

Dear Arthur Caplan, PhD,

RE: Your and Nirva R. Shah, MD's on-line article in JAMA, "Managing the Human Toll Caused by Seasonal Influenza New York State's Mandate to Vaccinate or Mask"

http://jama.jamanetwork.com/article.aspx?articleID=1746248&utm_source=Silverchair%20Information%20Systems&utm_medium=email&utm_campaign=JAMA%3AOnlineFirst09%2F30%2F2013

AN OPEN LETTER

Based on apparently the only double-blind placebo-controlled influenza vaccination and outcomes study conducted (in healthy children 6 to 15 years of age), which has been published in a peer-reviewed journal, it is clear that getting a flu shot greatly increases the risk (by 4-plus-fold) that a person who receives it will contract and potentially spread one or more non-influenza respiratory viruses, some of which are known cause serious infections in humans (see attached study).

In addition, the study established that the overall effect of vaccination for those who were vaccinated did not differ from the effect of giving a sterile-saline placebo when it came to protection from subsequently contracting influenza.

Since the gold standard of drug studies (double-blind, placebo-controlled with extended follow-up to monitor outcomes) has established the preceding realities, does not any recommendation to vaccinate healthcare workers with an influenza vaccine *not only* put the healthcare worker at increased risk of contracting non-influenza viral respiratory infections *but also* every patient with which he or she has contact?

In addition, the cited study's findings have established the reality that influenza vaccination is not effective in stopping influenza infection in those who have been so inoculated -- doesn't it?

Hopefully, after reading the cited study carefully, you will, *at a minimum*,

- a.** Support abandoning a mask-wearing practice that will be ineffective in protecting the patients and, *given the cited paper's findings*, is clearly

discriminatory -- which, because wearing a mask causes the wearer discomfort, is worse than some "Star of David"-like identifier -- without any scientific or medical validity, or

- b.** If there is scientific proof that wearing the masks provided to healthcare workers absolutely stops the transmission of all respiratory viruses, demand that all healthcare workers who get a flu shot or the live influenza vaccine (which is known to spread the influenza viruses it contains for weeks) must also similarly wear a mask after being inoculated since, *based on this study*,
- 1.** Those healthcare who have received a flu dose are at a 4-plus-fold increased risk infecting others with a non-influenza respiratory viral infection than that infection risk from those healthcare workers who get no flu shot and
 - 2.** Both groups, influenza-vaccine-inoculated and the non-inoculated, apparently have a similar risk of subsequently contracting and spreading an influenza virus.

Respectfully,

Paul G. King, PhD

<http://www.dr-king.com>

PS: Please do not try to use any of the prospective/retrospective studies that lack true saline-based controls and/or studies that are not double-blind and/or that do not attempt to follow-up on all subsequent respiratory infections to try to discount these findings as such responses would apparently be less than ethical as would, given the findings in the attached study, taking no action to modify your stated positions.

If there is another double-blind true-placebo-controlled independent published study with similar intensive follow-up for not less than 250 days, which has opposite findings, please share it with me, BECAUSE, to date, the study I have cited appears to be the only such "gold standard" influenza-vaccination study.

Managing the Human Toll Caused by Seasonal Influenza New York State's Mandate to Vaccinate or Mask FREE ONLINE FIRST

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New York State and the nation as a whole experienced one of the worst influenza seasons in a decade during the winter of 2012-2013. In the peak week ending January 19, 2013, New York alone reported more than 5000 cases of laboratory-confirmed influenza, more than 1120 hospitalizations as a result of influenza, and 5 flu-related pediatric deaths. By the season's end, more than 45 000 cases had been confirmed, more than 9500 people had been hospitalized, and 14 children had died.¹

The flu is especially threatening in health care settings such as hospitals, skilled nursing facilities, and nursing homes, where exposure to flu virus is heightened by ill patients and close and ongoing contact with infected health care professionals and staff. Public health officials have long urged health care personnel to get vaccinated. Even so, many do not.²

The ability to minimize the transmission of the flu from health care personnel to patients in health care environments largely depends on high rates of vaccination among those providing care. Studies examining the vaccine's preventive effects on patients and staff are limited but have been generally positive.³⁻⁵ Conversely, in New York State, high rates of vaccination coverage among patients in nursing homes has not been enough to prevent outbreaks in the face of low levels of staff vaccination.

Over the years, efforts to achieve high rates of flu vaccination through voluntary campaigns have failed to generate the requisite levels of participation to produce the maximal benefit for both patients and the health care workforce. Studies show rates of vaccination resulting from these campaigns in the 50% to 60% range. This has led to calls to mandate flu vaccination as a condition of employment in health care institutions.⁶

The state of New York is implementing a first-of-its-kind mandate for the use of masks in all unvaccinated health care personnel, both staff and volunteer. The new regulation, which goes into effect with the 2013-2014 flu season, requires unvaccinated health care personnel in regulated settings to wear a surgical mask in areas where patients or residents may be present. These settings include hospitals, nursing homes, diagnostic and treatment centers, home care agencies, and hospices.

Under the new regulations, health care facilities are obligated to report the numbers of personnel who have been vaccinated and must supervise unvaccinated staff to ensure the appropriate use of masks. Personnel who fail to comply will be subject to the same institutional disciplinary procedures imposed on workers who do not follow other infection control procedures. In addition, the state may cite a facility for failure to comply with these regulations if requirements are not met.

The privacy of those who choose to mask must be respected. The presence of a mask should be explained to patients by noting that it is part of a state policy to reduce the risk of infection by the flu and that this is one way to do so.

Mandates requiring masking for unvaccinated persons are controversial.⁷ Some doubt that flu vaccines and masking are efficacious enough to merit the creation of a mandate. Critics contend that neither method is 100% effective against the spread of the flu, and that in most cases, immunizations are less than 60% effective. The Centers for Disease Control and Prevention (CDC) does not dispute that number. According to the CDC, recent studies show that the flu vaccine can reduce the risk of flu illness by about 60% among the overall population, assuming that most circulating flu viruses are similar to those contained in the vaccine.⁸ In the 2012-2013 season, vaccine effectiveness was 56% for the general population but deemed “not statistically significant” among adults older than 65 years, results that ironically fortified opposition to a vaccine mandate even though the elderly are at high risk of infection.⁹

While neither immunization nor masks are fully effective in guarding against the transmission of the flu, the goal of the new regulation is to ensure that unimmunized health care personnel protect patients to the extent possible by wearing a mask, just as immunized health care personnel protect patients to the extent possible by immunization. In combination and with nearly universal compliance, the efficacy of vaccination and masking would be significant. The lack of 100% effectiveness is not a reason to forgo interventions that may still have substantial risk-reduction benefits.

Questions about the efficacy of immunization and masking are but one argument against New York’s new mandate. A key obstacle is the belief that a mandate violates the civil liberties of health care workers. Some argue that mandates are unethical in that they impose an obligation on health care workers that is not forced on other segments of the population. Still others view mandates as unnecessary, trusting that alternative precautions and behaviors may achieve the same goals sought by requiring vaccination or masking.

Among these objections the ethical concerns have attracted the most traction. However, these ethical objections are not sound. The New York State mandate reflects the belief that the ethical policy to follow is to require masking as a condition of employment for those involved in clinical care who refuse or cannot receive the annual flu vaccine. By adding the option of masking, the concept of a mandate has elicited more support from a broad constituency of the health care workforce.

Opponents who invoke choice or liberty in their objections to mandates fail to acknowledge the special obligations that health care practitioners have to their patients.⁶ The duty to mitigate risk

overcomes individual choice in that it is a moral requirement for those dedicated to the provision of health care. Mandates can be justified on the basis of 4 widely recognized and codified moral principles: (1) the professional duty to prioritize patients' interests above one's own; (2) The professional obligation to "do no harm"; (3) the requirement to protect those who cannot protect themselves; and (4) the obligation to set a good example for the public in terms of disease prevention.

The various codes of ethics for all health care professionals and personnel clearly state that patients' interests must be prioritized over those of clinicians. Thus, the mandate requiring health care personnel to wear a surgical mask if they forgo annual flu vaccination honors the professional commitment to patients' best interests. The requirement is in keeping with well-established and existing mandates for annual tuberculosis testing, measles-mumps-rubella vaccination, and documentation of immunity to measles and other diseases.

All health care personnel are obligated to honor the core medical ethics principle of "do no harm," as a matter of both professional ethics and the common law. The way to do this is to vaccinate or wear a mask.

Health care workers have a distinct duty toward those who are especially susceptible and who cannot protect themselves through vaccination such as elderly individuals, newborns, and those with immune disorders. The predictably poor response to influenza vaccine among the medically fragile and very elderly patients represents an especially important ethical obligation for health care worker vaccination and masking—to reduce transmission to individuals who are unlikely to or cannot benefit from vaccination.

Those who care for patients have an obligation to act as ethical exemplars for others. By achieving high vaccination rates in health care institutions or masking, health care workers can much more credibly urge others to seek flu and other vaccines.

The moral case for vaccination or masking is incontrovertible. Government policy, if it is to be grounded firmly in ethics and science, must acknowledge the special duties that health care professionals have and find ways to protect the public health, as well as the health of the vulnerable and the health care workforce. Imposing a requirement to mask on health care workers who do not receive influenza vaccination is absolutely consistent with sound and ethical public policy.

ARTICLE INFORMATION

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