

MTN 001

Lessons Learned

Beatrice A. Chen, MD MPH
University of Pittsburgh
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Topics

- Enrollment violation
- Lab follow-up
- Recruitment strategies

Scenario: Enrollment violation



- Subject enrolled with Hgb 9.4 (exclusionary value)
- Protocol violation not identified by study coordinator, physician, or site QA/QC procedure

Enrollment violation: lessons learned



- Exclusionary DAIDS values and second clinician signature added to MTN laboratory checklist

MTN laboratory checklist

MTN Laboratory Checklist

SCREENING VISIT

Visit Date: ____/____/____

Participant Name: _____

DONE	TEST	NORMAL VALUE	EXCLUSIONARY DAIDS VALUE
	WBC (thou/mcl)	3.8-1.6x10 ⁹ /uL	N/A
	Hemoglobin (g/dL)	11.6-14.6g/dL	≤10.0 Gradable if below 10.9g/dL
	Hematocrit	34.1-43.3%	N/A
	Platelet (thou/mcl)	156-369x10 ⁹ /uL	Less than 100,000/mm ³
	SGOT (AST) (units/L)	15-37 U/L	Greater than 46.25 U/L
	SGPT (ALT) (units/L)	30-65 U/L	Greater than 81.25 U/L
	Creatinine (mg/dL)	.6-1.0 mg/dL	Greater than 1.0 mg/dL
	Phosphorus	2.5-4.9 mg/dL	Less than 2.5 mg/dL
	Creatinine Clearance	N/A	Less than 70 mL/min
	HIV ELISA	Negative	Positive
	Syphilis	Non reactive	N/A
	Chlamydia	Negative	N/A
	Gonorrhea	Negative	N/A
	Hepatitis (HBsAg)	Non reactive	Reactive
	PAP (new or old)	Negative for Intraepithelial Lesion	ASCUS HPV+ or above
	Urine dipstick		2+ or greater protein
	NO abnormal exam findings with Grade 2 or higher genital lesions, erythema, or edema at		

Clinician signature & date

Clinician signature & date

Enrollment violation: lessons learned



- Exclusionary DAIDS values and second clinician signature added to MTN laboratory checklist
- Inclusion/exclusion pages of protocol printed out for enrollment visit
 - Each line reviewed and initialed by both clinicians
- QC/QA staff member also reviews all labs, exam findings, and visit documentation

Scenario: Lab follow-up

- Subject presented for study start visit 8 on 15DEC08 (Monday)
- Labs drawn, sent to lab with requisition forms
- How long does it take to get results?
 - Depends on type of lab

Scenario: Lab follow-up

- Lab results reviewed to complete CRFs on 19DEC08 (Friday)
- No HIV test results!
- Lab contacted regarding missing results
- Office was informed by email after hours that specimen was not processed due to oversight; sample already discarded

Scenario: Lab follow-up

- Reached subject on 22DEC08 (Monday) to ask her to return for re-draw
- Subject unable to return until 24DEC08 due to childcare issues (daughter with flu)
- 24DEC08: subject had flu, unable to come in
- 29DEC08: subject finally returned for follow-up, now out of window
 - Research office closed for holidays 25DEC08 – 28DEC08

Lab follow-up: lessons learned



- Lab tests say “pending” if lab was ordered but not resulted
- If lab test is not resulted or does not say “pending” within 3 days, office will contact lab to inquire
- Clinical laboratory manager instructed staff to review each study requisition and specimen label to make sure labs are ordered correctly
- Will notify PSRT to inquire about product hold if HIV tests are not resulted

Lab follow-up: lessons learned

- How has this plan worked?
- Subject presented for study start visit 8 on 20FEB09 (Friday), labs drawn and sent
- HIV not listed as “pending” on 23FEB09 (Monday)
- Lab notified on 23FEB09 but specimen had been discarded on 22FEB09
- Subject able to return within window for repeat HIV

Recruitment strategies

- Flyers:
 - Hospital clinics (staff member also available in family planning clinics to discuss study)
 - Community and college campuses
 - Fundraiser for Prevention Point Pittsburgh
- Web:
 - Craigslist (volunteers) weekly
 - Pittsburgh Post-Gazette online (Search Engine marketing)
 - UPMC's internal online newsletter quarterly
- Ads:
 - Pitt News, City Paper, University Times
- Prior studies:
 - Letter sent to ~240 former study participants who completed studies in our research office

Community outreach

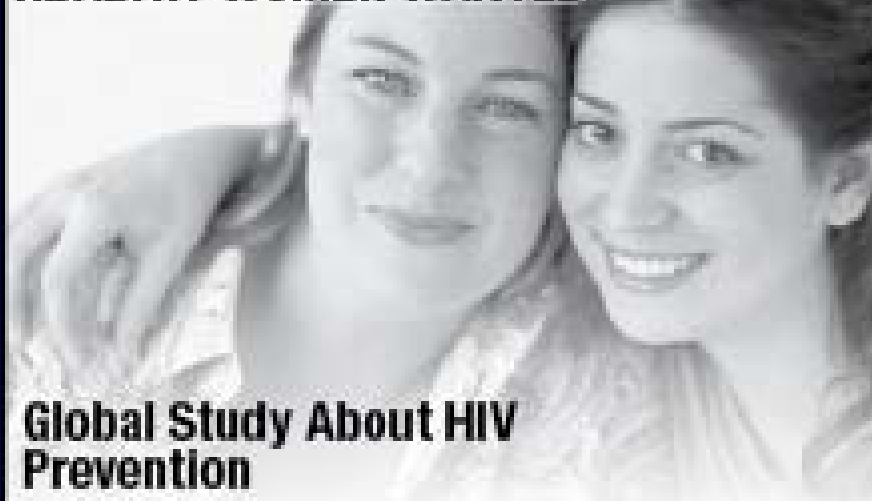
- Health fair at Penn State Beaver Campus to promote MTN-001 and HIV prevention
- Information table at World AIDS Day Event at University of Pittsburgh Graduate School of Public Health
- Information table at Inter–Course, a collaborative student-run HIV awareness event at University of Pittsburgh
- Presentation on global impact and implications of MTN-001 to Pitt’s Student Global AIDS Project members
- Partnership with Planned Parenthood’s outreach efforts at the University of Pittsburgh student union

SCREENING

- Of 57 participants screened, the sources were:
 - 17 from prior studies
 - 9 from City Paper (free weekly paper with news and entertainment info)
 - 6 referred by Infectious Disease research
 - 6 from flyers
 - 5 from website
 - 5 from Craigslist (volunteers)
 - 3 from emails
 - 6 from miscellaneous sources

Any questions?

HEALTHY WOMEN WANTED



Global Study About HIV Prevention

If you are a healthy woman:

Healthy Women Ages 18 to 45 needed for study medications used to prevent HIV. **YOU DO NOT NEED TO BE AT RISK TO PARTICIPATE.** Study involves 11 visits over 7 months to Magee-Womens Hospital. Volunteers will be paid at end of each visit for their time and travel expenses.



MAHEE-WOMENS HOSPITAL
RESEARCH
INSTITUTE

CALL NOW to see if you qualify!

The Center for Family Planning Research

412-641-5496 or visit www.birthcontrolstudies.org