

### FFX Investigation Protocol and other Studies

Presenters: Melissa Rolfes

14 November 2024

Contact : <u>unity@who.int</u>

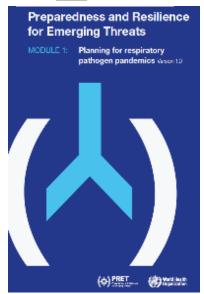
### **Definition and scope of Unity Studies**

- Suite of protocols and toolkits for gathering key information
  - Early during an epidemic/pandemic
  - That is not efficiently captured by existing surveillance
- Discrete, time-limited and specialized

Unity Studies are one tile in the respiratory surveillance mosaic and are an essential component to surveillance plans for pandemic preparedness



Web: Mosaic







# Key epi parameters to characterize an emerging influenza virus

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Secondary infection risk

Serial interval

Incubation period

Estimated generation interval

Duration of viral shedding

Possible routes of transmission

Risk factors for transmission

Reproduction numbers

#### **Case severity**

Clinical presentation

Symptomatic/syndromic/asymptomatic proportion

Case-hospitalization ratio (infection-hosp ratio)

Case-fatality ratio (infection-fatality ratio)

Risk factors for severe disease





## Key epi parameters to characterize an emerging influenza virus

#### **Transmissibility**

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Primary objectives

**Secondary objectives** 

The First Few X cases and contacts (FFX) comprehensive investigation template protocol for

Pandemic Influenza A(HxNy)





# Follow-up and specimen collection

- The First Few X cases and contacts (FFX) comprehensive investigation template protocol for Pandemic Influenza A(HxNy)
- Prospective case-ascertained transmission investigation
- Index cases <u>and</u> contacts followed for 28 days
  - Day 1 (day or recruitment\*): Survey for demographic, clinical, and epidemiologic information
  - Day 1-14: Daily symptom diary
    - Day 1, 2, 3, 5, 9: **respiratory specimens**
    - Day 1 & 28: **blood/serum specimen**
  - Day 28: Survey for **outcomes**, treatment, and updates

Day since recruitment	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Study visit																												
Respiratory samples																												
Blood/Serum sample#		Г																										
Other specimens (if/where relevant)		-																										

<sup>\*</sup> Index cases should be recruited as soon as possible after the case becomes known to public health authorities





Indicate activities that are mandatory for the investigation of influenza A(HxNy).

MEDIUM BLUE BOXES Indicate activities that optional but highly recommended, and may be undertaken with appropriate resources and capacity to provide additional information. These are more than is required from the minimum specimen requirements of this investigation.

LIGHT BLUE BOXES Indicate activities that may be undertaken in high resourced settings where there is substantial uncertainty in the biological and epidemiological characteristics of influenza A(HxNy).

indicate where additional specimen types could be collected to increase the information available.

## Other template protocols

### 5 template protocols published:

- 1. The First Few X cases and contacts (FFX) investigation
- 2. Household transmission (HHTI)
- 3. Closed settings transmission
- 4. Outbreak investigation of non-seasonal influenza
- 5. Population-based **seroprevalence** investigation

Separate protocols for influenza and respiratory pathogens with pandemic potential/pathogen X

### Protocols in development:

- 1. Rapidly assessing clinical severity
- 2. The **First Few X (FFX) Case Series** investigation
- 3. Vaccine effectiveness protocols



