



# Evaluating interest in an influenza A(H5N1) vaccine among laboratory workers who work with highly-pathogenic avian influenza viruses in the United States



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## ABSTRACT

**Background:** Highly pathogenic avian influenza A (HPAI) viruses found in poultry and wild birds occasionally infect humans and can cause serious disease. In 2014, the Advisory Committee on Immunization Practices (ACIP) reviewed data from one licensed ASO3-adjuvanted influenza A(H5N1) vaccine for consideration of use during inter-pandemic periods among persons with occupational exposure. To guide vaccine policy decisions, we conducted a survey of laboratory workers to assess demand for HPAI vaccination.

**Methods:** We designed an anonymous web survey (EpiInfo 7.0) to collect information on demographics, type of work and time spent with HPAI viruses, and interest in HPAI vaccination. Eligible participants were identified from 42 entities registered with United States Department of Agriculture's Agricultural Select Agent program in 2016 and emailed electronic surveys. Personnel with Biosafety Level 3 enhanced (BSL-3E) laboratory access were surveyed. Descriptive analysis was performed.

**Results:** Overall, 131 responses were received from 33 principal investigators, 26 research scientists, 24 technicians, 15 postdoctoral fellows, 6 students, and 27 others. The estimated response rate was 15% among the laboratory personnel of responding principal investigators. One hundred respondents reported working in a BSL-3E area where HPAI experiments occurred with a mean time of 5.1–11.7 h per week. Overall, 49% were interested in receiving an A(H5N1) vaccine. By role, interest was highest among students (80%) and among those who spent >50% of their time in a BSL-3E area (64%). Most (61%) of those who said they might be or were not interested in vaccine believed it would not provide additional protection to current safety practices.

**Conclusions:** Half of responding laboratory workers was interested in receiving an influenza A(H5N1) vaccine. HPAI vaccination of laboratory workers at risk of occupational exposure could be used along with existing safety practices to protect this population.

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## 1. Introduction

Highly pathogenic avian influenza (HPAI) viruses, including influenza A(H5N1) viruses, cause severe respiratory disease and death in birds and have been found in poultry and wild birds in Africa, Asia, Australia, Europe, and North America [1]. A(H5N1) viruses can also cause severe disease in humans. From 2003 through 2016, 16 countries reported 856 human infections of A(H5N1) virus, with 452 deaths (53% case fatality proportion), to

the World Health Organization (WHO) [2]. Most human infections with A(H5N1) virus occur from contact with infected birds or environments, but limited human-to-human transmission has been reported [3–6].

A(H5N1) viruses are considered to have moderate pandemic potential, and research to understand transmission and adaptability, and to develop vaccines, are public health priorities [7–10]. Laboratory work with A(H5N1) viruses is necessary to further our understanding of these viruses and the risk they pose to public health, and to develop vaccines. While best practices for working with HPAI viruses protect individuals from exposure, including enhanced BSL3 practices, some risk of inadvertent exposure exists [11–13]. In 2014, there were 173 principal investigators in the United States registered through the United States Department of

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Agriculture (USDA) Select Agent Program to work with HPAI viruses [personnel communication, Mark Hemphill]. Between 2007 and 2013, registered HPAI Select Agent laboratories reported a total of 44 incidents to the USDA, including needle sticks, animal bites, personal protective equipment failure, inadvertent leakage or spillage of materials, or work outside of containment areas [personnel communication, Mark Hemphill]. However, there has never been a laboratory-associated infection with an HPAI virus.

Vaccination is the primary method of preventing seasonal influenza and an important tool to prevent pandemic influenza [14]. In recent years, substantial research has been conducted on A(H5N1) vaccines, resulting in the development of licensed vaccine products for use during future pandemics and for pandemic stockpiles [7]. In 2013, the WHO Strategic Advisory Group of Experts (SAGE) Working Group on Influenza Vaccines and Immunizations updated their general recommendations on A(H5N1) vaccines to include use before pandemics (i.e., inter-pandemic) and strongly recommended vaccination of laboratory personnel working with A(H5N1) viruses [7]. In 2013, the Centers for Disease Control and Prevention Division of Select Agents and Toxins made specific recommendations for vaccination with an A(H5N1) vaccine for all laboratory workers working with influenza viruses containing hemagglutinin from the influenza A/goose/Guangdong/1/96 lineage [13]. However, without a licensed, available vaccine for use during the inter-pandemic period, access to A(H5N1) vaccine among laboratory personnel in the United States has been limited to participation in clinical trials.

A(H5N1) vaccines are not commercially produced in the United States, but the U.S. government supported limited production for testing and for pandemic stockpiles [15,16]. There are currently doses of four A(H5N1) monovalent vaccines in the U.S. stockpile. The U.S. Federal Drug Administration (FDA) licensed two of these for use in the United States during a pandemic [17]. FDA licensed Q-Pan H5N1 in 2013 for use in persons aged  $\geq 18$  years at increased risk of occupational exposure to influenza A(H5N1) virus. The vaccine contains antigen from the influenza A/Indonesia/05/2005 virus strain (Clade 2.1.3.2) and is intended to be administered with an oil-in-water emulsion adjuvant, AS03. The vaccine was prepared under contract with the U.S. Department of Health and Human Services as part of the national pandemic preparedness initiative. The U.S. Advisory Committee on Immunization Practices (ACIP) recently considered the use of a small amount (<3000 doses) of stockpiled Q-Pan H5N1 vaccine for persons with occupational exposure to HPAI virus (e.g., laboratory workers) during the inter-pandemic period [18].

To assess the demand for an A(H5N1) vaccine among laboratory personnel working with HPAI viruses, we conducted a survey to help guide decisions as to whether the stockpiled vaccine should be made available for persons at risk of occupational exposure during the inter-pandemic period. The primary objective was to quantify the demand for Q-Pan H5N1 vaccine among persons working in laboratories registered with the USDA to work with HPAI viruses. Secondary objectives were to describe and categorize the type and amount of work with HPAI viruses among laboratory workers, quantify the average weekly person-hours of work with various HPAI viruses, and identify access to an occupational health clinic through which a vaccine could be administered.

## 2. Materials and methods

### 2.1. Survey participants and study period

HPAI viruses are designated as Select Agents in the United States, and therefore any entity working with HPAI in the United States must register with the USDA Animal and Plant Health Inspection Service, Agriculture Select Agent Services. USDA identi-

fied 42 entities registered to work with HPAI in 2016, and sent an email containing information and a link to the electronic survey to all Responsible Officials and Alternate Responsible Officials at each of the identified entities. Each entity was requested to share the survey with principal investigators (PIs) working with HPAI viruses and all laboratory workers with access to their biosafety level 3 enhanced (BSL-3E) laboratory in which work with HPAI viruses are carried out. No identifying information was collected from respondents. CDC had no direct contact with respondents or institutions. The survey period was from August to September 2016. The survey and report were determined not to constitute human subjects research, but rather public health response.

### 2.2. Survey design and distribution

A web survey was created using Epi Info 7.0. The survey contained 21 questions pertaining to demographic characteristics, type of work with HPAI viruses, weekly person-hours of work with HPAI viruses, interest in HPAI and A(H5N1) vaccines, and access to vaccination through occupational health clinics. Additional information about Q-Pan H5N1 was not provided in the survey. PIs were asked to complete the self-administered electronic questionnaire accessed through a secure link, and to forward the secure link to all staff in their laboratory with access to a BSL-3E laboratory area where HPAI experiments occur. PIs were asked to request that all such staff complete the survey. PIs were also asked to report the number of persons in their laboratory with access to the BSL-3E laboratory in order to obtain the number of persons who would have received the survey. A reminder email was sent to all Responsible Officials and Alternate Responsible Officials at each of the identified institutions 2 weeks after the initial email.

### 2.3. Statistical analysis

Descriptive analysis of survey responses was performed using SAS 9.3. To estimate a response rate among PIs, we used a denominator of 173, the number of PIs registered in 2014 (database limitations prevented estimation of this number in later years). We estimated the response rate by occupational category using the numbers provided by each PI. Analysis was limited to those respondents who reported working in the BSL-3E area where HPAI experiments occur (and therefore could have been exposed to live virus or virus particles) with sub-analyses limited to those who worked directly with A(H5N1) viruses. Given that laboratory personnel may have varying work schedules in the BSL-3E area depending on occupational category and work (e.g., concentrated intermittent vs. regularly scheduled weekly hours), we asked respondents to estimate percentages of their total work time spent on various types of work with HPAI or A(H5N1) (<10%, 10–25%, 26–50%, 51–75% or >75%). To calculate the average time spent on each type of work with HPAI viruses, we multiplied the lower (1% for <10%, 10% for 10–25%, 26% for 26–50%, 51% for 51–75%, and 76% for >75%) and upper range (9% for <10%, 25% for 10–25%, 50% for 26–50%, 75% for 51–75% and 100% for >75%) of time spent performing each type of activity by either 40 h per week (if the respondent indicated that they were full-time staff), or 20 h per week (for part-time staff/employees). The means of the lower percentage and upper percentage were calculated across occupational categories to give a mean range of hours per week.

## 3. Results

### 3.1. Response rate

We received 131 responses, including 33 who self-identified as PIs (33 of 173 registered with USDA, 19% response rate) (Fig. 1).

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