



27 years of Human Bird Flu, Vaccines and Questions

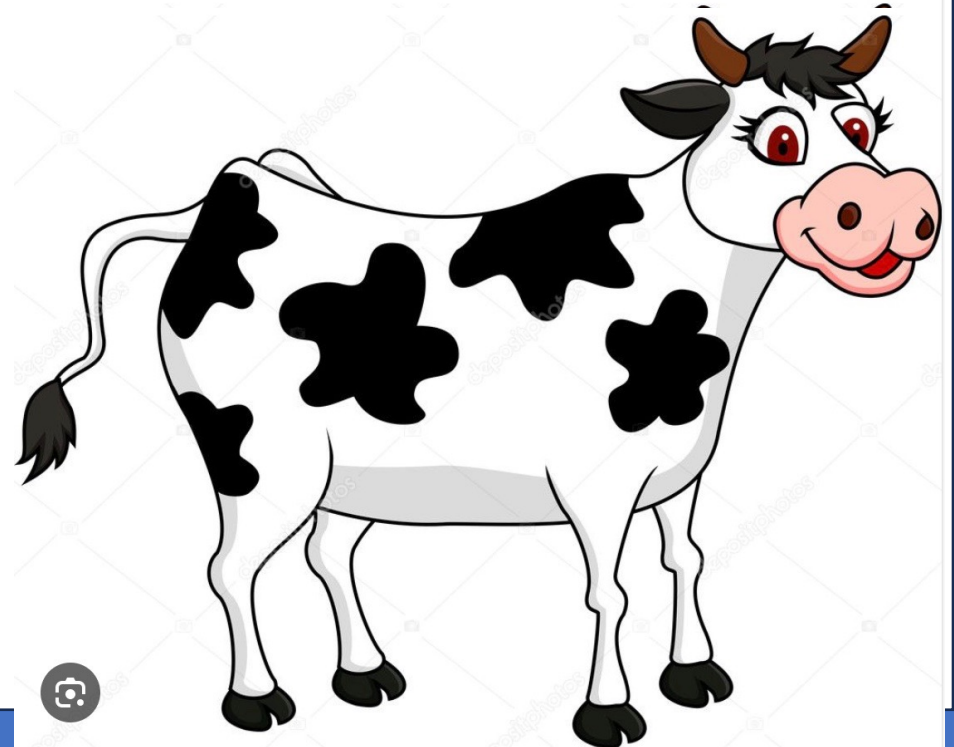
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July 29, 2024

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WHO Reveals Bird Flu is Nothing to Worry About

https://cdn.who.int/media/docs/default-source/influenza/h5n1-human-case-cumulative-table/2024_may_tableh5n1.pdf

Cumulative number of confirmed human cases[†] for avian influenza A(H5N1) reported to WHO, 2003-2024

Country	2003-2009*		2010-2014*		2015-2019*		2020		2021		2022		2023		2024		Total	
	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths
Azerbaijan	8	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	5
Bangladesh	1	0	6	1	1	0	0	0	0	0	0	0	0	0	0	0	8	1
Cambodia	9	7	47	30	0	0	0	0	0	0	0	0	6	4	5	1	67	42
Canada	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1
Chile	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
China	38	25	9	5	6	1	0	0	0	0	1	1	1	0	0	0	55	32
Djibouti	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Ecuador	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Egypt	90	27	120	50	149	43	0	0	0	0	0	0	0	0	0	0	359	120
India	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	1
Indonesia	162	134	35	31	3	3	0	0	0	0	0	0	0	0	0	0	200	168
Iraq	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2
Lao People's Democratic Republic	2	2	0	0	0	0	1	0	0	0	0	0	0	0	0	0	3	2
Myanmar	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Nepal	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1	1
Nigeria	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
Pakistan	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	1
Spain	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	2	0
Thailand	25	17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	25	17
Turkey	12	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12	4
United Kingdom	0	0	0	0	0	0	0	0	1	0	0	0	4	0	0	0	5	0
United States of America	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	0
Viet Nam	112	57	15	7	0	0	0	0	0	0	1	0	0	0	1	1	129	65
Total	468	282	233	125	160	48	1	0	2	1	6	1	12	4	7	2	889	463

*2003-2009, 2010-2014 and 2015-2019 total figures. Breakdowns by year available on subsequent tables.
[†]This count includes reported detections in asymptomatic individuals. In some cases, the confirmation of infection versus transient contamination of the nasopharynx/oropharynx with virus particles after exposure to infected birds or contaminated environment remains inconclusive. Total number of cases includes number of deaths.
 WHO reports only laboratory-confirmed cases. All dates refer to onset of illness.
 Source: WHO/GIP, data in HQ as of 3 May 2024.



According to the WHO, during the last **21 years** there have been **901 cases** of bird flu in humans + **463 deaths**.

In the last 4 years, there have been only 8 bird flu deaths: 2/year

Bird flu mutated years ago to become a **mild** disease, causing mostly **pink eye**.

HPAI in Great Britain since 1959

- Outbreaks in poultry
 - 1959 H5N1
 - 1963 H7N3
 - 1979 H7N7
 - 1991 H5N1
 - 2007 H5N1 x 2
- Incidents in wild and other birds
 - 2005 H5N1 Q
 - 2006 H5N1
 - 2008 H5N1

2004



The NEW ENGLAND
JOURNAL of MEDICINE

> N Engl J Med. 2004 Mar 18;350(12):1179-88. doi: 10.1056/NEJMoa040419. Epub 2004 Feb 25.

Avian influenza A (H5N1) in 10 patients in Vietnam

Tinh Hien Tran ¹, Thanh Liem Nguyen, Thi Dung Nguyen, Thi San Luong, Phuong Mai Pham, van Vinh Chau Nguyen, Thi Suu Pham, Cong Dong Vo, Thi Quynh Mai Le, Thi Thi Ngo, Bach Khoa Dao, Phuc Phat Le, Thanh Truong Nguyen, Thuy Long Hoang, Viet Tung Cao, Truong Giang Le, Dac Tho Nguyen, Hong Nga Le, Kim Tien Nguyen, Hoang San Le, Van Tuan Le, Dolecek Christiane, Tan Thanh Tran, de Jong Menno, Constance Schultsz, Peter Cheng, Wilina Lim, Peter Horby, Jeremy Farrar;
World Health Organization International Avian Influenza Investigative Team

Who raised the alarm about Bird Flu in 2004?

- * Jeremy Farrar
- * Jeremy Farrar's wife
- * Peter Horby, who Farrar (Wellcome Trust) funded to conduct the HCQ overdose trial in the UK with 400 deaths
- * The W.H.O.

Conclusions: Influenza A (H5N1) infection, characterized by fever, respiratory symptoms, and lymphopenia, carries a high risk of death. Although in all 10 cases the infection appears to have been acquired directly from infected poultry, the potential exists for genetic reassortment with human influenzaviruses and the evolution of human-to-human transmission. Containment of influenza A (H5N1) in poultry throughout Asia is therefore urgently required.



The Bird Flu Enigma

- No one has gotten the virus from cooking or eating cooked poultry
- No one has gotten the virus from eggs
- No one has gotten the virus from milk or dairy products, and FDA has found NO live virus in milk—and failed to investigate an infected raw milk situation
- No one has gotten the virus from eating beef
- It is unlikely you can wipe out the disease by culling animals since it is in the wild bird and mammal populations—spillover from them, or not?
- Are we wiping out flocks that would develop immunity?
- **WHY HAVE OVER 500 MILLION CHICKENS, DUCKS AND TURKEYS BEEN CULLED, OFTEN INHUMANELY, IN A VAIN ATTEMPT TO STOP THE VIRUS?**

How do you give **experimental** vaccines quickly to an entire population?

There are 2 possible methods:

1. **EUA** (Emergency Use Authorization)
2. **Mock-up** or **Pre-pandemic** vaccine scam: you create a **prototype vaccine** that will never be used, but you generate all the required paperwork, and you *put it through the motions of a licensing process and issue a license*. Later, you **grandfather in** a pandemic vaccine on the basis of this sham license.

[Pandemic influenza vaccines. Concepts, European **mock-up licenses**, and acceptance criteria]

Began in 2003

"The concept of identifying appropriate scientific and regulatory principles to ensure rapid availability of pandemic influenza vaccines when needed were already developed starting in the year **2003**. These principles **allowed licensing of three so-called mock-up vaccines far ahead of any real presenting pandemic event.** Those licenses (Marketing Authorizations) were immediately adapted to the novel H1N1 strain shortly after its identification in April 2009 ensuring that as early as September 2009 large parts of the German as well as of the EU population had access to licensed products which had undergone sufficient evaluation before first use in humans. **In contrast, for pandemic vaccine without a previously licensed mock-up version it generally took twice as much time to accumulate data supporting the granting of a Marketing Authorization."**

Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2010 Dec; 53 (12): 1242-9.

<https://pubmed.ncbi.nlm.nih.gov/21161474/>

Current and next generation influenza vaccines: Formulation and production strategies

Peter C. Soema^{a b}, Ronald Kompier^{a c}, Jean-Pierre Amorij^a  , Gideon F.A. Kersten^{a b}

- "In addition to H1N1 vaccines, several pandemic H5N1 mock-up vaccines have been currently licensed. **Mock-up vaccines are developed to generate a registration dossier, which can subsequently be used for the licensing of an actual pandemic vaccine after inclusion of a pandemic vaccine strain. This could speed up the regulatory approval process in case of a pandemic.**"
- "Nonetheless, extra care should be given to the safety profile when combining powerful adjuvant with [complex protein](#) vaccines such as WIV, split, virosomal or subunit influenza vaccines, since the induction of broad antibody responses increases the risk of cross-reactivity with self-proteins.
- [European Journal of Pharmaceutics and Biopharmaceutics](#) [Volume 94](#), August **2015**, Pages 251-263

<https://www.sciencedirect.com/science/article/pii/S0939641115002556>

... But the concept of mock-up vaccines is irreparably flawed

- **2009: "Once the mock-up had received registration (in this case the H5N1 containing vaccine), licensing of the real pandemic vaccine (in this case Pandemrix) was cut down to five days (4).**
- Analogy, however, in this case has a very weak evidence base. In **2008** the American National Vaccine Advisory Committee (NVAC) report "The role of adjuvants and new technologies" stated "antigen/adjuvant combination is vaccine specific and no data are available currently that would allow an extrapolation to another antigen or even to the same formulation given by a different route"(5).
- WHO in its **2007** guidance stated that "Because of the inherent variability in the assay systems used to measure immune responses, it is unwise to directly compare results from different studies (6).
- This view was still held in **2013**, when WHO (7) warned that "an adjuvant-mediated enhancement of the immune response to one vaccine antigen, as a rule, cannot be extrapolated to the enhancement of the immune response to another antigen."
- The EMA **2005** Guideline also stresses the uncertainties of novel adjuvant use: "Unpredictability of adjuvant effects in humans results from a complex interplay between such factors as route of administration, antigen dose and the nature of the antigen. For this reason, a final safety evaluation of the newly developed vaccine formulation can only be conducted on the basis of clinical trials"(8)." <https://www.bmj.com/content/362/bmj.k3948/rr-22>



CEPI was announced in Davos in 2017 by Bill Gates and Jeremy Farrar.

CEPI received \$1.95 billion in 2022 alone.

<https://static.cepi.net/downloads/2023-12/CEPI-Annual-Progress-Report-2022.pdf>

The 2023 report highlights how the world could deliver future pandemic-beating vaccines in 100 Days and outlines five key areas of innovation that are needed to contribute to accelerated development of vaccines: 1. pre-existing prototype vaccines for representative pathogens

Making pandemic vaccines in 100 Days #100DaysMission

CEPI About us Get involved Research Equitable Access News & stories

Preparing for future pandemics

A photograph of a healthcare worker wearing a blue face shield and a white surgical mask. The worker is looking towards the camera. The background is slightly blurred, showing what appears to be a clinical or laboratory setting. The image is part of a promotional graphic for CEPI.



But in order for bird flu to become dangerous to humans, it would have to acquire **two different sets of mutations** simultaneously:

- the ability to spread human to human, and
- the ability to cause severe disease in humans

That would only happen in a laboratory doing GOF research

One health, many interpretations: vaccinating risk groups against H5 avian influenza in Finland

June 20, 2024

[Hanna Nohynek](#)¹ and [Otto Matias Helve](#)¹



- "The rationale was the precautionary principle, i.e. to provide protection via immunisation to enable continued fur farming in Finland."
- **"Risk groups to whom the Finnish national public health institute recommends vaccination with the MF59-adjuvanted avian influenza vaccine"**
 - Persons in contact with farmed fur animals;
 - Persons in contact with poultry;
 - Persons handling sick or dead animals or cleaning the related facilities;
 - Persons in charge of ringing birds;
 - Person taking care of birds in animal care facilities;
 - Persons working with birds in bird or livestock farms;
 - Veterinarians working in the public sector;
 - Laboratory personnel working with testing of avian influenza;
 - Close contacts of confirmed or suspected human avian influenza cases."
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11191420/>

One health, many interpretations: vaccinating risk groups against H5 avian influenza in Finland

[Hanna Nohynek](#)¹ and [Otto Matias Helve](#)¹

June 20, 2024



Surveillance for the A(H5N8) vaccine safety will be **passive**.

"The fact that an **MF59-adjuvanted vaccine has never been used** in the national immunisation programme in Finland before may raise questions..."

There are also **questions on the degree and duration of protection** the vaccine will provide.

This issue must be evaluated within a framework which considers the intricate interplay between the environment, animals, and humans [18]. Recognising this interconnectedness and the vast array of environmental impacts of human activity is crucial, and our protective measures should consider the overarching goal of maintaining and enhancing planetary health.—*Let's create a "One Health" justification to explain why we are vaccinating because it makes no sense otherwise*

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11191420/>

Avian influenza in Finland in 2024

<https://www.ruokavirasto.fi/en/animals/animal-health-and-diseases/animal-diseases/poultry/avian-influenza/avian-influenza-in-finland/>

- **As of June 12, Finland has detected only ONE bird with H5N1 virus during all of 2024, no cows and no people**

Table of the HPAI cases in birds detected in Finland in 2024

Case number	Date of detection	Location where the disease was found	Bird species	Avian influenza
1	3.6.2024 (found 24.1.2024)	Helsinki	Northern goshawk	highly pathogenic H5N1

More information

[Avian influenza cases in Finland 2016-2023](#)

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Conditioning
the public:
Not **IF** but
WHEN do we
"pull the
trigger" and
start
vaccinating?

April 2024

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The Observer Bird flu

'The issue is when to pull the trigger': how prepared are we for human bird flu?

The H5N1 virus has been devastating bird populations, and is now infecting mammals too. Is human-to-human transmission next? And are we ready for another pandemic?



Marks confident in bird flu vaccine stockpile

April 2024

By DAVID LIM and LAUREN GARDNER | 04/02/2024 12:00 PM EDT



Dr. Peter Marks, the FDA's top vaccine regulator, said Monday he's confident the U.S. stockpile of avian flu-specific vaccines would work well if deployed. The remarks came the same day [the CDC confirmed](#) that a Texas dairy worker fell ill with bird flu.

"We believe that, if we needed to, they would be reasonably good matches," Marks said at the World Vaccine Congress in Washington,

Whether the federal government would activate new vaccine production depends on how the situation unfolds, Marks indicated.

"... there's probably a pretty low threshold to pull the trigger here," he said. "This is one case we're a little luckier because it's a pathogen that we know. We know what this is and what we have in the freezer, so to speak. We have a little bit of a leg up on at least getting started."

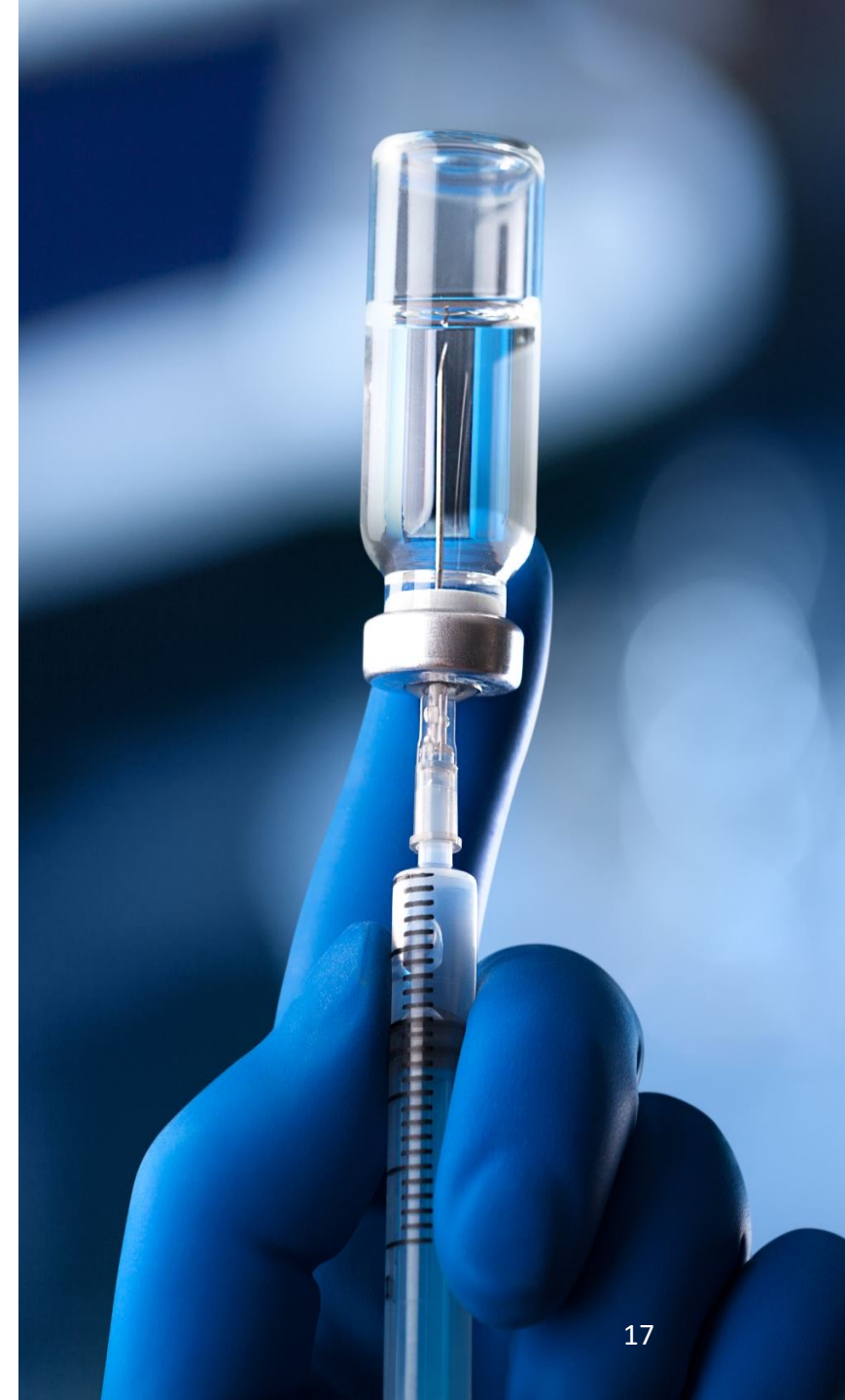
But at the conference, Dr. Luciana Borio, a former FDA official, questioned the vaccines' potency "I'm not as confident as Dr. Marks," she said after his remarks.

<https://www.politico.com/newsletters/prescription-pulse/2024/04/02/marks-confident-in-bird-flu-vaccine-stockpile-00150008>

US: licensed H5N1 and unlicensed* H5N8 vaccines

- **Sanofi** – Licensed for adults in 2007 with 103 subjects
- **GSK** -- Q-pan, Licensed for adults in 2013 and for children over 6 months in 2016. **ASO3 adjuvant**.
- **CSL Seqirus** -- Audenz, Licensed for adults in 2020, **MF59 adjuvant**

-
- * **CSL Seqirus** contract for **H5N8** vaccine and a Phase 2 trial in 2022, **MF59 adjuvant**
 - * **Sanofi** factory being built in 2023 for ? pandemic vaccines
 - * **Moderna** contract for **H5N8 mRNA** vaccine 2024



AMA announces CPT update for avian influenza vaccines

July 19, 2024. Sequirus H5N8 vaccine, MDCK cell culture-derived, Holly Springs, NC

- "The provisional CPT code is effective for use on the condition the **H5N8** Influenza virus vaccine candidates receive **emergency use authorization** from the U.S. Food and Drug Administration.
- For quick reference, the new product code assigned to H5N8 influenza virus vaccines is: 90695 Influenza virus vaccine, H5N8, **derived from cell cultures**, adjuvanted for intramuscular use
- The new CPT code for H5N8 influenza virus vaccines should be used with one of the following administration codes.
- For children (through 18 years of age) the administration codes are: 90460, 90461 (for additional doses)
- For adults the administration codes are: 90471, 90472 (for additional doses)..."

<https://www.ama-assn.org/press-center/press-releases/ama-announces-cpt-update-avian-influenza-vaccines>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

**Declaration of Emergency Pursuant to
the Federal Food, Drug and Cosmetic Act**

<https://www.govinfo.gov/content/pkg/FR-2024-07-24/pdf/2024-16247.pdf>

of HPAI A(H5N1). Additionally, we cannot be sure that the cases known to be associated with the dairy cattle outbreak represent the full spectrum of disease from this currently circulating HPAI A (H5N1) strain, nor can we be assured that the virus will not mutate to cause more severe disease and/or to become more transmissible (e.g., acquire a mutation conferring facile mammal-to-mammal transmission).

Therefore, I have now amended the April 19, 2013, determination to recognize that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves biological agents, namely pandemic influenza A viruses and influenza A viruses with pandemic potential.