1

Overview of Hospital Training

- Background of AFM and AFM Project
- Role of Hospitals
- Inclusion and Exclusion Criteria
- Identifying and reporting AFM Biorepository participants
- Introducing the Biorepository
- Consenting participants
- Consent Requirements
- Specimen collection guidelines
- Specimen packaging and shipping guidelines
- Convalescent Collections
- AFM Biorepository contacts

2

On-Site Hospital Coordinator Materials

1. Hospital Factsheet (English and Spanish)
2. CDC Diagnosis Criteria
3. AFM Biorepository Factsheet
4. AFM Biorepository FAQ
5. All Specimens Informed Consent Form/Permission Form and Assent 15-17
6. Assent Language >7 and <15 Years old
7. Consent process talking points – Hospital enrolled
8. Acute Hospital Staff Collection Guidelines
9. Pictures of kit and kit content
10. Hospital Worker envelope content
    a) Acute AFM Kit Content List (Fisher)
    b) Acute AFM Collection Kit Return Packaging Instructions
11. Specimen Submission Form
12. Project Contact List

AFM Biorepository Team

- Dr. Wendy Kaye – Principal Investigator
- Dr. Lindsay Rechtman – Hospital Coordinator
- Laurie Wagner – Biorepository Coordinator
- Elana Spaulding – Participant Coordinator
- Ayana Hart – Research Assistant

We are working in collaboration with CDC's National Center for Immunization and Respiratory Diseases, Division of Viral Diseases

Background of AFM Project

- Acute Flaccid Myelitis (AFM) is a rare neurological condition characterized by the sudden onset of limb weakness, loss of muscle tone and reflexes.
- Most AFM cases have been diagnosed in children and there has been an increase of AFM cases every other year starting in 2014.
- CDC contracted with General Dynamics Information Technology (GDIT)/McKing Consulting Corporation (McKing) to facilitate the collection and storage of AFM specimens.
- The goal of this project is to build a bank of specimens matched with epidemiological and clinical data that can be used by researchers to determine the causes and risk factors for AFM as well as better treatment options for individuals affected by this condition.
- It is important to collect and store specimens from AFM patients that can be used for research purposes when needed.

5

Role of Hospitals

Identify Potential Participants

Conduct Informed Consent

Collect & package specimens for shipment

6

Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Age: 3 months or older • Onset of limb weakness involving one or more extremities suggestive of AFM **within** previous 30 days • Physician provided possible or suspected diagnosis of AFM • Agrees to future use of specimens	• AFM patient under investigation at a NIH participating hospitals • Known condition other than AFM causing flaccid limb weakness • Refusal to consent/ assent for participation • Wards of the state • Prisoner

7

Identifying and Reporting Participants

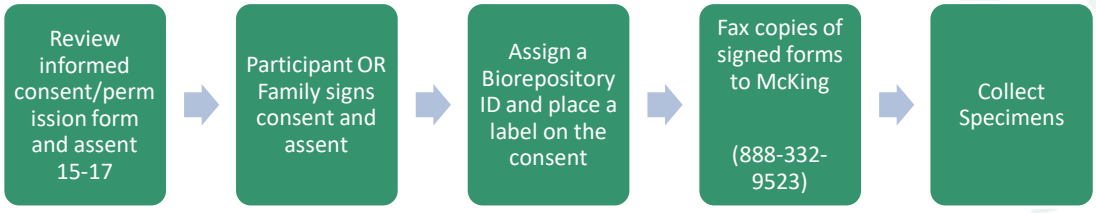
Review hospital admissions 2-3x week to identify potential participants → Confirm with treating physician of possible AFM diagnosis → Contact McKing Biorepository Office to notify of potential case

8

Introducing the AFM Biorepository

9

Consenting Participants



10

Consent Requirements

- Individual must understand English or Spanish at an 8th grade reading level.
- Adult participants will sign the informed consent form for themselves.
  - a representative may sign if the participant wants to participate but is unable to physically sign.
- Children under 18 – parent or legal guardian must sign the parental permission section of the consent form.
  - Children ages 15 – 17 will be required to sign the assent section of the consent form to participate.
  - a representative may sign if the participant wants to participate but is unable to physically sign.

11

Specimen Collection- Children

Sample to be collected	Description of collection
Blood Tube #1	EDTA Purple Top – 6mL
Blood Tube #2	Plain (no anticoagulant) – 6mL
Stool sample	Stool Collector Sterile Container OR rectal swab
Respiratory sample	NP or OP swab
CSF	Leftover sample from diagnostics – 0.25 – 2ml *(---Frozen is acceptable)*

12

Specimen Collection- Adults

Sample to be collected	Description of collection
Blood Tube #1	EDTA Purple Top – 10mL
Blood Tube #2	Plain (no anticoagulant) – 10mL
Stool sample	Stool Collector Sterile Container OR rectal swab
Respiratory sample	NP or OP swab
CSF	Leftover sample from diagnostics – 0.25 – 2ml *Frozen is acceptable)*

Acute Blood Collection Kit

Packed Kit

Kit Contents

Specimen Shipping

- Samples will be placed back into the collection kit
- Sealed and labeled with the provided return label
- Brought to a FedEx facility to ship to Fisher Laboratory in Maryland

15

Convalescent Collections

- Will take place 4-8 weeks after limb weakness onset
- Blood only collection
- If patient is still admitted to hospital we will coordinate collection with you

16

AFM Biorepository Team

Wendy E. Kaye, PhD, Principal Investigator – wkaye@mcking.com
Lindsay Rechtman, DrPH, MCHES, Hospital Coordinator – lrechtman@mcking.com
Laurie Wagner, MPH, Biorepository Coordinator – lwagner@secure.mcking.com
Elana Spaulding, MPH, Participant Coordinator – espaulding@secure.mcking.com
Ayana Hart, Research Assistant – ahart@secure.mcking.com

Toll-Free Phone: 1-855-874-6912
Toll-Free Secure eFax: 1-888-332-9523
Email: AFMproject@secure.mcking.com
Website: www.cdc.gov/afm

16

17

To complete the training please answer the survey:

https://www.surveymonkey.com/r/HT6P6G9

17

18