CEIRS Human Influenza Surveillance of Health Care Centers

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Objectives:

- To develop a robust domestic and international influenza surveillance network which will allow rapid identification of circulating influenza viruses, including those with pandemic potential in human populations.
- Collect relevant clinical samples to include nasopharyngeal (NP), nasal aspirates and serum samples from patients with suspected and confirmed influenza.
- To identify the added benefit of serology when combined with PCR for identification of influenza infections.
- To characterize the immunologic basis of severe illness due to influenza.

Sites:

Johns Hopkins Healthcare System

    Johns Hopkins Hospital (JHH) – Active and Passive surveillance
    Johns Hopkins Bayview Medical Center (JHBMC) – Active and Passive Surveillance
    Howard County General Hospital – **ONLY passive surveillance**
    Suburban Hospital – **ONLY passive surveillance**
    Sibley Memorial Hospital – **ONLY passive surveillance**

Chang Gung Memorial Hospitals (CGMH) Taiwan

    CGMH Linkou – Active and Passive surveillance
    CGMH Taipei – Active and Passive surveillance
    CGMH Keelung – Active and Passive surveillance

Sites will participate in either active and passive surveillance, or only passive surveillance.

- *Active surveillance: emergency department (ED) patients will be consented, enrolled and will contribute nasopharyngeal and serum samples.*
- *Passive surveillance: There will be no direct patient contact, and patients will be enrolled under a waiver of consent. We will collect waste nasopharyngeal samples in coordination with the virology laboratory, and retrospectively obtain relevant clinical information from the electronic medical record.*

Study Duration:

This study is funded for 7 influenza seasons.
The below requests refer to annual study goals for each of the 7 influenza seasons.

Population:

Active Surveillance: Adult subjects (ages 18-100 years) presenting to JHH, JHBMC, or CGMH EDs with (symptomatic, n=400) and without (asymptomatic, n=100) influenza like illness each year.

We will recruit an additional 100 adult subjects (ages 18-100 years) presenting to JHH, JHBMC, or CGMH EDs with laboratory confirmed influenza (for purposes of ensuring adequate sample size for serological studies) each year.

Passive Surveillance: Adult and pediatric subjects (ages 0-100 years) who tested positive for Influenza A in either the inpatient service, ED or outpatient clinics of the Johns Hopkins (n=125) or Chang Gung Healthcare Systems (n=125) each year.

Procedures:

Active Surveillance:
- Enrollment
  - Screening to determine eligibility
  - Written consent
  - Enrollment questionnaire including basic demographic data, vaccination history, co-morbid illness, initial vital signs and history of present illness.
  - Collection of serum sample
  - Collection of nasopharyngeal swab sample
  - Test for influenza
  - If influenza positive, then collect nasopharyngeal wash sample
- Follow up visit
  - Follow up questionnaire to assess clinical course
  - Collection of serum sample
  - Medical record review to assess clinical course

Passive Surveillance:
- Screening to determine eligibility
- Chart review including basic demographic data, vaccination history, co-morbid illness, initial vital signs and history of present illness.
- Collection of nasopharyngeal waste sample
- Medical record review to assess clinical course

Schematic of Study Design

Active Surveillance

Enrollment
Active Surveillance
Subjects not yet tested for influenza
- 400 Symptomatic
- 100 Asymptomatic
- Screen and enroll
- Obtain Informed Consent
- Collect baseline clinical data

Sample Collection
- Nasopharyngeal Swab
- Serum (baseline)

Influenza Testing (Xpert Flu)
Negative / Positive

Influenza Positive

Enrollment
Influenza Positive subjects
- 100 subjects with laboratory confirmed Influenza
- Obtain Informed Consent
- Collect baseline clinical data

Sample Collection
- Serum (baseline)

420 Negative Subjects

Follow-up visit
- 3-4 weeks after enrollment
- Interview – clinical outcomes
- Chart review – clinical outcomes

Sample Collection
- Serum (convalescent)

180 Positive Subjects

Sample Collection
- Nasopharyngeal Wash

Follow-up visit
- 3-4 weeks after enrollment
- Interview – clinical outcomes
- Chart review – clinical outcomes

Sample Collection
- Serum (convalescent)

Passive Surveillance

Enrollment
Passive Surveillance
- 250 subjects with laboratory confirmed Influenza
- Remnant sample available in clinical laboratory

Sample Collection
- Remnant sample from clinical laboratory

Follow-up Chart Review
- 3-4 weeks after enrollment
- Chart review – clinical outcomes