



FFX Investigation Protocol and other Studies

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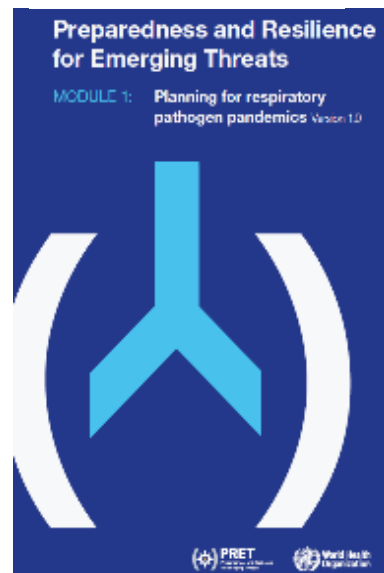
Definition and scope of Unity Studies

- 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](#)



Web: [PRET Respiratory](#)

Key epi parameters to characterize an emerging influenza virus

Transmissibility

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

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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 and contacts followed for 28 days
 - Day 1 (day of 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 [#]																												
Other specimens (if/where relevant)																												

* Index cases should be recruited as soon as possible after the case becomes known to public health authorities

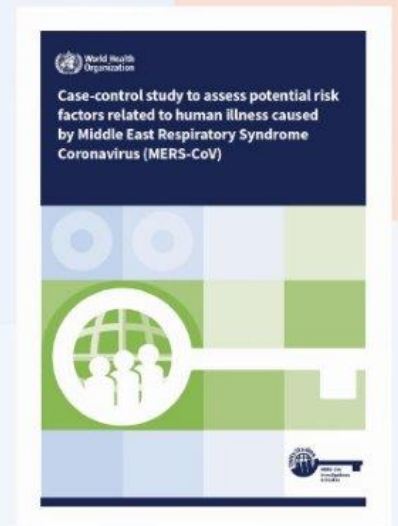
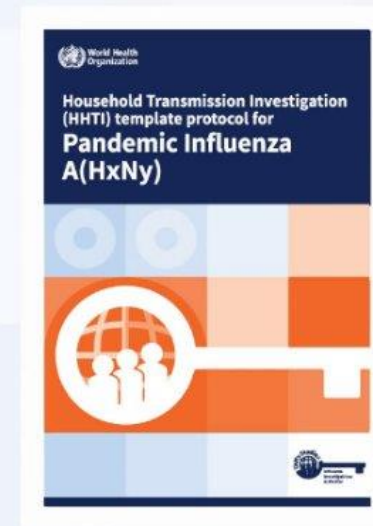
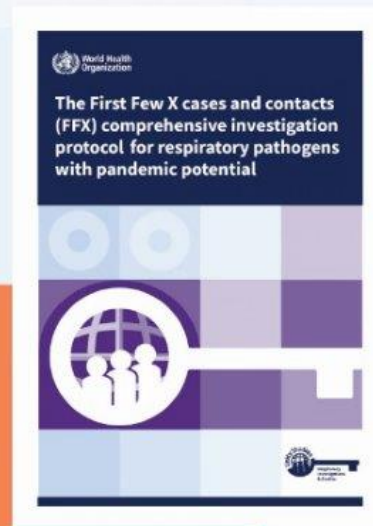
Other template protocols

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



Global operational network

