SHEA GUIDANCE STATEMENT

# The Use of Live Attenuated Influenza Vaccine (LAIV) in Healthcare Personnel (HCP): Guidance from the Society for Healthcare Epidemiology of America (SHEA)

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Because of the live viral backbone of live attenuated influenza vaccine (LAIV), questions have arisen regarding infection control precautions and restrictions surrounding its use in healthcare personnel (HCP). This document provides guidance from the Society for Healthcare Epidemiology of America regarding use of LAIV in HCP and the infection control precautions that are recommended with its use in this population.

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Vaccination of healthcare personnel (HCP) against influenza is a key component of efforts to protect patients and other HCP from healthcare-associated influenza transmission. HCP influenza vaccination rates are slowly increasing, reaching 63.5% for the 2010-2011 influenza season,1 but they remain well below the Healthy People 2020 Goal of 90%. Fortunately, an increasing array of influenza vaccines are or will soon be available to optimize recipient immune response to the vaccine as well as allow for different modes of vaccine delivery. These options include various types of inactivated influenza vaccines, such as the standard seasonal trivalent inactivated vaccine (TIV), the high-dose TIV that produces an improved immune response in older adults,<sup>2</sup> and the intradermal TIV, which uses a smaller needle and less viral antigen than the standard intramuscular TIV.3 A new inactivated quadrivalent vaccine is being developed that adds a second influenza B strain in order to reduce the potential for vaccine mismatch when compared with circulating wild-type strains.<sup>4</sup> Finally, a non-egg-based influenza vaccine grown in a cell line will likely be available in the United States in a few years.<sup>5</sup>

The other major type of licensed influenza vaccine is the live attenuated influenza vaccine (LAIV). Currently utilized LAIVs are trivalent, but a quadrivalent LAIV vaccine (that targets 2 strains of influenza A and 2 strains of influenza B) was recently approved by the US Food and Drug Administration, although it is not expected to be commercially available until the 2013–2014 influenza season. LAIV is an attenuated live viral vaccine with a temperature-sensitive adaptation that precludes replication of the virus at human core body temperatures. Administered intranasally, the vaccine replicates in the lower-temperature area of the nasal mucosa, allowing for the development of mucosal as well as systemic immunity. LAIV, which is licensed for healthy, nonpregnant persons aged 2–49 years, provides adults with another option for influenza vaccination, particularly for those with an aversion to needles. However, in a study of persons aged 18–49 years, although LAIV was efficacious in preventing laboratory-confirmed influenza, it was not as efficacious as TIV, a finding that differs from analysis of data obtained in children.<sup>6,7</sup>

On the basis of currently available data, TIV appears to be the preferred vaccine for adults, with LAIV as an acceptable alternative. Because of its live viral backbone, questions have arisen regarding infection control precautions and restrictions surrounding the use of LAIV in HCP. This document provides guidance regarding the use of LAIV in HCP and the infection control precautions that are recommended with its use in this population.

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### LAIV AND VIRAL SHEDDING

Shedding of attenuated vaccine virus is common in the first few days following vaccination with LAIV;8,9 however, the quantity of attenuated virus shed in adults is 100-10,000-fold lower than the median human infectious dose required for LAIV vaccination in adults.8 Reversion of LAIV virus to wildtype virus has never been demonstrated despite extensive testing.<sup>10</sup> Importantly, secondary transmission from a person who recently received the LAIV that resulted in clinically important illness has never been reported in the medical literature,11 and to date there has been only 1 documented episode of LAIV virus transmission, which occurred in a day care attendee as part of a placebo-controlled LAIV trial.<sup>12</sup> The virus obtained from this subject retained LAIV attenuation, and virus could not be recovered in additional specimens collected from the subject. No additional cases of LAIV transmission have been reported to the manufacturer of the only licensed LAIV (C. Rizzo, MedImmune, personal communication, April 13, 2012).

## USE OF LAIV IN HCP

On the basis of a theoretical concern for transmission and despite the absence of evidence of an increased risk of secondary transmission of infection by LAIV recipients, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices and Healthcare Infection Control Practices Advisory Committee have recommended that LAIV not be administered to HCP who interact with patients who at the time of contact require a protective environment (defined as a "specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes," as found in myelosuppression or stem cell transplantation units).<sup>13,14</sup> This recommendation was made as a result of an abundance of caution and a desire to err on the side of patient safety. Updated guidelines from 2010 even note that "some healthcare facilities might choose to not restrict use of LAIV in close contacts of severely immunocompromised persons, based on the lack of evidence for transmission in health-care settings since licensure in 2004."14

Studies have noted the safety of administering LAIV to some populations of immunocompromised patients of concern, including HIV-positive children<sup>15</sup> and adults,<sup>16</sup> older adults with chronic obstructive pulmonary disease,<sup>17</sup> children with cancer,<sup>18</sup> and adults aged 65 years and older who have chronic medical conditions,<sup>19</sup> although none of these studies included subjects considered to be markedly immunocompromised. During the influenza A/California/7/2009 (H1N1) pandemic, the first wave of available vaccine consisted of LAIV and many of the initial doses of LAIV were earmarked for HCP. Some HCP expressed concern regarding the use of a "live" vaccine in persons that might have close contact with immunosuppressed patients, highlighting continued confusion and uncertainty regarding the use of LAIV among HCP.<sup>20</sup> Admittedly, because most healthcare facilities have avoided the use of LAIV in HCP, there continues to be limited experience with and data on the use of LAIV in healthcare settings.

## SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA (SHEA) GUIDANCE ON THE USE OF LAIV IN HCP

SHEA endorses the use of LAIV as an alternative to the inactivated influenza vaccine, particularly for those HCP who avoid an annual influenza vaccination because of fear of needle injections. SHEA also agrees with the restriction of LAIV from those HCP who, in the week following vaccination, have frequent contact with patients who reside in a protective environment (eg, HCP in a bone marrow transplantation unit), but it notes that this recommendation is made as a result of an abundance of caution. Those HCP who have frequent contact with patients in protective environments but who will not care for such patients in the week following vaccination may still receive LAIV. HCP who have the potential for infrequent contact with patients in protective environments (ie, when the majority of patients contacted do not reside in a protective environment, such as a radiology technologist performing a chest radiograph or an emergency department physician during the initial patient evaluation) should not be excluded from vaccination with LAIV. Finally, HCP who provide care to other immunosuppressed populations (eg, neonatal and burn unit patients and oncologic patients undergoing chemotherapy but not requiring a formal protective environment) may still receive LAIV.

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