

# Influenza Risk Assessment Tool (IRAT) Virus Report

Prepared by the CDC Influenza Division

Highly pathogenic avian influenza A(H5N1) virus; clade 2.3.4.4b Virus  
Strain: A/Texas/37/2024

Date of Evaluation: June 2024



## Purpose:

The current overall individual and population health risk to the general public posed by the avian influenza A(H5N1) virus presently spreading in cows, poultry, and other mammals **remains low**. Systematic comparisons of data related to this avian influenza A(H5N1) virus using the Influenza Risk Assessment Tool (IRAT) to data from other influenza A viruses has scored this virus's future pandemic potential as “moderate risk” based on information through June 26, 2024. This is **similar to previous assessments** of earlier avian influenza A(H5N1) viruses.

The IRAT uses expert opinion to evaluate the potential of a representative novel influenza virus to gain the ability for person-to-person spread and the resulting potential public health impact if that were to happen, compared to other viruses evaluated in past IRAT reports. The IRAT does not assess the immediate risk to the public's health, which is unchanged and remains low, and it does not predict future pandemics.

This report summarizes the findings of an IRAT conducted on a recent avian influenza A(H5N1) virus from a human case in Texas (A/Texas/37/2024). The score places the currently circulating avian influenza A(H5N1) virus in the category of “moderate risk” for potential future emergence and public health impact. This is similar to previous assessments of earlier avian influenza A(H5N1) viruses. The scores for this IRAT were submitted June 26, 2024, prior to additional human cases in Colorado. The report was completed expeditiously based on data as of June 26 to inform ongoing preparedness discussions.

During a public health response, the IRAT can be used to assess the appropriateness of the ongoing response efforts and whether additional actions are warranted based on the risk score. The results of this IRAT validate the proactive, coordinated U.S. government response. Assessing risk is an iterative process with new information being assimilated regularly and response activities adjusted as indicated.

## Introduction

Human infections with influenza A viruses that commonly circulate among animals are rare, and the likelihood of sustained human-to-human transmission of these viruses remains low [1,2]. Sporadic human infections with animal influenza A viruses have occurred, usually after exposure to infected animals or to a virus-contaminated environment. The Influenza Risk Assessment Tool (IRAT) was created to prioritize and maximize pandemic preparedness investments [3]. The IRAT is used to examine multiple attributes of influenza A viruses that circulate among animals but have not gained the ability to transmit from human-to-human, and to evaluate the potential of these viruses to acquire this ability and the consequent potential public health impact. The IRAT is an evaluative tool, not a predictive tool, and is not intended to predict the next pandemic.

## Situation

Since January 2022, highly pathogenic avian influenza (HPAI) A(H5N1) virus clade 2.3.4.4b has been detected in the United States in numerous wild bird species, including aquatic birds such as ducks, and in commercial and backyard domestic poultry in most states [4].

The A(H5N1) clade 2.3.4.4b virus emerged in 2020, spreading across Europe, Asia, and Africa, in both wild aquatic birds and domestic poultry, and by 2021, replaced the previously circulating A(H5N8) clade 2.3.4.4b viruses [5]. This virus was first reported in migrating wild aquatic birds in North America in December 2021 and in South America in January 2023. In 2023, the virus was detected in around 70 countries. The first detections in the United States were from migratory wild aquatic birds but the virus has also been detected in domestic poultry [6,7]. Sporadic incursions of the virus into aquatic and terrestrial carnivorous mammals have occurred in the United States and other regions, including an outbreak in a farmed mink unit in Spain and elephant seals in Argentina [8–10].

From January 2022 through July 17, 2024, thirty-seven cases of influenza A(H5N1) virus infection in humans have been reported globally. Of those with available sequence data, nineteen of these cases were identified with A(H5N1) clade 2.3.4.4b viruses. Four of these cases resulted in severe/critical lower respiratory tract disease with one fatality [11–14].

In the United States, during January 2022 through July 17, 2024, there have been five cases of A(H5N1), and five cases of A(H5) reported in humans. One human case of A(H5N1) was reported in the United States in April 2022 in a farm worker who experienced fatigue without any other symptoms while depopulating poultry at a poultry farm with confirmed A(H5N1). However, it is possible that this case did not represent a true infection, but rather detection of a low level of A(H5N1) viral RNA in a respiratory specimen due to environmental contamination. Environmental contamination was previously attributed to two asymptomatic cases in poultry workers reported in Spain [15].

Since April 2024, four human cases of A(H5N1) and five cases of A(H5) have been reported in the United States. Three A(H5N1) cases and one A(H5) case have been associated with the ongoing multi-state outbreak of A(H5N1) in dairy cattle: on April 1st, the State of Texas announced that a person tested positive for A(H5N1), in May, Michigan announced detection of two A(H5N1) cases occurring at different farms, and on July 3rd, Colorado announced a human case of A(H5). All of these cases have been associated with the ongoing multi-state outbreak of A(H5N1) in dairy cattle. Additionally, all infections occurred in dairy workers who had direct exposure to cattle presumed to be infected with A(H5N1) virus. All patients reported eye redness/watery eyes, and one patient also had cough without fever. No patients have been hospitalized [16,17].

One additional A(H5N1) case and four cases of A(H5) were recently identified in Colorado. All of these cases were in farm workers who were involved in the depopulation of poultry at a poultry facility experiencing an outbreak of HPAI A(H5N1) virus. These workers reported symptoms after being exposed to A(H5N1) virus-infected poultry. All workers who tested positive reported mild illness. The workers reported redness/watery eyes and respiratory symptoms [18].

Phylogenetic analysis of A(H5N1) clade 2.3.4.4b viruses shows high levels of genetic similarity to previously circulating A(H5Nx) clade 2.3.4.4b viruses, with little evidence of mammalian adaptation [11,19,20]. The hemagglutinin (HA) genes of currently circulating wild bird and poultry A(H5N1) clade 2.3.4.4b viruses show a high level of genetic similarity to previous clade 2.3.4.4 viruses, with some genetic variation noted among the N1 neuraminidase (NA) gene, which is wild bird adapted [5,7].

Previously recommended A(H5) candidate vaccine viruses (CVVs) are expected to be effective against A(H5N1) viruses currently circulating among wild birds, poultry, and cattle. In addition, A(H5N1) virus genetic analysis suggests that a majority of viruses remain susceptible to available FDA-approved influenza antiviral medications [21,22]

Using the IRAT, the Centers for Disease Control and Prevention (CDC) assessed the pandemic potential of HA clade 2.3.4.4b, HPAI A(H5N1) viruses using A/Texas/37/2024 as the prototype strain. Previously, CDC has assessed two other HPAI A(H5N1) clade 2.3.4.4b viruses, the A/American wigeon/South Carolina/AH0195145/2021 and the A/mink/Spain/3691-8\_22VIR10586-10/2022. Both viruses had overall estimated IRAT scores in the moderate risk category range of 4.0 to 7.9.

## IRAT Evaluation

Influenza subject matter experts (SMEs) from CDC, the Food and Drug Administration, the Department of Defense, the Administration for Strategic Preparedness and Response, the Department of Interior, and the United States Department of Agriculture were asked to evaluate A(H5N1) clade 2.3.4.4b viruses including the prototype virus, A/Texas/37/2024, using the ten risk elements defined in the IRAT. Each SME scored 1 to 5 elements based on their

areas of expertise. The point estimate scores for each risk element, which can range from 1 to 10, were averaged, multiplied by predetermined weights, and totaled to give an aggregate weighted score for each of the two IRAT risk questions related to

1. potential risk for emergence of the virus to achieve sustained human-to-human transmission and
2. potential public health impact if the virus gained the ability to spread efficiently between humans [3]. The impact refers to the severity and burden of disease.

The overall estimated IRAT scores placed this virus in the moderate risk category, which ranges from 4.0 to 7.9. The average risk score for the estimated potential emergence of the virus was 5.79, in the mid-low range of the moderate risk category (Table 1 below). The average risk score for the virus to potentially impact public health was 6.12, in the mid-range of the moderate risk category (Table 2). These scores reflect an increase of 0.66 in the emergence question and a decrease of 0.12 in the impact question compared to the previous A(H5N1) evaluation last year, but both questions still fall into the moderate risk category. The average SME confidence level in the available data of all 10 risk elements was 2.26 (SME confidence range: 0.00-4.00).

Some variation was seen among SME point estimate scores in the risk elements, Global Distribution of Animal Influenza Viruses and Transmission in Animal Models, where the scores ranged from moderate to high risk. This indicates some uncertainty in interpretation and confidence of the available data.

Sensitivity analyses using the lowest and highest scores for these two risk elements resulted in adjusted ranges for the overall emergence risk and the potential impact risk that continued to place this virus in the mid-range of the moderate risk category, indicating that the categorization of A(H5N1) clade 2.3.4.4b virus including A/Texas/37/2024, as moderate risk was unchanged by the range of scores within the Global Distribution of Animal Influenza Viruses and Transmission in Animal Models risk elements exhibiting variation.

**Table 1: Estimated Weighted Risk of Potential Emergence<sup>1</sup> for Highly Pathogenic Avian Influenza A(H5N1) virus clade 2.3.4.4b; A/Texas/37/2024 evaluated in June 2024**

<b>Risk Element</b>	<b>Weight (W)</b>	<b>Risk Score (RS)</b>	<b>W X RS</b>
<b>Human Infections</b>	0.2929	4.75	1.39
<b>Transmission in Animal Models</b>	0.1929	7.00	1.35
<b>Receptor Binding</b>	0.1429	3.00	0.43
<b>Population Immunity</b>	0.1096	9.14	1.00
<b>Infections in Animals</b>	0.0846	7.00	0.59
<b>Genomic Analysis</b>	0.0646	6.50	0.42
<b>Antigenic Relatedness</b>	0.0479	4.71	0.23
<b>Global Distribution in Animals</b>	0.0336	6.17	0.21
<b>Disease Severity and Pathogenesis</b>	0.0211	6.71	0.14
<b>Antiviral Treatment Options</b>	0.0100	3.40	0.03
<b>Total</b>	<b>1.0001</b>	<b>5.79</b>	

<sup>1</sup> Footnote for Table 1 and Table 2:

1. Trock SC, Burke SA, Cox NJ. 2012. Development of an influenza virologic risk assessment tool. Avian Dis 56:1058-61.
2. Cox NJ, Trock SC, Burke SA. 2014. Pandemic preparedness and the Influenza Risk Assessment Tool (IRAT). Curr Top Microbiol Immunol 385:119-36.
3. Trock SC, Burke SA, Cox NJ. 2015. Development of Framework for Assessing Influenza Virus Pandemic Risk. Emerg Infect Dis 21:1372-1378

**Table 2: Estimated Weighted Risk of Potential Public Health Impact<sup>1</sup> for Highly Pathogenic Avian Influenza A(H5N1) virus clade 2.3.4.4b; A/Texas/37/2024 evaluated in June 2024**

<b>Risk Element</b>	<b>Weight (W)</b>	<b>Risk Score (RS)</b>	<b>W X RS</b>
<b>Disease Severity and Pathogenesis</b>	0.2929	6.71	1.97
<b>Population Immunity</b>	0.1929	9.14	1.76
<b>Human Infections</b>	0.1429	4.75	0.68
<b>Antiviral Treatment Options</b>	0.1096	3.40	0.37
<b>Antigenic Relatedness</b>	0.0846	4.71	0.40
<b>Receptor Binding</b>	0.0646	3.00	0.19
<b>Genomic Analysis</b>	0.0479	6.50	0.31
<b>Transmission in Animal Models</b>	0.0336	7.00	0.24
<b>Global Distribution in Animals</b>	0.0211	6.17	0.13
<b>Infections in Animals</b>	0.0100	7.00	0.07
<b>Total</b>	<b>1.0001</b>	<b>6.12</b>	

## Individual Risk Element Summaries<sup>2</sup>

**Human Infections:** Since Jan 2022, there have been 31 sporadic human infections with HPAI A(H5N1) reported to WHO from nine countries. Fifteen (52%) of these were identified as clade 2.3.4.4b viruses. All human cases of 2.3.4.4b have been sporadic, and there has been no evidence of human-to-human transmission. Additionally, all human cases, except for the case in Chile for which the exposure source was unknown, had exposure to infected animals.

**Transmission in Animal Models:** Over the years, animal studies have been conducted to assess the transmissibility of the clade 2.3.4.4 (H5) viruses. The 2.3.4.4b H5N1 viruses, such as A/Chile/25945/2023, A/mink/Spain/3691-8\_22VIR10586-10/22, and A/bovine/Texas/98638/2024, have displayed consistent same-cage transmission, while significant airborne or respiratory droplet transmission (RDT) of clade 2.3.4.4b; A(H5N1), A(H5N2), A(H5N6), and A(H5N8) viruses has not been demonstrated in any animal model examined. However, in ferrets, the recently isolated clade 2.3.4.4b Texas/37/2024 virus displayed some (4 of 6) RDT transmission and efficient transmission in the Direct Contact (DC) model suggesting a more moderate risk over the previously low risk observed with these viruses.

**Receptor Binding:** Sequence analysis of the HA for A/Texas/37/2024 H5N1 virus and recently isolated clade 2.3.4.4b viruses, including A/American wigeon/SC/22-000345-001/2021 virus reveals no HA substitutions at residues 190, 225, 226, and 228 (H3 numbering) that are known to switch receptor preference from avian-type to human-type. This indicates that recent A(H5N1) viruses have the typical 'avian pocket' in the Receptor Binding Site (RBS) and predominantly bind  $\alpha$ 2,3-linked sialic acid (SA). In glycan array assay, the recombinantly expressed H5-HA protein of the A/Texas/37/2024 virus showed  $\alpha$ 2,3-specific SA binding. Taken together, based on sequence and binding data of 2.3.4.4b viruses, including A/Texas/37/2024 HA is expected to bind to avian-type receptors with very little to no binding to  $\alpha$ 2,6-linked SA human like receptors.

<sup>2</sup> The IRAT SME's were asked to enter their scores for the A/Texas/37/2024 virus by June 26th, 2024, before the cases in Colorado in July 2024 were identified.

**Population Immunity:** A meta-analysis and literature review from 2020 reported universally low population seroprevalence estimates of antibody reactivity against A(H5N1), <5% even among populations with poultry exposure. Additionally, a recent report showed no to extremely low antibodies detected to HA1 of 2.3.4.4b H5N1 virus (A/American Wigeon/South Carolina/22-000345-001/2021), suggesting the U.S. population is highly susceptible. Finally, assessments focused on whether seasonal influenza vaccination will induce cross-reactive HA antibodies to 2.3.4.4b H5N1 showed no antibody rise was detected to HA1 of 2.3.4.4b H5N1 following seasonal influenza vaccination. These data suggest that there is little evidence for population immunity against A(H5N1) clade 2.3.4.4b viruses.

**Infections in Animals:** The H5N1 clade 2.3.4.4b panzootic has affected at least 26 countries and more than 48 mammal species (including terrestrial, freshwater, and marine wild mammals in the United States). Poultry outbreaks have occurred in the United States since 2022 but are more sporadic than sustained. Most recently, clade 2.3.4.4b genotype B3.13, has spread widely in U.S. cattle and has transmitted from cattle to humans, cats, and poultry. However, while there has been transmission from infected dairy cattle to a number of other mammals including, humans, mice, racoons and cats, there are limited data on whether there is sustained transmission of clade HPAI 2.3.4.4b B3.13 virus in mammals other than dairy cattle.

**Genomic Analysis:** The A/Texas/37/2024 virus contains two of three factors that increase its genomic risk: 1) Reassortment between different lineages (Eurasian and American) and/or subtypes from similar hosts, and 2) Molecular signature of importance for mammalian/human infection and disease (PB2 627K). The segments are moderately to significantly divergent from known host-adapted viruses of low risk. However, the PB2 627K mutation is known to facilitate host adaption for enhanced virus replication in mammals. This mutation has been observed in other human isolates from avian origin.

**Antigenic Relatedness:** Recently circulating 2.3.4.4b (H5N1) antigens show only moderate reductions in titer to stockpiled or non-stockpiled pre-pandemic vaccine candidate viruses in homologous/heterologous titer in 1-way HI assay. Specifically, A/Texas/37/2024 was recognized well by post-infection ferret antiserum raised to the A/Astrakhan/3212/2020 and A/American wigeon/South Carolina/22-000345-001/2021 CVVs (HI data showed 2- to 4-fold reduction). Post-infection ferret antiserum raised to an additional clade 2.3.4.4b CVV under development, A/chicken/Ghana/AVL-763\_21VIR7050-39/2021-like (IDCDC-RG80A), also recognized A/Texas/37/2024 well, no reductions.

**Global Distribution in Animals:** The continued global isolation of H5N1 clade 2.3.4.4b viruses from various mammalian and avian species increases risk potential for the virus. The distribution of HPAI 2.3.4.4b genotype B3.13 is currently widespread among dairy herds in the United States with several states affected. There has been spread from affected dairies to wild birds, poultry farms, and both peri-domestic and wild mammals with mortality events. While a substantial portion of the spread among dairies is via animal movement, other pathways related to people and fomites may also be contributing and need to be further investigated. Additionally, the possibility that the B3.13 genotype is circulating in some wild bird populations, cannot be ruled out without additional wild bird surveillance.

**Disease Severity and Pathogenesis:** There have been fifteen human cases of A(H5N1) clade 2.3.4.4b virus infection identified from January 2022 to June 2024, seven cases were asymptomatic, four cases were mild (all U.S. cases), and four cases were severe with one death (outcome unknown for one of the four severe cases). Limiting to the seven cases of clade 2.3.4.4b HPAI A(H5N1) that were symptomatic, four had severe illness (57%). While recent human data on clade 2.3.4.4b HPAI A(H5N1) are limited, and the four human cases detected in the United States from January 2022 to June 2024 have been clinically mild, ferret studies show high mortality rates among ferrets infected with this virus.

**Antivirals and Treatment Options:** Analysis of the M2, NA, and PA sequences showed that no known or suspected markers previously associated with resistance or reduced susceptibility to FDA-approved antivirals (M2 blockers, NA and CEN inhibitors) were detected in the genome of either A/Texas/37/2024 or A/Michigan/90/2024 viruses. Additionally, a report that examined sequences from over 1000 HPAI Clade 2.3.4.4b HPAI A(H5N1) viruses, and found mutations associated with inferred antiviral resistance in <1% of those sequences. Thus, there is no current evidence to suggest antiviral resistance in A/Texas/37/2024.

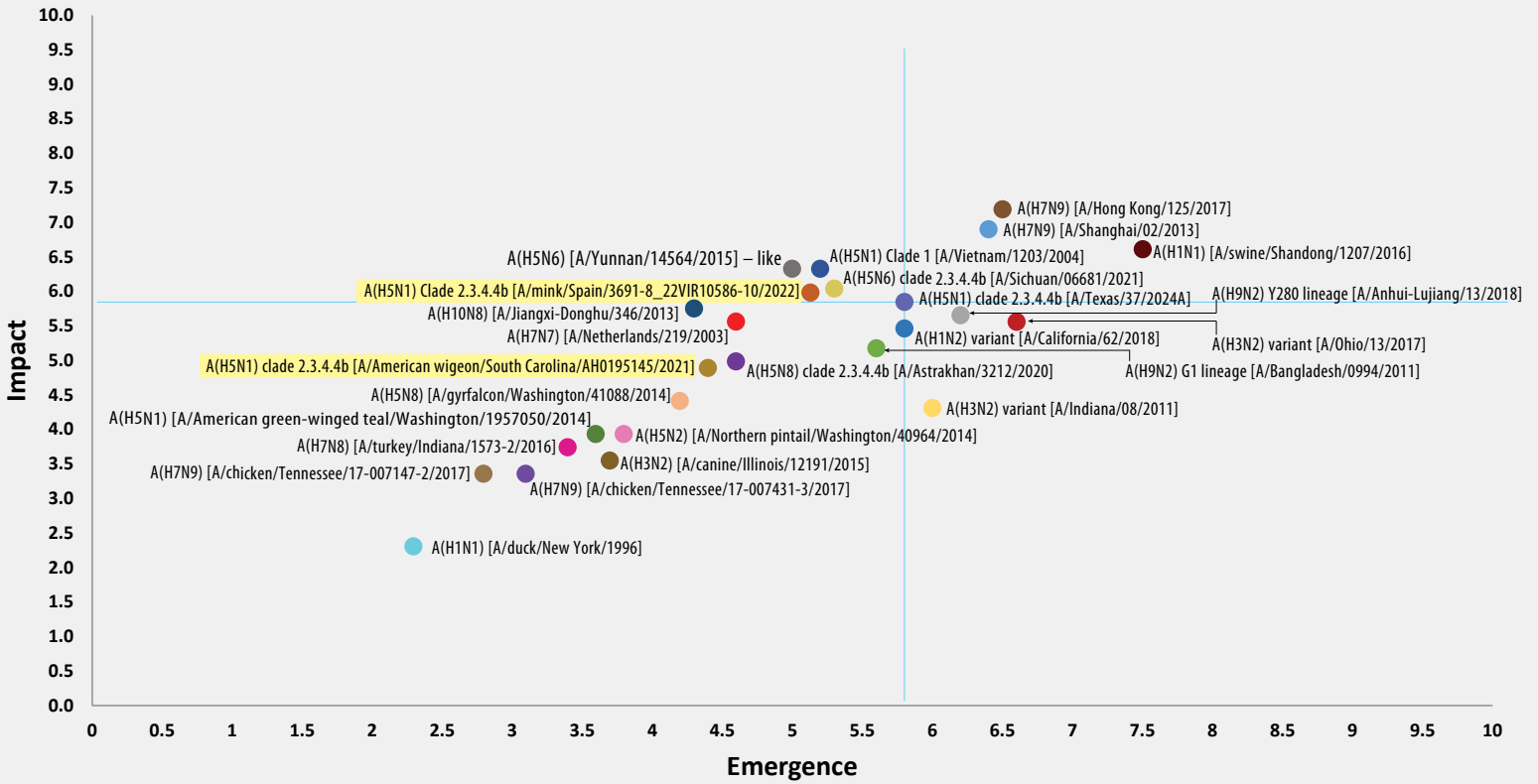
## Comparison to other Viruses Scored with IRAT

The average score estimates for the potential emergence and public health impact risk elements for this A(H5N1) clade 2.3.4.4b virus were plotted along with a selection of fifteen other previous influenza viruses scored using the IRAT (Figure). The estimates for this A(H5N1) clade 2.3.4.4b virus were in the mid-moderate range for both risk of potential emergence and risk of potential public health impact. The average score estimates ranked this virus sixth for the emergence and seventh for the impact risks when compared to the other fifteen viruses scored with the IRAT to date.

**Figure—IRAT Virus Emergence and Impact—Average Risk Scores:** Updated potential pandemic risk for A(H5N1) clade 2.3.4.4b viruses plotted by emergence and impact average weighted risk score estimates (older viruses highlighted in yellow). The most recent 2.3.4.4b virus scored is highlighted with blue crossbars. Additional selected viruses scored using the IRAT are displayed for comparison.

Note: IRAT results were generated using information and data known to influenza subject matter experts at the time of the evaluation. Subsequent findings may change the overall risk estimates associated with the virus.

For accessible explanation of the graph go to [Appendix for Accessibility on page 10](#).



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## Appendix for accessibility

### Figure—IRAT Virus Emergence and Impact—Average Risk Scores

This dot graph plots the average weighted risk scores for “public health impact” and “emergence” for viruses subjectively assessed by the IRAT’s panel of expert reviewers. This graph includes the June 2024 assessment for the highly pathogenic avian influenza A(H5N1) virus; clade 2.3.4.4b Virus Strain: A/Texas/37/2024. This updated assessment indicates that this A/Texas/37/2024 virus has scored slightly lower in some risk elements and slightly higher in other risk elements compared with the previously assessed H5N1 clade 2.3.4.4b viruses: A/mink/Spain/3691-8\_22VIR10586-10/2022 and A/American wigeon/South Carolina/AH0195145/2021, which were assessed in April 2023 and March 2022, respectively. The average risk score for the estimated potential “emergence” of the Texas virus was 5.8, which falls within the range of the moderate risk category. In comparison, the mink virus was 5.1, which falls within the range of the moderate risk category, and the American wigeon virus scored a 4.4, which falls within the lower range of the moderate risk category. The average risk score for the Texas virus to potentially “impact public health” was 6.1, which also falls within the range of the moderate risk category. In comparison, the mink virus was 6.2, which also falls within the range of the moderate risk category, and the American wigeon virus scored a 5.1, which falls within the lower range of the moderate risk category. In addition to these viruses, a selection of 14 other influenza viruses previously assessed by the IRAT have been plotted for comparison. Among all of the viruses plotted, the virus that scores highest in terms of risk of “emergence” is A(H1N1) [A/swine/Shandong/1207/2016], which has a weighted average risk of “emergence” score of 7.5 and a weighted average risk of “public health impact” score of 6.9. The virus that scores highest in terms of risk of “public health impact” is A(H7N9) [A/Hong Kong/125/2017], which has a weighted average risk of “public health impact” score of 7.5 and a weighted average risk of “emergence” score of 6.5. [\[Return to page 7\]](#)