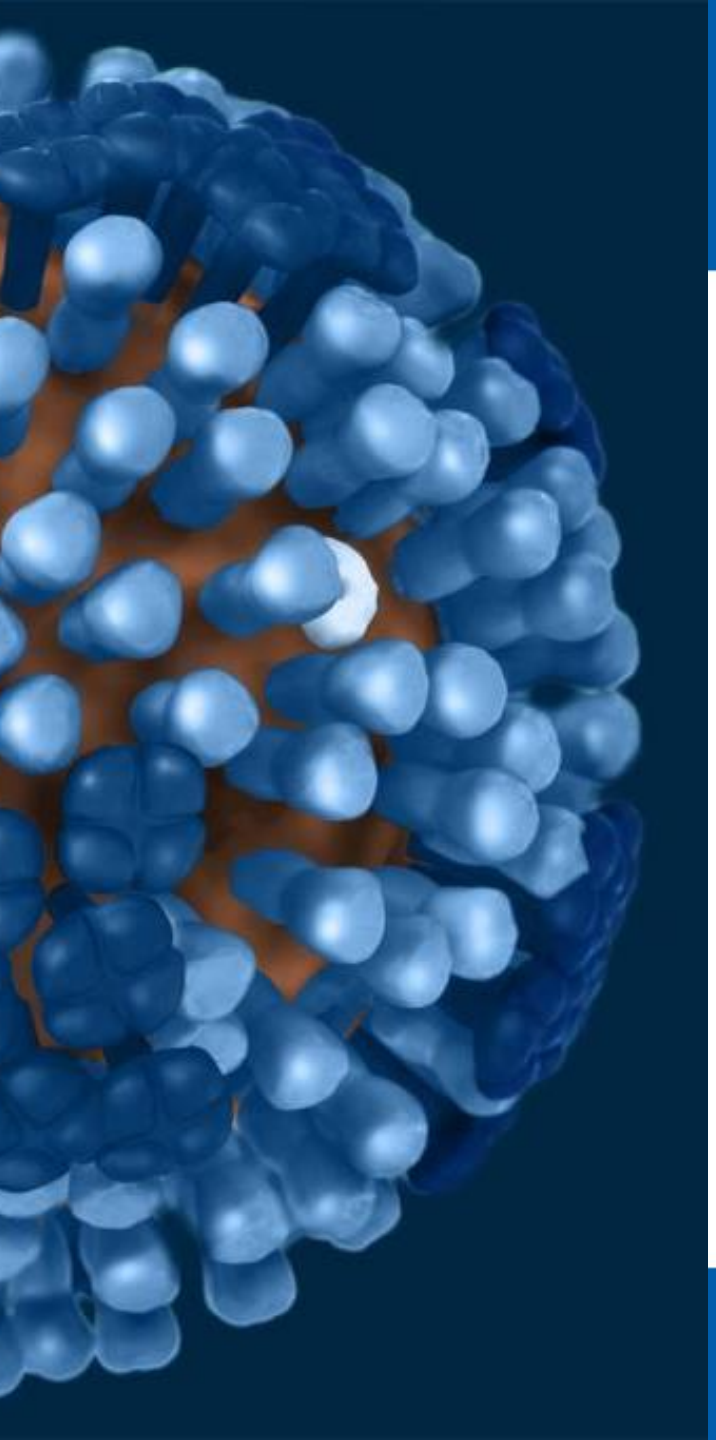

Influenza Risk Assessment Tool

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Influenza Risk Assessment Tool (IRAT)

- A global public health tool to prioritize pandemic preparedness activities
  - Evaluates risk from novel viruses currently circulating in animals, i.e. in pre-pandemic period
- Assess potential pandemic risk for:
  - Emergence of a novel influenza virus in humans
    - Human-to-human transmission
  - Public health impact
    - Severity
- The IRAT cannot predict the next pandemic strain

Why do we need the IRAT?
Multiple Emerging Novel Influenza A Viruses

H9N2 — *1998-2014*

H5N1 — *1997, 2003-2014*

H7N7 — *2003*

H3N2v — *2011-14*

pH1N1 — *2009-14*

H7N9 — *2013-14*

H5N6

H6N1

H10N8

H7N3 — *2012*

Increasing Novel Infections Demand Responses

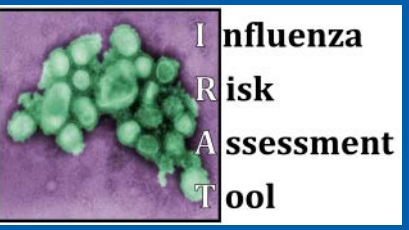
- H7N9
  - >400 cases
  - ~30% CFR
  - Minimal mammalian adaptations
  - No population immunity

- H3N2v
  - >300 cases
  - Very low CFR
  - Significant human adaptation
  - Substantial population immunity

- Very different problems require very different solutions and investments
- Risk assessments are needed to assist decision-making:
  - Vaccine development, testing, manufacturing
  - Countermeasure procurement and preparedness planning

Benefits of the Influenza Risk Assessment Tool

- Objective, risk measure applied consistently with minimal bias
- Provides documentation to support decisions
- Builds on strong global influenza network for virus and genetic sequence sharing (WHO/GISRS)
- Identifies gaps in knowledge/data
  - Encourages sharing and input from both public health and animal health sectors
- Evaluated and reviewed regularly in an iterative process
  - Easily, rapidly updated with new information or data collection methods
- Effective communication method for policy makers

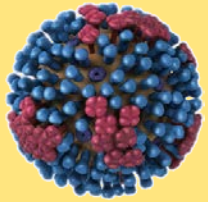


Influenza Risk Assessment Tool (IRAT)[1,2]

- **Design –** A simple, additive, multi-attribute assessment tool
- **Process –**
  - Subject matter experts from different disciplines evaluate available evidence to provide a quantitative assessment to answer the following questions:
    - What is the likelihood that a virus will emerge?
    - What is the likely impact of that virus if it emerges?
  - Ten elements are scored as “Low”, “Moderate”, or “High”:
  - Scores are weighted to answer “emergence” and “impact” questions
  - Each reviewer provides a “confidence score” to address uncertainty
- **Implementation –**
  - IRAT has been used to evaluate H7N9, H5N1, H9N2, H3N2v to inform vaccine development and procurement decisions by USG.

1. Trock SC1, Burke SA, Cox NJ. Development of an influenza virologic risk assessment tool. Avian Dis. 2012 Dec;56(4 Suppl):1058-61.
2. CDC. Influenza Risk Assessment Tool. http://www.cdc.gov/flu/pandemic-resources/tools/risk-assessment.htm

Ten Elements Evaluated in IRAT In Three Groups



Virus

1. **Genomic variation**
2. **Receptor binding**
3. **Transmission in Laboratory animals**
4. **Antivirals and Treatment Options**

Population

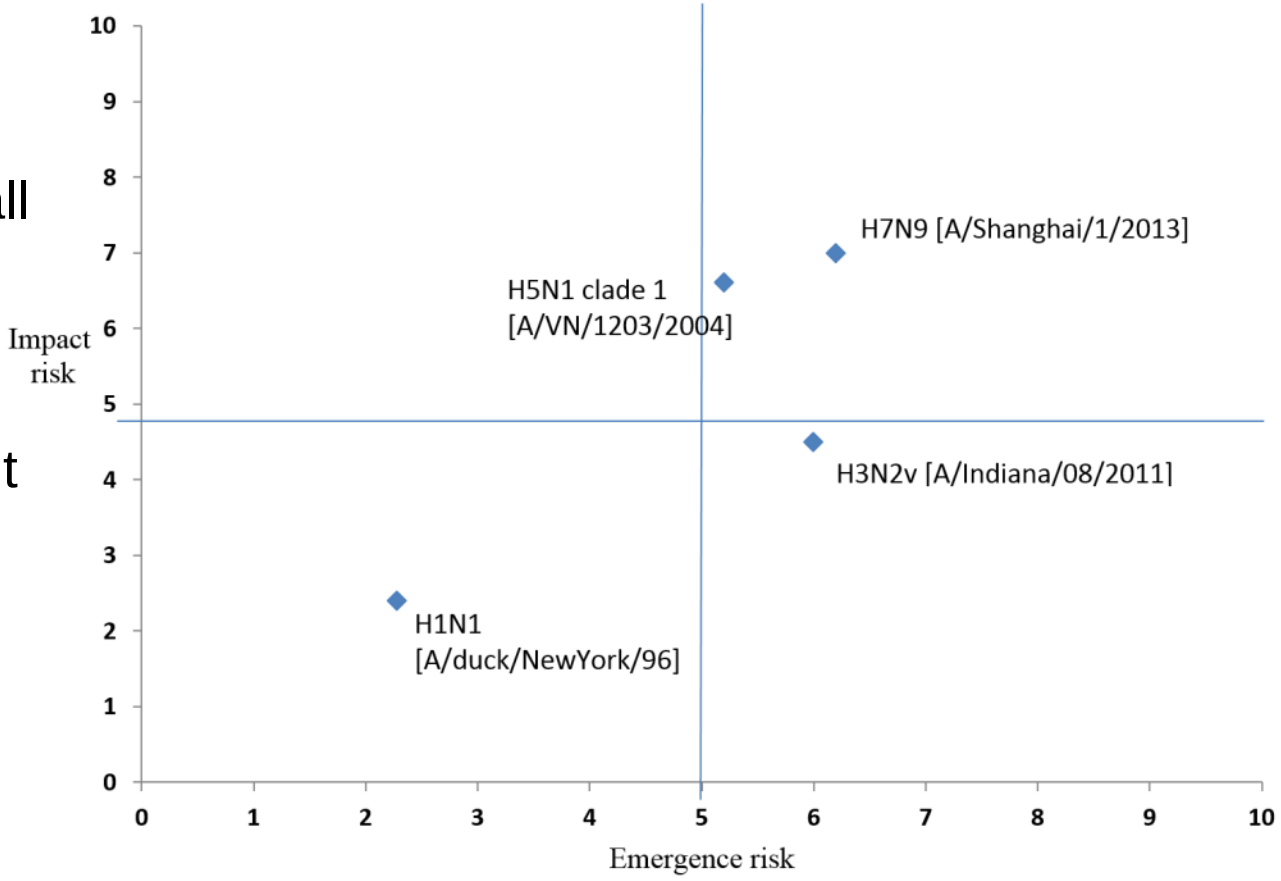
5. **Existing Population Immunity**
6. **Disease Severity and Pathogenesis**
7. **Antigenic Relationship to Vaccine Candidates**

Ecology

8. **Global Geographic Distribution**
9. **Infection in Animals, Human Risk of Infection**
10. **Human Infections and Transmission**

Example IRAT H7N9 Plot for Emergence and Impact

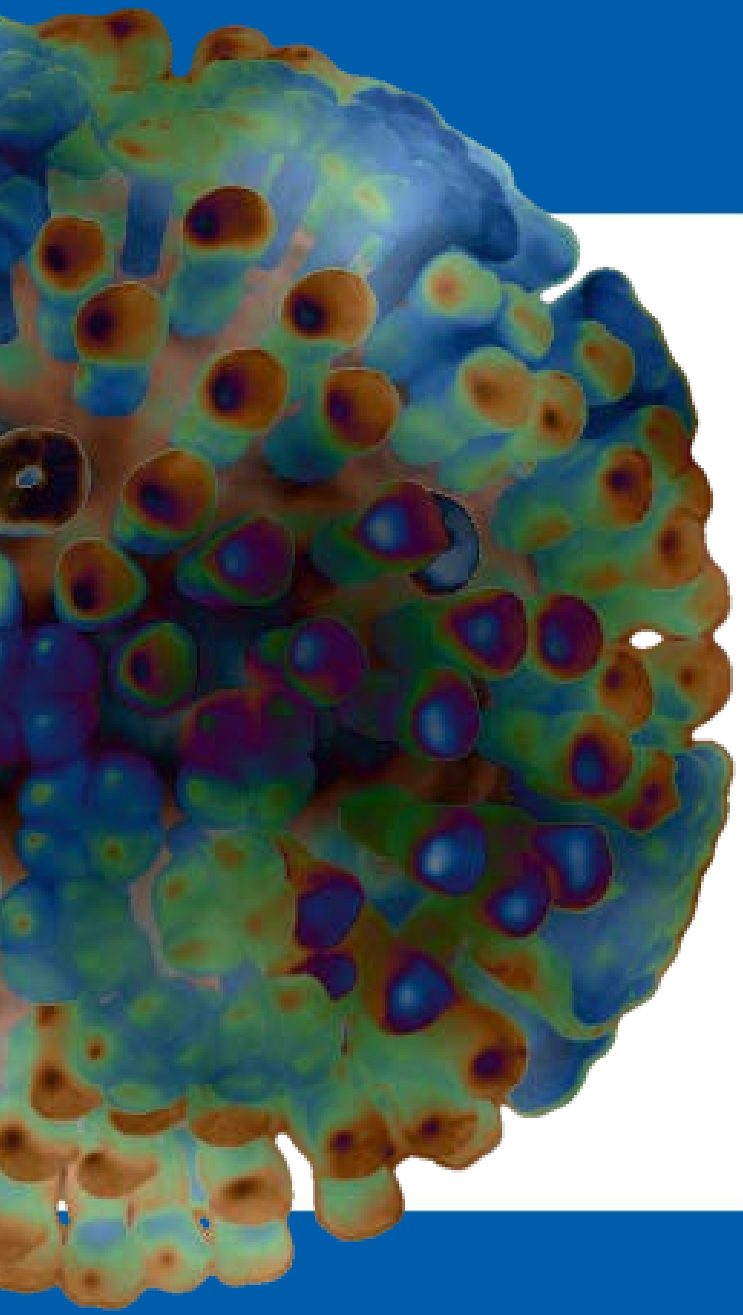
- Each element is scored, weighted, and combined with all reviewer scores
- Data are provided to decision-makers on vaccine development
- Process revisited when more data
- So far, scores have changed:
  - H3N2v lowered
  - H7N9 rose slightly



Trock S, Burke S, Cox N. CDC Unpublished Data.

IRAT and Pandemic Vaccine Priorities

- IRAT scores provided regularly to HHS/BARDA on a regular basis to guide pre-pandemic vaccines and stockpile decisions
  - One component of multi-faceted decision process
- Question:
  - Which additional vaccine antigens should be produced, stockpiled or selected for clinical trials to mitigate potential public health impact of emerging virus
- Assess 5 elements relevant to vaccine
  - Human infection; Antigenic relationship; Global distribution; infection in animals; genomic variation
  - Which H5N1 virus poses greatest risk to impact public health when considering vaccine development and vaccines available in SNS ?
  - Which virus poses greatest risk to impact public health when considering vaccine development and available candidate vaccine viruses?



Questions?

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