave policies that support and in no way penalize workers for staying home themselves or with family members exhibiting symptoms of influenza-like-illness; housekeeping; information and education for all workers; and program evaluation. In order to achieve effective design and implementation of such a program, the involvement of healthcare workers in every aspect is critical.

The USW supports effective, voluntary programs for influenza vaccination of healthcare workers that include culturally sensitive information and education in the languages and literacy levels of **United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union**

the workforce, and vaccinations that are free and offered at accessible locations and times. Meaningful worker involvement in the design and elements of the vaccination program are essential to promote effective outreach to diverse populations including those who may have concerns about the influenza vaccine.

Studies have demonstrated that such comprehensive, voluntary vaccine programs can achieve over 90% coverage without a coercive component that threatens healthcare workers with disciplinary action including job loss if they choose to forgo influenza vaccination. (1)

Unfortunately, even though fourteen (14) of the twenty-four (24) voting members of the Health Care Personnel Influenza Vaccination Subgroup [HCPIVS] did not support a mandatory program with influenza vaccination as a condition of employment for all but those with a valid medical contraindication; mandatory, condition-of-employment vaccination policy appears to be codified in the subcommittee's Recommendation #4 ("For those HCE and facilities that have implemented Recommendations 1, 2 and 3 above and cannot achieve and maintain the Healthy People 2020 goal of 90% influenza vaccination coverage of HCP in an efficient and timely manner, the HCPIVS recommends that HCE and facilities strongly consider an employer requirement for influenza immunization. HCPIVS also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services [including the Public Health Service, HHS staff and Federally Qualified Health Centers] and urge all other HCE and facilities to do the same"). (2)

Our comments below will focus on three particular areas that speak against such a mandatory vaccination program for the healthcare workforce: concerns with influenza vaccine effectiveness; barriers that can discourage workers from being immunized; and U.S. labor law considerations.

Problems with the Effectiveness of Influenza Vaccinations and Reliance on Vaccination in Infection-control Strategies

Mandatory vaccination programs are not supported by an evidence-based review of the science. The HCPIVS draft report barely mentions the most recent review of medical studies with in-depth analyses of the effectiveness of the flu vaccine (3). The review and meta-analysis of these studies, undertaken by Osterholm et al, estimated the overall effectiveness of the seasonal influenza virus to be around 59%, much lower than other vaccines offered to healthcare workers. (4) Thus, over 40% of those who receive the vaccine can get no protection. This same study reported that some seasonal vaccine formulations barely offered any protection at all. It is heartening that the CDC revised and downgraded its vaccine effectiveness estimates on its website as a result of this study. It is essential that the most up-to-date evidence-based scientific information is communicated, so that public health agencies and officials maintain credibility with the public. It is equally essential that these findings are integrated into policy recommendations.

Another recent study that focused on influenza vaccination for healthcare workers who work with the elderly reported that there was no evidence that influenza vaccinations impact complications including pneumonia, or transmission; and concluded that at best influenza vaccines may be effective against 10% of all circulating viruses (influenza A and B) that cause influenza or influenza-like illnesses. (5) Most recently, a review published in the journal *Vaccine* in November, 2011 highlighted the lack of sound evidence for the effect of the influenza vaccination on influenza complications among those with co-morbidities, including pneumonia,

hospitalization and mortality. The authors concluded that influenza vaccines should not be mandatory at this time among healthcare workers, and the benefit of healthcare worker vaccinations on patient health remains "highly questionable". (6) An earlier review by Jefferson et al offered the following explanation for a continued reliance on vaccine that was not evidence-based: "The optimistic and confident tone of some predictions of viral circulation and the impact of inactivated vaccines, which are at odds with the evidence, is striking. The reasons are probably complex and may involve 'a messy blend of truth conflicts and conflicts of interest making it difficult to separate factual disputes from value disputes' or a manifestation of optimism bias (an unwarranted belief in the efficacy of interventions)." (7)

Even with the vaccine efficacy problems noted above, we believe that healthcare workers should be encouraged to get vaccinated, and that employers should make vaccinations free and readily accessible to all. Further, problems with vaccine efficacy speak to the need for better vaccines. We support the subcommittee's Recommendation #5, which encourages development of new and improved influenza vaccines and vaccine technologies. Given the problems with influenza vaccine effectiveness, it also makes sense for comprehensive infection control strategies to be implemented in healthcare settings that are not limited to nor focused solely upon a vaccination strategy. In light of these serious problems with vaccine efficacy, however, it makes no sense to mandate vaccination as a condition of employment.

The Need for Enhanced Outreach and Education Strategies

None of the five recommendations for increasing influenza vaccine coverage among healthcare workers includes the word "education". While education is mentioned as an important element in a comprehensive program to reach the 90% coverage goal in the body of the subcommittee's report, it was not emphasized in the text of any recommendation. This is an unfortunate oversight.

While there have been several studies reviewing healthcare worker decision-making about getting vaccinated, the majority have focused on physicians and registered nurses. The healthcare workforce includes LPN's, nursing assistants, technicians and therapists, housekeeping, transport, unit secretaries, dietary, laundry, maintenance, and more. This workforce includes lower-wage workers, immigrants and workers from communities of color. There is a long history of suspicion and mistrust of medical and public health authorities in general, and of vaccines in particular, among some from communities who have suffered particular injustice. It is essential that those making public health policy understand barriers that can exist as a result of this history of injustice and develop policies accordingly.

Some have linked such distrust in the African-American community with the "Tuskegee Study of Untreated Syphilis in the Negro Male," a 40-year government study from 1932 to 1972 under the aegis of the U.S. Public Health Service in which hundreds of African American men were recruited to participate in a study, and those found to have syphilis went untreated while they went blind and insane from the disease. (8) The Tuskegee Study was reported on in medical journals for almost 40 years without protest from those in the medical and public health communities. (9) However, the Tuskegee study was by no means the only government-aided medical assault on minority communities. (10) A public health and medical historian and researcher noted, "The powerful legacy of the Tuskegee Syphilis Study endures, in part, because the racism and disrespect for Black lives that it entailed mirror Black people's contemporary experiences with the medical profession." (11)

Revelations in the 1990's regarding a measles vaccine study financed by the U.S. Centers for Disease Control and Prevention (CDC) reflect this legacy. In 1989 during a measles epidemic in Los Angeles, the CDC, in cooperation with others, began a study to test whether an experimental vaccine could be used for children who were too young to use the standard vaccine. By 1991, approximately 900 infants, primarily African-American and Latino, received the experimental vaccination. The infants' parents were never informed that the vaccine was not licensed in the United States, nor were they told that this vaccine had been associated with increased death rates in Africa. The 1996 disclosure of this information prompted charges of medical racism and medical professionals' continued exploitation of minority communities. (12) In exploring the Tuskegee legacy into the 21st century, Professor Heintzelman concluded, "The most enduring legacy.... is its repercussions in the African American community.... The study laid the foundation for African Americans' continued distrust of the medical establishment, especially public health programs and a fear of vaccinations. It reinforced views about the medical establishment and the federal government, as well as disregard for African American lives." (13)

Additional communities have experienced medical racism, with vaccination at its center. In 1900, when an autopsy performed on a deceased Chinese man in San Francisco found a bacteria suspected of causing Bubonic Plague, public health officials required people of Chinese ancestry in San Francisco to be vaccinated with a dangerous experimental vaccine before traveling out of their community. A federal court found this requirement unconstitutional, after which city officials quarantined the Chinatown area, "drawing a contorted map that included only the homes and businesses of Chinese Americans." (14)

According to a 2003 review of health disparities, the few studies that have focused on the Latino population identified mistrust of the medical community and biomedical research. (15)

In 2010 it was revealed that from 1946 to 1948, a U.S. Public Health Service physician ran a disease inoculation project in Guatemala, co-sponsored by the U.S. National Institutes of Health and others, during which over 1,000 prisoners, mental patients, soldiers and others were infected with sexually transmitted diseases without their permission or knowledge. (16) A Presidential Commission for the Study of Biomedical Issues was established in response to this revelation, and their report, "Moral Science: Protecting Participants in Human Subjects Research," was released last month (December, 2011). (17) Most recently (January 10, 2012), the United States government dismissed a lawsuit brought against it on behalf of victims of this Guatemala "experiment", saying that since the harm was suffered in a foreign country, the United States has sovereign immunity under the Federal Tort Claims Act. (18)

There are repercussions from this long, sordid and continuing history of medical injustice that must be understood by public health policy-makers, including those who currently favor making influenza vaccines a condition of employment for the healthcare workforce in this country.

A 2008 study and report on perceptions in certain communities that have the potential to threaten or even halt disease eradication programs noted that populations who develop mistrust and beliefs against government agencies and programs are often responding to injustices from the past or to inequalities in current experiences. In order to overcome such barriers, the report counsels that historical reasons for distrust must be addressed openly and people-centered approaches facilitated. The report concludes with the following advice:

“...[T]hrough tensions between improving public health and respecting individual freedoms are not new, they continue to confront policy makers with difficult decisions. In light of the success of the smallpox eradication programme, which did resort to coercive methods in the final stages...there are some analysts who recommend similar tactics whenever non-compliance threatens a health initiative. Though each case must be judged separately, evidence suggests that coercion succeeds only in ensuring coverage of a programme, not *sustainability*. Populations that experience extremely coercive vaccination interventions may display increased resistance to future initiatives and an increased propensity to *exit*. Thus, when long-term community support is needed to perpetuate programmes year after year, a non-coercive pragmatism is preferable.” (19)

Resistance to taking the influenza vaccine can be related to concerns about its safety, to not understanding the importance of herd immunity in protecting others from disease, to distrust of vaccines in general, to distrust of public health vaccination programs or public health programs in general. It is imperative that information and education designed to encourage vaccination among healthcare workers include a focus on overcoming the range of obstacles, barriers and concerns resulting in workers choosing to not be vaccinated. In order to do this, meaningful involvement in the design of outreach, information and educational programs and materials of those from affected communities within the workforce must be welcomed, nurtured and supported.

In light of decades and centuries of wrong-doing, exploitation and injustice in medical and public health arenas, we urge public health officials serving on the NVAC to reject mandating vaccinations as a condition of employment. An article on cultural perspectives on vaccination, part of the History of Vaccines Project of the College of Physicians of Philadelphia, concluded, “Divergent cultural perspectives and opinions toward vaccination, including libertarian and religious objections, as well as vaccine suspicions, signal the need for continued communication and collaboration between medical and public health officials and the public regarding acceptable and effective immunization policies.” (20) Robust efforts must be directed at understanding, naming and overcoming obstacles and barriers, and promoting rather than shutting down dialogue.

Public Policy Should Not Promote Employer Actions that Violate the National Labor Relations Act or other Labor Laws

Employers are prohibited by the National Labor Relations Act, and other labor laws with similar provisions, from making unilateral changes in conditions of employment including health and safety. A mandatory vaccination policy would certainly fall within this category. If an employer in a unionized setting wants to implement a new or changed vaccine policy that will require vaccination as a condition of employment, the employer must notify the union(s) of this proposed change, and provide an adequate opportunity to bargain. If the union(s) request bargaining, the matter must be negotiated. Those developing public health policy regarding influenza vaccination for healthcare workers must understand this tenet of labor law and assure that recommended policies are aligned.

In conclusion, we urge NVAC to drop the recommendation for mandatory vaccination as a condition of employment for healthcare workers, and instead focus on the kinds of information, education and dialogue that are necessary, in light of all that we have included in these comments, to encourage healthcare workers to voluntarily be vaccinated against influenza.

Sincerely,

Nancy Lessin

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