Implementing the PMTCT standard of care under routine conditions with and without the Enhanced Mentor Mother ProgrAm (EMMA): A site-randomized impact evaluation study among maternal and child health clinics supported by the South Rift Valley PEPFAR Program in Kenya

Short title: The EMMA study
Study Conducted by US Military HIV Research Program

Study Supported by
Data Coordinating and Analysis Center, (DCAC), MHRP
Henry M. Jackson Foundation (HJF)
<table>
<thead>
<tr>
<th>Case Report Form</th>
<th>Page No.</th>
<th>Total No.</th>
<th>Visit</th>
<th>Doc</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. EMMA Mother Visit Data Extraction Form</td>
<td>4</td>
<td>2</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>2. Mother- Infant Extraction Form</td>
<td>6</td>
<td>2</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>3. EMMA Mentor-Mother/Patient Visit Record Form</td>
<td>8</td>
<td>1</td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>
RV465 Case Report Form
General Completion Instructions

(See detailed information in CRF Completion Instruction)

All entries:
• Case Report Forms (CRF) must be completed for every subject who is assigned a subject identification number SUBJECT ID for this study.
• Record the Subject ID in format stated in the protocol, which is 4 digits [first 2 site code, next 2 enrollment number (01-30 per site)]
• Use black or blue ballpoint pen to write entries; do not use pencil.
• Mark with an ‘X’ in applicable check boxes.
• Avoid using abbreviations unless otherwise specified.

Corrections on the CRF:
• Do not erase entries; do not use correction fluid
• Draw a single line through the incorrect entry
• Write the correct information close to the original entry; do not write over the previous entry.
• Initial and date the corrections. All changes must be initialed and dated by study personnel.

Shapes/Lines on the CRF:
• [ ] A check box - Mark all options that apply following the check boxes
• [ ] A circle field - Mark only one that apply among the options
• [ ] When brackets are provided for a field, enter one character per box.
• [ ] _______ A short line with a bar at both ends is a field of a numeric value.
• _______________ A long line after Other, Specify/Comments label is a field for long text entry.

Dates on the CRF:
• Dates will be recorded in DDMONYYYY format, e.g., 01JAN2012.
• DD is for day and it must be given in 2 digits. (for example: 01, 02, 14, 25 etc...)
• MMM is for month and it must be written only the first 3 letters of the month in English language as: (JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC)
• YYYY is for year and must be given in 4 digit (for example: 2017)
EMMA MOTHER VISIT DATA EXTRACTION FORM

EMMA MOTHER VISIT

Nature of Visit:  
1. Scheduled  2. Unscheduled

Note to data extraction team: Fill in once for first ANC visit

PMTCT entry:  
1. New HIV diagnosis  2. HAART clinic

Most recent CD4 result*:  |___________| cells/mm³  Result Date:  |____|____|____|____|____|____|____|____|____|____|____|

Most recent VL result*: |___________| copies/mL  Result Date:  |____|____|____|____|____|____|____|____|____|____|____|

(* If CD4 or Viral Load testing not previously done, please enter N/A for result)

Date of last menstrual period (LMP):  |____|____|____|____|____|____|____|____|____|____|____|

Expected date of child birth:  |____|____|____|____|____|____|____|____|____|____|____|

Gestation in weeks:  ______

Was this patient on ART prior to 1st visit for antenatal care for this pregnancy?  
1. Yes  0. No

Date Started on ARVs:  |____|____|____|____|____|____|____|____|____|____|____|

Medications (ordered during this visit)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Strength</th>
<th>No of Days Supplied</th>
<th>Medication</th>
<th>Strength</th>
<th>No of Days Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td>5.</td>
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<tr>
<td>2.</td>
<td></td>
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<td>6.</td>
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<tr>
<td>3.</td>
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<td>7.</td>
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<tr>
<td>4.</td>
<td></td>
<td></td>
<td>8.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What tests were ordered for the patient? (Mark all that apply)

- None
- VDRL
- Sputum for AFB
- Full Hemogram
- ALT (Alanine Aminotransferase)
- Chest x-ray
- CD4 Count Assay
- AST (Aspartate Aminotransfrase)
- Other, specify:
- Creatinine
- Electrolytes
- HIV Viral Load
- Pregnancy Test
- VDRL
- Electrolytes

CD4 result if ordered at this visit:  |___________| cells/mm³

HIV Viral load result if ordered at this visit:  |___________| copies/mL

Form Completed by: _________________________  Date:  |____|____|____|____|____|____|____|____|____|____|____|

QC/QA: _________________________  Data Entry: 1st _________________________  2nd _________________________

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EMMA MOTHER VISIT DATA EXTRACTION FORM  

EMMA MOTHER VISIT

What referrals were made for the patient? *(Mark all that apply)*

- None
- Alcohol Counseling/Support groups
- Psychosocial Counseling
- Disclosure Counseling
- Family Planning Services
- TB Treatment/DOT Program
- Inpatient care/Hospitalization
- Nutritional Support
- Adherence Counseling
- Social Support Services
- Mental Health Services
- Other, specify: ____________________

Was this patient transferred to another facility for future HIV care after this visit?

- Transferred out? Date: [____-____-____]  
  Where: ____________________

- Died? Date: [____-____-____]

When is the patient’s next appointment? *(Mark appropriate field)*

- 1 week
- 2 weeks
- 1 month
- 3 months
- 6 months
- Other, specify: ___________

Next Scheduled Appointment, Date: [____-____-____]

<table>
<thead>
<tr>
<th>Professionals seen at this visit</th>
<th>Mark ‘Yes or No’</th>
<th>Professionals seen at this visit</th>
<th>Mark ‘Yes or No’</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Doctor</td>
<td>Yes</td>
<td>4. Counselor</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Clinical Officer</td>
<td>Yes</td>
<td>5. Lab Technician</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Nurse</td>
<td>Yes</td>
<td>6. Pharmacist</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Additional Professionals seen, specify: ________________________________________________________________

Form Completed by: _____________________________________ Date: [____-____-____]  
  QC/QA: __________________   Data Entry: 1st _______________ 2nd _______________
MOTHER-INFANT EXTRACTION FORM

MOTHER PROFILE

Date of Birth: __-__-______-______-______ Para: _________ Gravida: _________
Mode of Delivery: 01 SVD 02 C-Section
Place of Delivery: 01 Facility 02 Home
Mother counselled on feeding options: 01 Yes 00 No Mark below feeding option chosen:
01 Exclusive Breastfeeding 02 Exclusive Replacement Feeding 03 Mixed

INFANT PROFILE

Date of Birth: __-__-______-______-______ Birth Weight (kg): _________
Sex: 01 Male 02 Female
Alive: 01 Yes 00 No If No, date of death: __-__-______-______-______

LABORATORY INFORMATION

<table>
<thead>
<tr>
<th>Date Sample Collected (DD-MMM-YYYY)</th>
<th>HIV Test Type*</th>
<th>Results**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

*HIV Test Type: 1. PCR 2. Antibody
**Results: 0. Negative 1. Positive 2. Indeterminate 3. No Result

"Ideal timing for testing is at the 6 weeks of age, 6 months of age, 12 months of age, and 18 months of age, however please include all tests completed on the extraction form."

Form Completed by: ___________________________ Date: __-__-______-______-______
QC/QA: ___________ Data Entry: 1st ___________ 2nd ___________
<table>
<thead>
<tr>
<th>Visit Date* (DD-MON-YYYY)</th>
<th>Age (wks/mths)</th>
<th>Weight (Kgs)</th>
<th>Height (cm)</th>
<th>Infant Feeding**</th>
<th>Medication (Indication dose)</th>
<th>TB Assessment Outcome***</th>
<th>Milestones****</th>
<th>Date of Next Appointment (DD-MON-YYYY)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
<td>(j)</td>
<td>(k)</td>
</tr>
<tr>
<td></td>
<td>(g)</td>
<td>(h)</td>
<td>(i)</td>
<td>(j)</td>
<td>(k)</td>
<td>(l)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Visit Dates should correspond to the test dates above.

**Infant Feeding 1. Exclusive Breastfeeding (EBF) 2. Exclusive Replacement Feeding (ERF) 3. Mixed (BF+RF)


****Milestones by Age

<table>
<thead>
<tr>
<th>Age Ranges</th>
<th>Milestones</th>
<th>5-9 Months</th>
<th>Sitting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3 Months</td>
<td>Head Holding/Control</td>
<td>7-13 Months</td>
<td>Standing</td>
</tr>
<tr>
<td>2-3 Months</td>
<td>Turns toward the origin of sound</td>
<td>12-18 Months</td>
<td>Walking</td>
</tr>
</tbody>
</table>

Form Completed by: ______________________________ Date: _____________

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EMMA Mentor-Mother/Patient Visit Record Form

Subject ID: ___________ - ___________   Visit Date: ___________ - ___________ - ___________ - ___________ - ___________

1. Age of baby or gestational age (Mark what applies during this visit and circle wks or months)
   - Gestational age: ___________ wks / months
   - Age of Infant/baby: ___________ wks / months

2. Did Mentor-mother recap all the key clinic processes with the patient/mother? (appointment schedule should guide the discussion, attend to any questions and clarifications.)
   - Yes
   - No

3. Was EMMA Mentor-mother guidelines (Adherence, Psychosocial support, Treatment support, Partner involvement) discussed during final interaction with patient/mother?
   - Yes
   - No

4. Contact information – Mark all that apply (ensure contact tracing for is updated.)
   - Full consent for telephonic follow up
   - Call only
   - Sms / Text only
   - No consent for telephonic follow up
   - Full consent for home follow up
   - No consent for home follow up

5. Next visit date: ___________ - ___________ - ___________ - ___________ - ___________ - ___________

6. Text / Sms reminder scheduled on EMMA system based on No. 4 information.
   - Yes
   - No

Comments:_________________________________________________________________________________
________________________________________________________________________________________

Form Completed by: _____________________________________ Date: ___________ - ___________ - ___________ - ___________ - ___________

QC/QA: ___________________   Data Entry: 1st ___________   2nd ___________