

What strategies have worked to ensure that pregnant participants have adequate antenatal care and delivery ?

Friday Saidi
24 January 2023



- **Strong collaboration** with Ministry of Health and the referral health facilities within study catchment areas:
 - Have MOU with locations where they might deliver- Experience from IMPAACT studies
 - Site staff provide clinical care at collaboration facilities
 - Community Engagement
 - Incentives to staff who support with study procedures
 - Trainings to referral facility staff on the study
 - Point-persons with the referral facilities

- Informed consent and allowing for time for participant to make decision
- Individualized pregnancy plan and continuous engagement with participant
- Encourage disclosure to relatives who are key in supporting participants
- Education on importance of ANC
- Transport support

- Use of Pregnancy tracking tools, EDD logs
- Booking pregnancy women on same day
- Discussing the pregnancy scenarios during weekly meetings
- Having a team “on call” in case of any delivery
- Learning from each delivery event- what worked well and what didn’t

- Combining ANC visits and study visits on same day
- Easy access to hospital records
- Some sites conduct all ANC procedures at study sites

- Provide a bridge between study procedures and standard of care
- Conduct Obstetric scans on sites

A FEW TIPS

- Be flexible and learn from each pregnancy
- Be realistic with your plans
- Remember labor gives an opportunity for further planning

Acknowledgments

Sponsor

- U.S. National Institute of Allergy and Infectious Diseases (NIAID), all components of the U.S. National Institutes of Health (NIH)

Additional funding support

- ViiV Healthcare
- Bill & Melinda Gates Foundation
- National Institutes of Mental Health

Pharmaceutical support

- Gilead Sciences

HIV Prevention Trials Network

- Leadership and Operations Centre, FHI360
- Laboratory Centre (Johns Hopkins)
- Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center
- HPTN Leadership

HPTN 084 Study team

- 20 sites in 7 countries in sub-Saharan Africa
- Community advisory boards and partners

... and our study participants!

What worked to maximize consent on pregnancy sub-study

Ribka Berhanu
24 January 2023



What worked to maximize consent on pregnancy sub-study

- Previous site and participant experience/comfort with infant studies (e.g., MTN 042 sites)
- Anticipatory guidance: preconception counseling
- Give the participant time to decide/discuss with partner and extended family (split visit)
- Understand the participant's objections and offer options:
 - Option to decline CAB LA during pregnancy
 - Option to decline infant participation in sub-study
- Be sensitive and alert to disclosure concerns around the time of delivery (risk of lost to follow-up at this time even with prior adherence to visits).

HPTN 084: Lessons learned for supporting PrEP CHOICE

Sinead Delany-Moretlwe
24 January 2023



Influences

- Fear of injection site pain
- Preference for a discreet, convenient method
- Pregnancy concerns and preferences
- Other participants
- Other individuals in social network
- Notable that discussions re reversibility and/or switching did not factor in – may be an area to prioritise as we plan for exit

Strategies

- Focussed counselling visit that includes detailed explanation of the pros/cons of each method and verification of existing knowledge, time to make decision, peers who provided testimony about their method choice, identification of social support structures to support decision; counselling tool useful
- Specific interventions for injection site pain included symptomatic treatment, injection technique, identification of individuals with past ISR
- Evidence of successful pregnancy outcomes at site builds confidence

HPTN 084: What has worked to keep participants engaged and retained on study, especially young participants and key populations engaged

Yaw Agyei
24 January 2023



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What has worked to keep participants engaged and retained on study, especially young participants and key populations engaged

- Participation in the study is for local and global good.
- Let them have ownership of the study.
- Give gifts-hand bags/pens/groceries.
- Curtesy calls to check on participants- happy and sad occasions.
- Wi-Fi access at clinic/life skills/phone charging ports/computers to create CVs
- Mats and pillows for resting (sex workers).
- Play areas for children.
- Legal person and police to assist when laws lead to harassment.
- Provision of primary care services- STI/contraception/vaccination assistance for their children/alcohol abuse counselling.
- Engage stakeholders for skills development- night school.
- Confirm what kind of snacks/meals they prefer.
- Come down to their level- be young at heart and use their language (slang).

What lessons have been learned about managing transitions between protocols to avoid protocol deviations due to missed procedures or incorrect procedures

Estelle Piwovar-Manning
24 January 2023



What lessons have been learned about managing transitions between protocols to avoid protocol deviations due to missed procedures or incorrect procedures

Site

- Trainings dry/wet runs involve all clinic, data and lab staff, commercial lab staff as applicable, use mock files, review difficult scenarios, include review of SOE and FOOTNOTES
- Update master files/SOPs; Develop job aids and checklists, create workflows
- Review participant files ahead of time, day before/day of –
 - Check for notes from last visit/double check last visit
 - Mark files regarding transition
 - Inform lab of transition
 - Have a meeting in a group prior to participant
 - Consult CMC ahead of time, reschedule within window if needed so not have to do a split visit
 - Ensure lab prepared backs are ready and contain checklist/reqs with appropriate blood draw/tests
 - Agree on visit coding ahead of time
- Limit clinic visits at start, one type of visit on certain days, perform QA, internal audit checks with clinic and lab
- Visit schedule that works and shared amongst team
- Prepare participants regarding version 4
- Have weekly meetings between clinic, data and lab
- Update reagent stock outages on weekly basis
- Have discussions within CTU, within country

Protocol team and site

- Update FAQ/ Tips and Lessons learned
- SCHARP to provide dummy PTIDS to practice Rave ahead of time
- "Add Event" will be helpful
- SCHARP to send transition reports to help with scheduling/cross checks
- Provide protocol versions for site reviews to help prevent LOA/CMs
- Push to activate
- Update Reference ranges as received for fewer QAs
- Weekly calls with LC

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UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center).

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What are lessons learned about audit preparation and audits

Scott Rose
24 January 2023



- Refer to the DAIDS Score Manual- CRS regulatory inspection preparedness
 - <https://www.niaid.nih.gov/sites/default/files/crs-inspection-prep-checklist.pdf>
 - <https://www.niaid.nih.gov/sites/default/files/crs-inspection-readiness.pdf>
 - Review DAIDS activation listing and initiation/ monitoring checklist
- SANAS and SADCAS (RSA audit prep courses)
- Internal team audits
 - SOPs (up to date, everyone trained?)
 - Audit SOP
 - QA/QC audit (review procedures, what has been checked, is it accurate)
 - Training to include what staff what modules when, how, by whom and should match the DoD log for responsibilities
- External audits
 - Conference calls with other sites on lessons learned
 - Review materials from other inspections you have had OR lessons learned from other sites
 - Have other sites visit/ inspect your site if feasible

- Review of GCP guidelines vs. DAIDS guidelines (GCP now has guidance on audits); GCLP training is available on the DAIDS Learning Portal. CLS offers a course, but it is not DAIDS approved for training purposes.
- Maintain proper, complete filing systems
- File documents immediately
- Have a master Index for what is filed where for ease of finding
- Create storyboards on CAPA or deviations and Timelines for protocol amendment approvals vs. when implemented at site

- Practice audit interviews (and compile a listing of Frequently Asked Questions during audits)
 - It's ok to say “we will get back to you”
- Set up an audit point person and a scribe
 - Go between for all files and staff
 - Have the point or scribe immediately tell all staff what was asked/ how answered so you are consistent in replies
- Limit the # of participant visits the week prior and during an audit so team is focused
- Start working on issues that came up during an audit
IMMEDIATELY

What are lessons learned about counselling and managing participants with discordant results

Sybil Hosek
24 January 2023



Counseling and Managing Discordant Test Results

- Lessons for Staff

- Working with each pt as a team; includes consistency in messaging, addressing staff questions/concerns, making sure every member of the team is on the same page
- Learning to be comfortable with uncertainty of each scenario; support for each other
- Increased staff training about testing and purpose of tests
- Adequate staff time for discordant result discussion with pts

- Lessons for Participants

- Don't assume participants understand what each test actually does
- Recognize and empathize with pts anxiety about testing
- Keep pts engaged throughout - counseling at each step of the algorithm – i.e., where do results stand, what is the next step
- Query for social support resources

- Lessons for Community

- Be aware of community conversations and misunderstandings
- Prepare community through ongoing discussions about testing

Recommendations & Requests

- More staff training
 - Sharing data from 084 and 083 thus far
- Participant-facing tools
 - Fact sheets: HIV tests and interpreting results; ARV treatment interruption
- Add the possibility of discordant results to the informed consent discussion
- Pros and cons of providing ART for pts at the research sites
- Decisional balance practice re: starting ART

Infant Assessment and Collection

Best Practices

Mina Hosseinipour

24 January 2023



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Delivery Visits

- Provide Transport- Pick up the mother for delivery, post partum visits. Include the nanny if necessary
- Have communication- Hotline, Call center, Airtime to Mother, regular phone check-ins
- Have MOU with Locations where they might deliver
- Have staff on call for delivery
- Provide a “delivery” Pack- includes key items for delivery including cord blood collection
- EDD log to know when the baby is coming
- Provide documentation of research requirements of Pregnancy study with participant
- Home Visits if allowed by IRB (Consideration of Sites but not yet implemented)

Infant Sample Collection- Concerns about Pricking the infant

- Have experienced staff due the collection
- Put Baby in bassinet for collection rather than mother holding
- Have Research Staff hold baby rather than the mother (to relieve mother anxiety)
- Only disrobe the baby once

Reservations about infant blood collection in sub-study

- Education of staff to have common language stressing importance
- Use Peer Mother (Participant who has participated) to provide reassurance
- Provide both mother and infant transport reimbursement

Cultural Society Issues

- Provide Vehicle for early post natal visits
- Present “gifts” to mom/baby at time of first visit (delivery visit)
- Be support of the mother and her baby- Show you care

Mother/Infant visits

- Prioritize the mother/infant pair to be seen immediately
- Feed the mother immediately
- Study “Nanny” to support baby while Mom having her visit components
- Limit how many people examine the baby. Only unswaddle the baby once.
- Provide a good environment for the baby
 - Nappies
 - Mats
 - Play Space
- Milestone Visit Incentives

1 year assessments

- Retain the mother
- The baby will always be with mom
- Pay for transport for both the mom and baby

General Issues

- Provide Good Customer Care
- Good Rapport
- Reassurance
- Tokens of Appreciation for Milestones

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