MTN-020 Algorithm

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MTN-020

- Review of MTN-020 Algorithm
- Case Scenarios
  - Discordant Rapids at Screening
  - Unusual Result Pattern at Follow-Up
  - HIV Positive at Quarterly Visit
- Lessons Learned from VOICE
MTN-020 Screening

Ineligible for study → +/+ → 2 different rapid tests → +/− → Notify the MTN Network Laboratory for follow-up.

-start-

−/− → Report as HIV-uninfected
MTN-020 Follow-Up/Endpoint

START
2 different rapid tests

-/+ or +/-

-/-
Report as HIV-uninfected

+/+
Report as HIV infected

+/–

WB

– or ind
Notify MTN NL

HIV RNA
HIV DNA if indicated

+/

Repeat Western blot after 1 month

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MTN-020 Follow-Up/Endpoint
Case 1

- A screening participant has these results:
  - What is her HIV status?
  - Should she be enrolled?
  - What should be done next?
Case 2

- Participant B had the following test results at visit 7.0:
  - Two positive rapid tests
  - Indeterminate WB
  - Undetectable HIV RNA

What is her HIV status?
What should be done next?
What results are needed to resume study product?
Case 3

Participant C had two positive rapids at visit 6.0 (quarterly visit).

- **Scenario 1:** The rapids were done by fingerstick.
- **Scenario 2:** The rapids were done by venipuncture.

How much blood should be drawn next? What will the blood be used for?
Plasma Storage Scenario 1: Monthly Visit

Draw 1: HIV rapids only

Perform 2 different rapid tests

+/+ or +/−

Draw 2:
WB, CD4, RNA, **Plasma storage**
Plasma Storage Scenario 1: Monthly Visit

- Simple Situation logistically
- Draw enough whole blood with second draw to store 6 mL of plasma
- Plasma is marked with code “CON” in LDMS
Plasma Storage Scenario 2: Quarterly Visit

Draw 1: HIV rapids, Plasma storage, FBC, Chemistries
Perform 2 different rapid tests

+/+ or +/-

Draw 2: WB, CD4, RNA, Plasma storage
Plasma Storage Scenario 2: Quarterly Visit

- Situation less simple
- Routine plasma storage minimum is 4 mL
- HIV algorithm confirmation plasma storage minimum is 6 mL
- Routine plasma is marked with code “RPS” in LDMS
- Confirmation Plasma is marked with code “CON” in LDMS
Plasma Storage Scenario 2: Quarterly Visit

- Current Guidance
  - SSP states that no more than 6 mL plasma needs to be stored at a visit
  - NL had told MRC they can collect enough additional plasma with second draw to meet 6 mL minimum
  - No specifications about handling plasma storage codes (RPS/CON) when routine and confirmation plasma storage needed at same visit
Plasma Storage Scenario 2: Quarterly Visit

- Proposed operational improvements:
  - Change guidance so that when routine and confirmation plasma storage needed at same visit, 6 additional mL of plasma are stored from the second draw.
  - Minimum 4 mL would be stored from the first draw and marked as “RPS” in LDMS.
  - Minimum 6 mL would be stored from the second draw and marked as “CON” in LDMS.
  - Total minimum stored would be 10 mL.
Plasma Storage Scenario 2: Quarterly Visit

- Proposed operational improvements:

  - Benefits
    - Plasma tested at NL would be same plasma used for WB at the site.
    - Would standardize and simplify HIV algorithm plasma storage draws between visit types.
    - There would be additional plasma available at visits where there are positive rapids which are of greater scientific interest.
    - Reduces chances that plasma storage would be completely missed at a visit with positive rapids.
Plasma Storage Scenario 2: Quarterly Visit

- Questions for sites
  - Would this present challenges for sites to track two plasma storages separately from the same visit (CRF, specimen labeling, requisition forms/LDMS tracking sheets/LDMS storage)?
  - Informed consent blood volumes?
  - Any additional concerns for sites performing fingerstick HIV rapids?
Lessons Learned from VOICE

- Lesson 1: Staff collecting specimens must review frequently the algorithm, related sample collections and procedures.
Lesson 2: Have reference materials available where specimens are collected. SOP’s Cheat sheets, checklists etc…
Lesson 3: Labs need to closely oversee kit inventories.
Lessons Learned from VOICE

Lesson 4: Communications are key. Sites clinics and labs should meet periodically and speak frequently. The NL will strive to improve communications with the sites.
Lesson 5: Rapid HIV tests. Simple? Not so simple!

- Do not become complacent with the little details.
  - Timers
  - Supply set up
  - Weak bands

- Documentation requirements are challenging.
- Provide frequent and comprehensive oversight