Manual for field doctors

IBBA - 2005

CONTENTS

Chapter 1 Introduction

The purpose of the Integrated Bio-Behavioural Assessment (IBBA), a survey, is to gather data for impact monitoring and evaluation of the Avahan India AIDS Initiative funded by the Bill & Melinda Gates Foundation in 71 districts of 6 States and five highway sites. The survey will be carried out in 29 districts of 5 states and the national highways. The first district where the IBBA will be conducted is Karimnagar in Andhra Pradesh. This document gives standard operating procedures for the clinical component of the survey to be carried out by the doctor.

Brief introduction of the survey

Study Population:

In the five states the study population comprises of:

- Female Sex Workers - Brothel Based (FSW-BB)
- Female Sex Workers - Non-Brothel Based (FSW-NBB)
- Male Sex workers (MSW)/Men who have sex with men (MSM)
- Male clients of Female Sex Workers
- Injecting Drug Users (IDU)

In the national highway segments the study population comprises of:

- Truckers and Assistants
- Female sex workers Highway-based (FSW-HB)

Site of the study:

The site where the actual study will be carried out to interview the participants and take biological specimens has been chosen after extensive and careful preparation including discussions with the HIV/AIDS programme staff from NACO and State AIDS Control Societies, the district authorities, the various study partners and the community from where the participants will be recruited. The final sites for collection of behavioural and biologic data will be finalized in each of the 29 districts after the development of a sampling frame.

Staff:

The team members for carrying out the study at the field level will be:

- Medical Officer
- Supervisor
- Community liaison worker
- Interviewers (3 in a team)
- Laboratory technician
- Editor

Depending on the area there might be more than one team working in one district. The job responsibilities of each member have been defined but all members work as a team to carry out the study based on the protocol while maintaining appropriate rapport with the

community, ensuring co-operation from the study participants and maintaining cordiality at the site.

The doctor is the team leader for the biological component of the survey which includes the laboratory and the clinical component. The manual for the laboratory at the field level is a separate document and is part of the training curriculum for the doctors of IBBA. This document pertains to the clinical component.

Job responsibility of the Medical doctor:

- Team leader of the biologic data collection team;
- History taking and external examination of IBBA participants who provide consent for biologic survey;
- Provide appropriate management of participants who complain of various STI related symptoms syndromically;
- Ensure that sample collection, storage and transport of various specimens is been conducted in a proper manner;
- Ensure that proper infection control measures and sound waste management practices are being followed;
- Ensure that clients who want to know their HIV status are referred to the nearest VCT center;
- Ensure proper follow-up of syphilis results and management and other referrals;
- Ensure that ethical practices are followed and participation of clients in the survey is voluntary;
- Facilitate the setting up of field sites in consultation with the Field Supervisor and behavioral team; and
- Ensure coordination with Field Supervisor for smooth conduct of biological survey

Job responsibilities of the other team members are listed elsewhere

Various tests for biological survey:

IBBA procedures for STI testing and treatment and HIV testing and counseling are outlined in the table below.

Venous blood draw on FSW, MSW, MSM, Clients of FSW • HIV (prevalence/incidence) • Syphilis • HSV2 on subset **Dry blood spot on IDUs** • HIV (prevalence/incidence) • HBV • HCV • Syphilis (Treponostika)
First catch 20 ml urine - prepare and store for Ng/Ct testing using nucleic acid amplification tests

(NAATs) – Gen probe Aptima Combo assay 2
Ulcer swab mPCR for TP/HD/HSV2 if report external clinical ulcer
Treatment and follow-up • Syndromic management for STIs consistent with Avahan guidelines • Refer to Avahan clinic if report symptom of ulcer which cannot be identified by external examination • STI and HIV Education • Provision of syphilis serology test results and free treatment if positive • Escort to VCT centre for retesting (for those who so desire)

Ethical issues for consideration

Keeping in mind the sensitive nature of the IBBA top most priority will be attributed to the protection of participants at all phases of the assessment and during dissemination of the results. The IBBA has been designed to maximally protect the participants balanced with the individual benefit and community benefits from this IBBA.

Participation will be voluntary with subjects free to withdraw at any time. Withdrawal will not affect services they would normally receive.

Informed consent is written with the option of oral witnessed consent. The consent form is translated, pilot tested and translated into the local language. Participants will be offered a written statement regarding the research. The ethical committee of the ICMR in India felt that written consent is the preferred method to obtain consent for IBBA. They however realized that given the clandestine and potentially illegal nature of some of the behaviors of the study participants that signing consent may deter participation. As such, the committee also wanted the option of a witnessed oral consent.

No names will be recorded. All documentation is anonymous, linked only by a unique respondent number. IBBA staff will be trained in discussing sensitive issues and protecting participants' confidentiality and human rights. Specific procedures have been developed to ensure that there is maximal anonymity and that there are no "employer" reprisals for non-participation. All data collected will be kept in locked files and accessible only to assigned study staff.

Chapter 2: Procedure for the conduct of biological component of IBBA

The participant would come to the doctor through the laboratory technician along with the biological component referral card (BCRC) which would indicate if the participant has agreed for only the laboratory component, or the clinical component or both.

Biological Component Referral Card (BCRC)

- This card helps the interviewer to refer individuals to the biological component of the survey and also helps track how many people visited the doctor for clinical examination and the laboratory technician for giving samples
- The front side of the card is filled by the interviewer and the backside by the lab technician and the doctor
- The front side of the BCRC will be filled by interviewer at the end of the interview
- The front side indicates whether respondent needs to see doctor for STI treatment or giving laboratory samples
- Steps to fill the BCRC card:
  1. Interviewer fills in ID number and Date
  2. Interviewer refers to Block I, Question 3 – if the respondent consented to participate in the biological part of the assessment, circle YES. Otherwise, circle NO.
  3. Interviewer asks the respondent if she wants to see the doctor. If yes, she checks YES for all respondents on 'Sent to Doctor For Check up"
  4. The interviewer should escort the respondent to the Community liaison person who will accompany respondent to the biological team.

FRONT SIDE

Biological Component Referral Card

ID _____

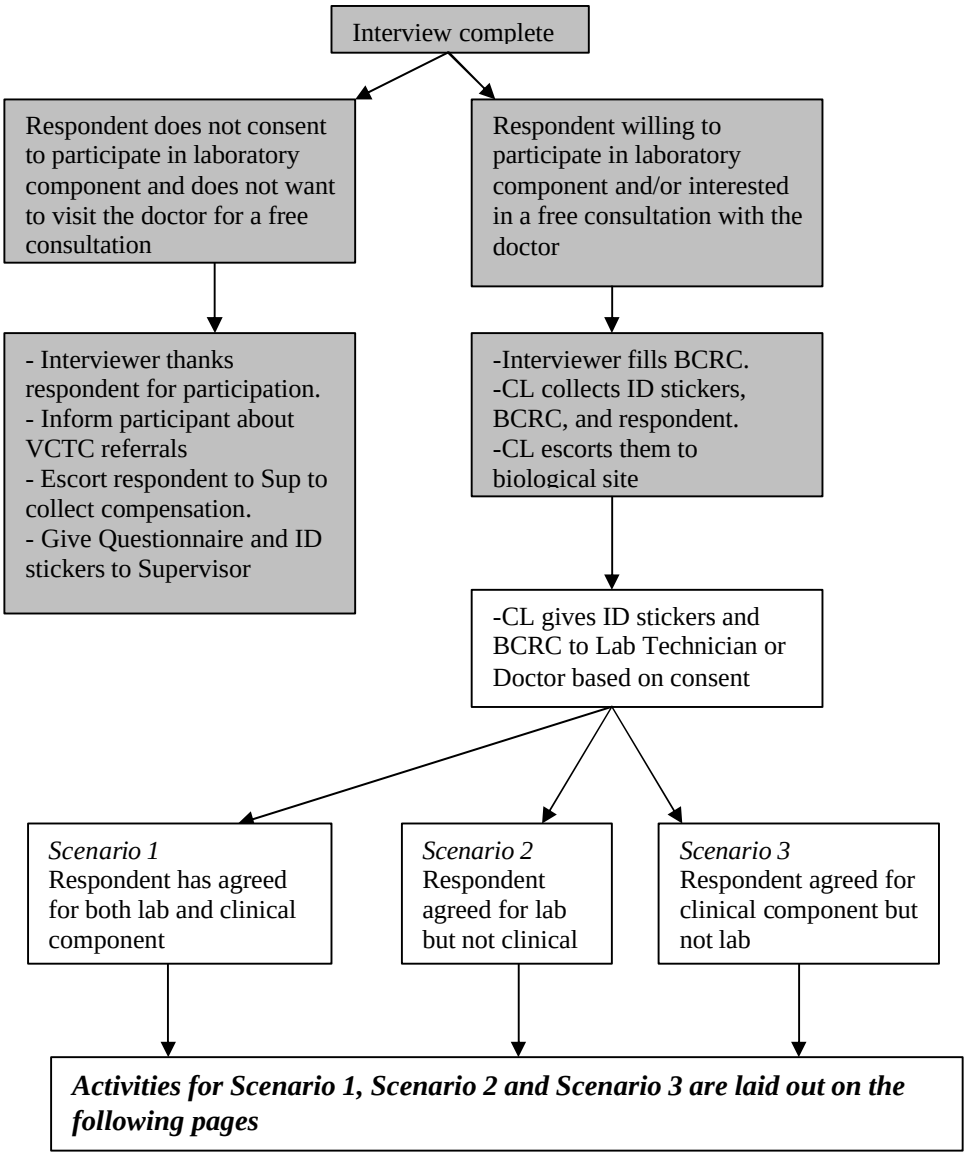
Date: _____

Consented for Laboratory Tests	**Yes**	**No**
Respondent wants consultation With doctor	**Yes**	**No**

Interviewer name: _____

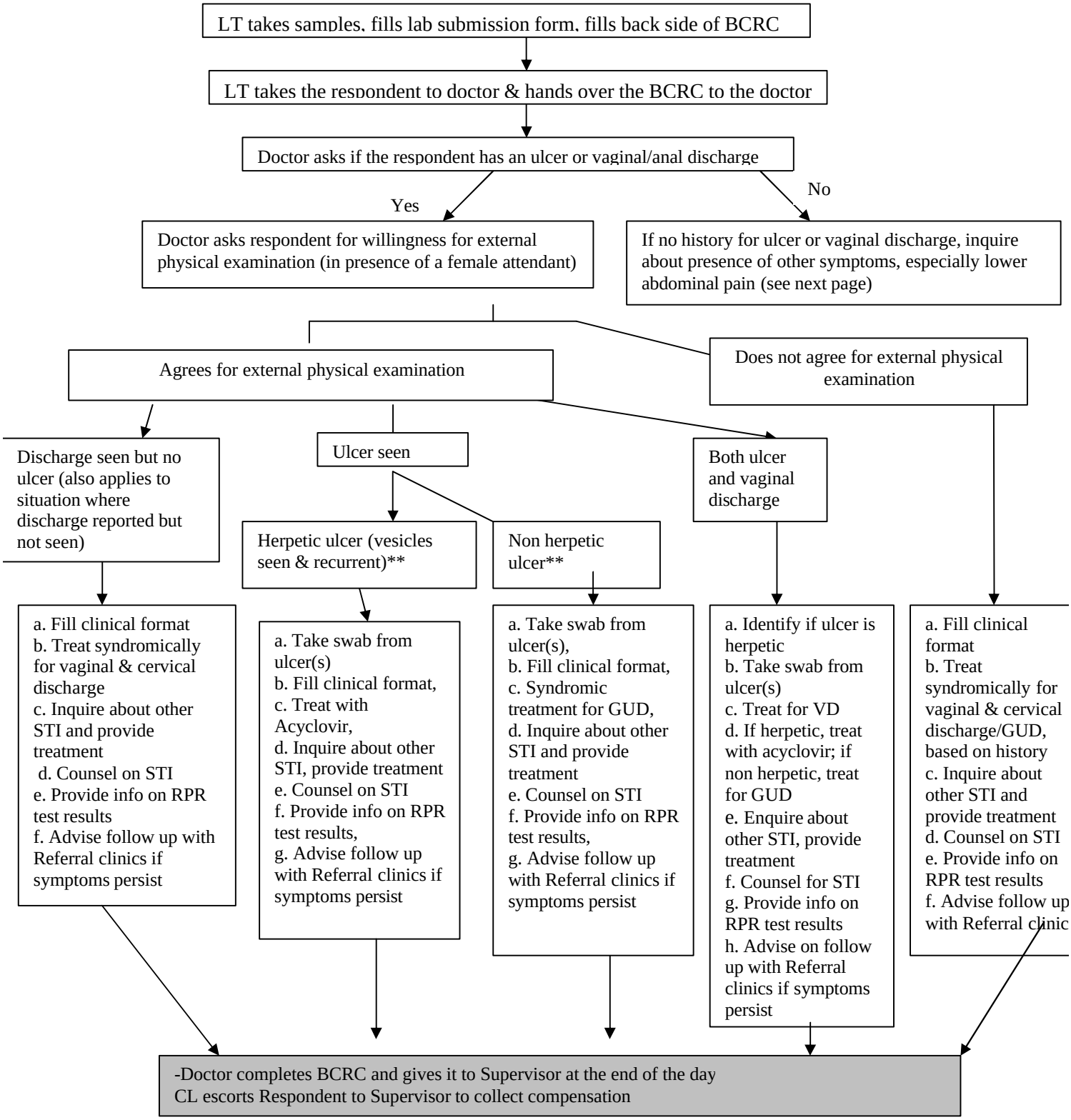
See what is indicated in the BCRC and proceed as per the flow chart below.

FLOW OF ACTIVITIES IN BIOLOGICAL PART OF IBBA



Abbreviations
CL – community liaison
Sup – Supervisor
BCRC – Biological Component Referral Card
LT – Lab Technician

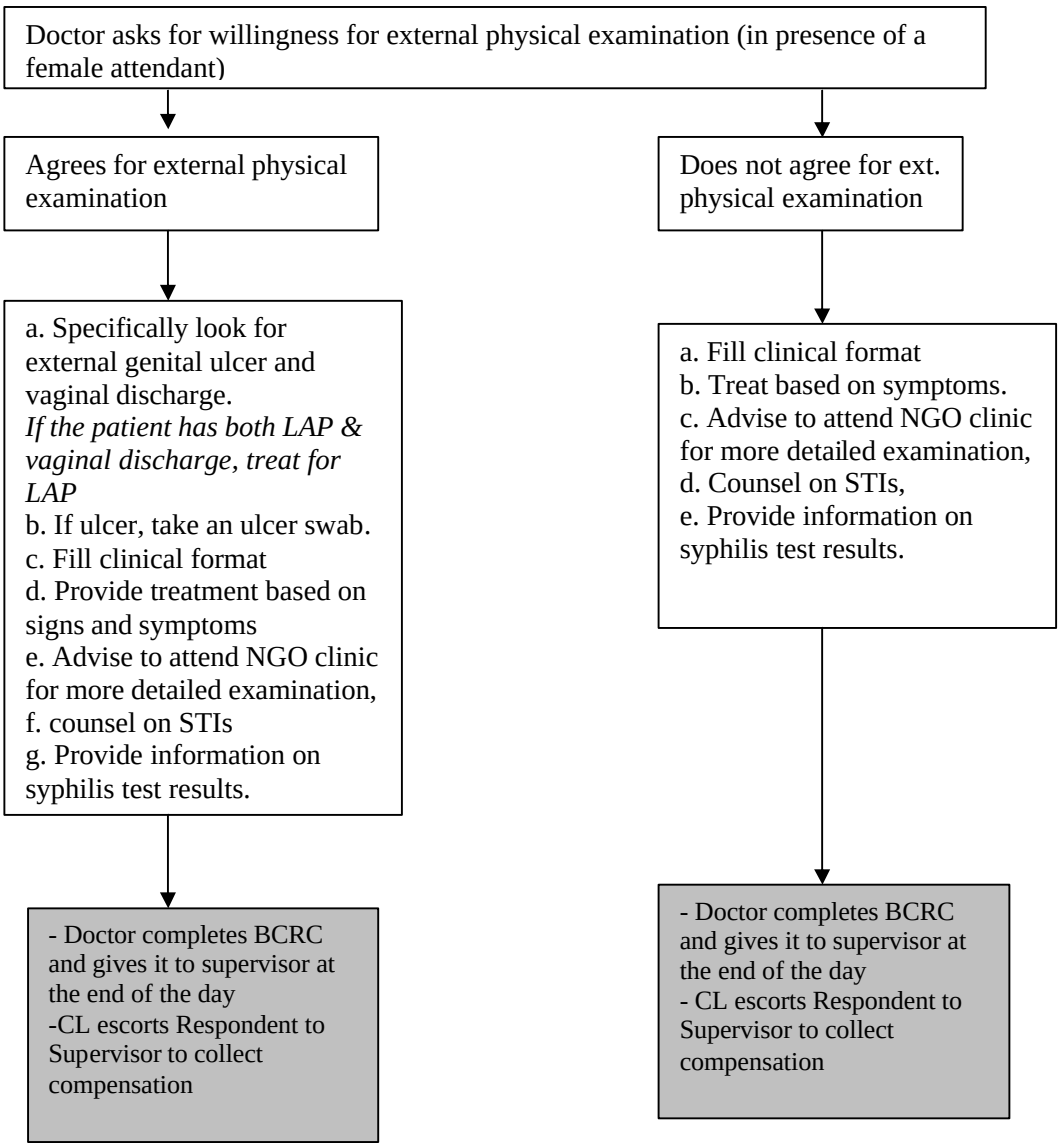
SCENARIO 1 – (For females) Respondent agreed for both lab & clinical component



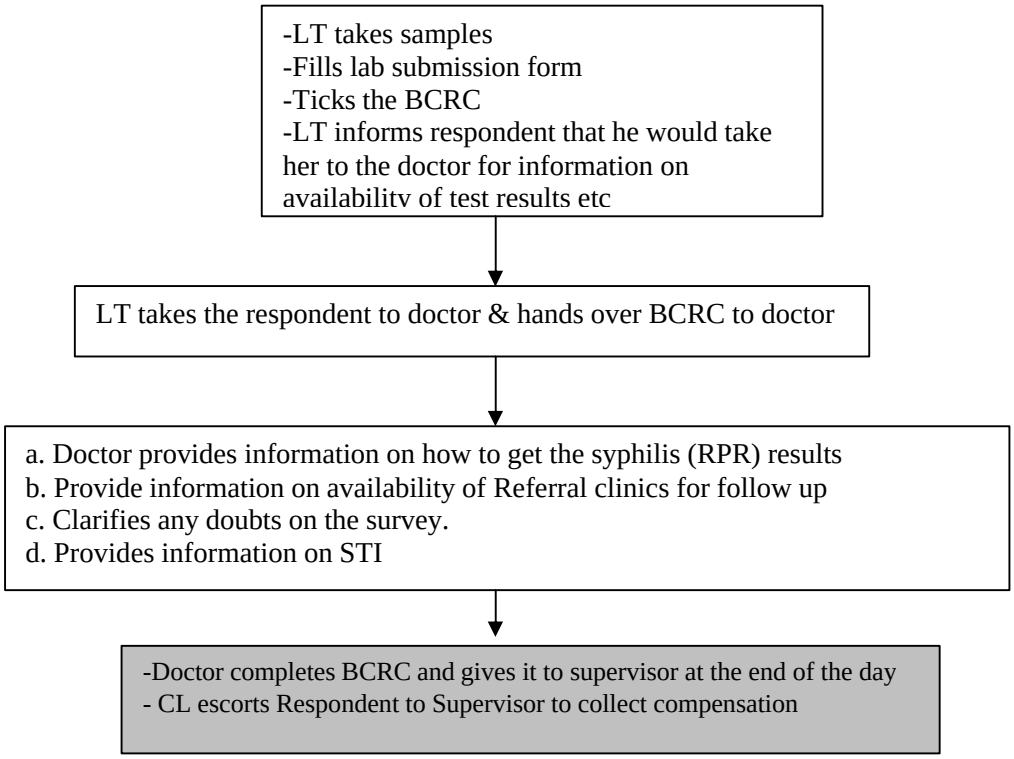
**if NOT classic Herpes, treat as for non-herpetic.

Scenario 1 continued – (For Females)

***FOR SYMPTOMS OTHER THAN ULCER & VD (Urethral discharge; Lower Abdominal Pain; Inguinal swelling and Ano-rectal discharge)**

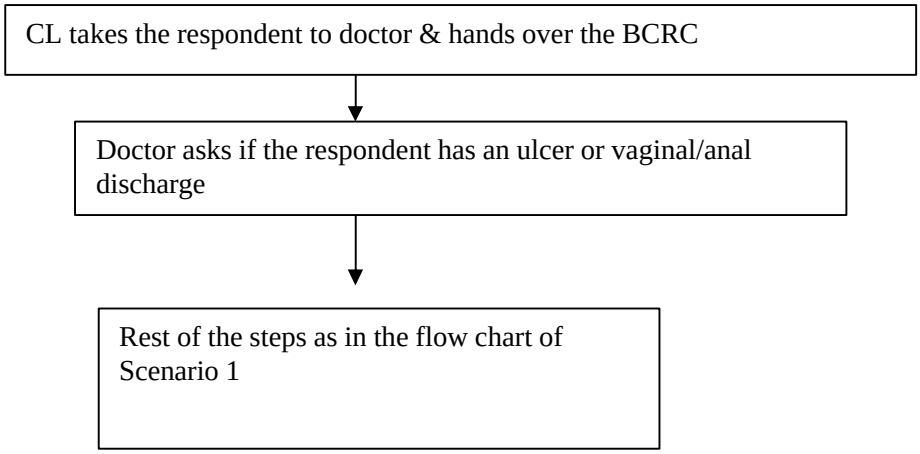


SCENARIO 2- For females- Respondent agreed for lab but not clinical component

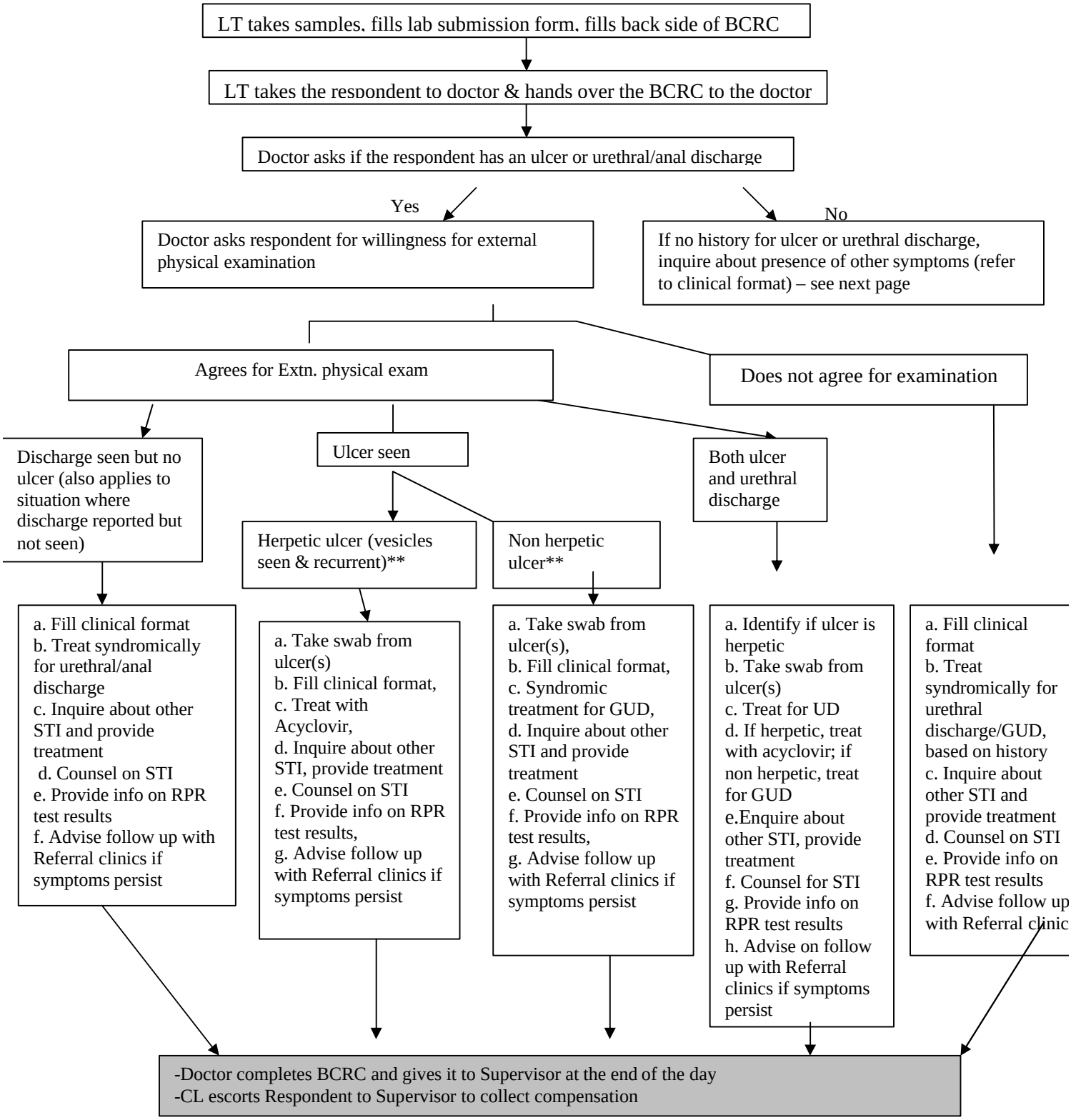


Note: If the respondent changes her mind after meeting the doctor and wants a clinical referral then she should be entertained.

SCENARIO 3: (for females) - Participant agreed for clinical component but not the lab component



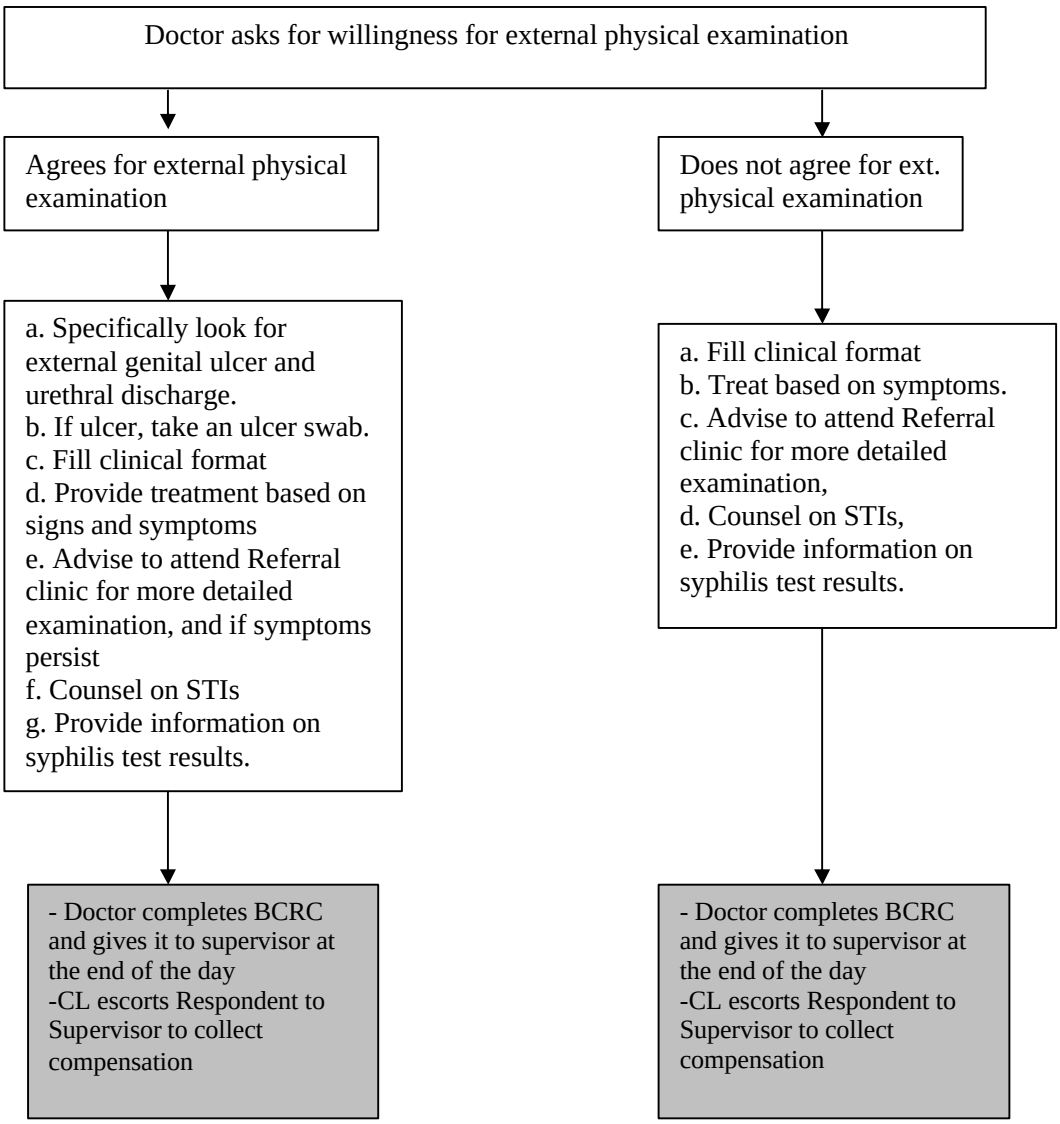
SCENARIO 1 – (for males) - Respondent agreed for both lab & clinical component



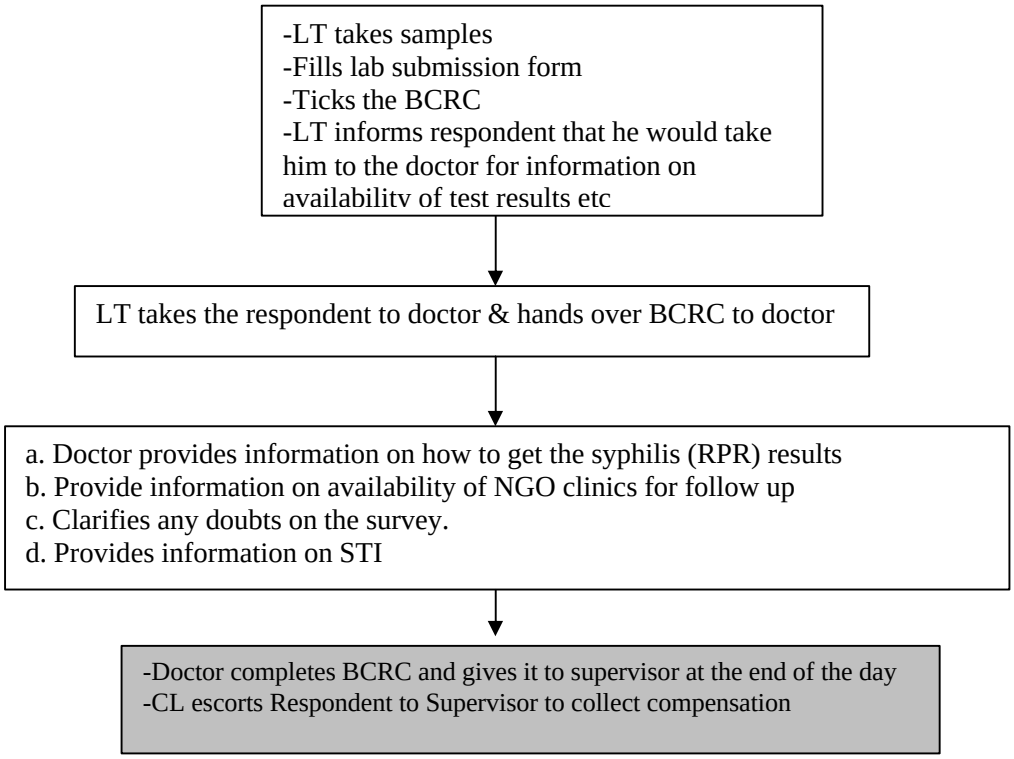
**if NOT classic Herpes, treat as for non-herpetic.

Scenario 1 continued – For males

***FOR SYMPTOMS OTHER THAN ULCER & VD (Urethral discharge; Scrotal swelling; Inguinal swelling and Ano-rectal discharge)**

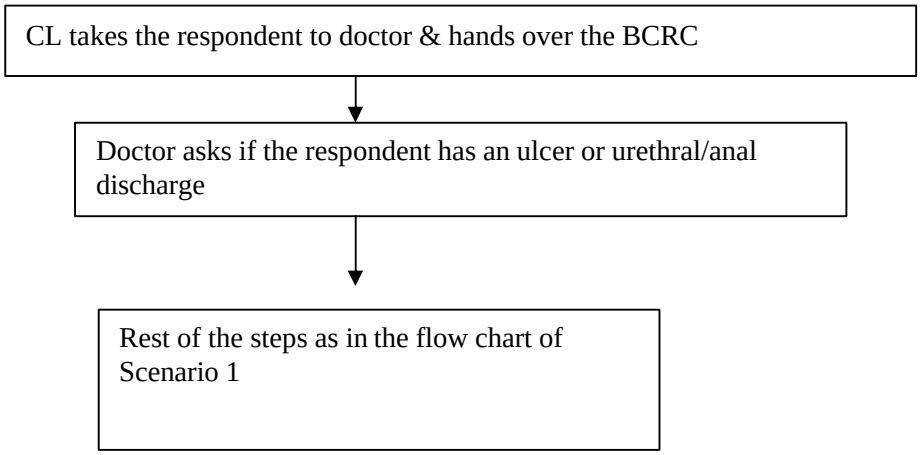


SCENARIO 2 (for males) - Respondent agreed for lab but not clinical component



Note: If the respondent changes his mind after meeting the doctor and wants a clinical referral then he should be entertained.

SCENARIO 3: Participant agreed for clinical component but not the lab component



The doctor would, thus, do the following:

- Take the history (see chapter 3 for clinical examination)
- Complete an external examination (but no internal examination)
- Provide treatment for the STI through syndromic case management.
- Respondents complaining of genital ulcers and willing to give laboratory samples will be examined by the field doctor and swab of the ulcer will be collected.
- Fill the clinical format
- If they agree, respondents will be referred to the closest referral clinic for more comprehensive evaluation and treatment.
- Give details for getting the results of syphilis testing from the designated referral clinics within five days after recruitment.
- Advise the respondents on follow up with the referral clinic.
- Give the participants a IBBA follow up card with their ID no. and which they would present at the designated referral clinic for above activities.
- Complete the back side of the BCRC and hand it over to the supervisor at the end of the day.

BACK SIDE of the BCRC – FILLED BY DOCTOR AND LAB TECHNICIAN

Steps to fill in the card

1. If the individual has consented to participate in the biological part of the assessment, the lab technician should tick the appropriate option in the upper part of the back side of the card

2. The IBBA doctor should fill in the next section of this card. If the individual consented to participate in the biological component of the survey (see reverse side of the card) the IBBA doctor will do a clinical exam and, if he sees an ulcer, will take a genital swab. The doctor should use the following definitions for filling in this card:

Swab taken – the respondent consented to participate in the biological component of the survey and the doctor took a swab from an external genital ulcer

Swab not taken – the respondent either: did not consent to take part in the biological component of the survey so no swab was taken or the respondent consented to participate in the biological component of the survey, but no ulcer was seen on genital examination.

(To be filled by Doctor and sent to Supervisor to fill Block 1 of Interview)

Filled by Lab Technician (select appropriate category):

Respondent gave only blood sample	
Respondent gave only urine sample	
Respondent gave blood and urine sample	
Respondent did not give any samples	

Filled by Doctor (select appropriate category):

Swab not taken	
Swab taken	

At the end of the day, all BCRCs should be handed over to the supervisor.

Other important facts:

- The doctors will enforce the importance of returning for syphilis results and treatment in the case of a positive result.
- All participants will know through the consent process that their blood is being drawn for syphilis and HIV testing and that it will be stored for potential future research on HIV infection.
- IBBA respondents wishing to know their HIV status will be referred to the referral clinic so that they could be accompanied to a VCT center where they can undergo counseling and testing for HIV (using a separate test and separate blood-draw from the IBBA). The IBBA team would bear the transport costs and user fees.
- All testing will be linked anonymous testing whereby all specimens are linked only to a unique respondent number. Participants will be have this number on the

IBBA follow up card which they will have to produce to get their syphilis test results, if they so desire. (Please see later for details on IBBA follow up card.)

Chapter 3 History taking, examination and provision of treatment

History, examination findings and the treatment dispensed /prescribed for STIs to the study participants/respondents will be documented and entered into the data base for analysis in the survey.

If the doctor is a male he should before beginning the examination of the female participant, make sure that a female health care worker (team member) is present. All doctors (male or female) should ask the participants (male or female) if they would be more comfortable if they prefer or would be more comfortable if someone particular were present during the examination or counseling.

History Taking

General advice to be followed while taking history

- Make the patient feel at ease
- Be tactful, tolerant and non-judgmental
- Stress on privacy and assure absolute confidentiality
- Use simple terms that the patient understands.
- Ask the less sensitive questions first.
- Get a clear chronologic description of the present problem

Ask for the following:

For Females:

- Do you have any current problem?
- Do you currently have an abnormal vaginal discharge?
- Do you currently have genital itching?
- Do you currently have lower abdominal pain associated with fever?
- Do you have any genital ulcer?
- When was your last menstrual period?
- Do you have any drug allergies? If yes, what reaction? What drug?

For Males:

- Do you have any current problem?
- Do you currently have an abnormal urethral discharge?
- Do you currently have ano-rectal discharge or pain?
- Do you currently have scrotal swelling?
- Do you have any genital ulcer?
- Do you have any drug allergies? If yes, what reaction? What drug?

Physical Examination:
General advice to be followed while doing physical examination

- Standard STI examination should proceed in an ***orderly and consistent sequence***

***so as** to* prevent errors of omission and minimize patient's movement.

- Maintain rapport by talking about informal topics/matters and keeping the patient at ease, explaining the procedures which will done and why and describing what tests which will be requested depending on what you find on examination.
- The examiner should be gentle, confident and professional and preferably of the same gender as the patient. **If only a male provider is available when a female is being examined make sure there is a female HCW in the room**
- The examination room/ area should be clean, private, quiet, well lit and contain appropriate furniture (e.g., couch, chairs, illumination, waste disposal) and any necessary equipment and instruments needed are available
- When the history is complete, the doctor should say 'now we are going to do short examination, to find out the what the problem is. Do we have your permission for this?' Have the latex gloves ready and slip them on as soon as the patient says 'yes'. If the patient says 'no', smile and move on with the treatment as outlined in the flowchart.
- With the patient in a sitting position facing the examiner, inspect the patient's hands, forearms and inside the elbow. Note any rashes, nail changes or "needle track" marks. Take the patient's hands in your hands. Examine the dorsal aspect, then the palmar aspect. Then, look up to the patient's eyes and check for pallor or jaundice. Ask the patient to open their mouth, stick out their tongue and say 'Ah'.

Then say to the patient 'I need to examine your genitals and bottom, please remove your underwear and lie up on the couch'. At this point, the male doctor examining a female patient should turn away and busy himself with the notes, then return when she is ready to be examined.

Genital Examination in Women:

Initial steps:

- Wash hands in an area where the patient can see it being done
- Maintain a casual, friendly but respectful relationship with the patient by conversation.

Pelvic area examination:

- Ask patient to remove her underwear
- palpate pelvic abdomen and inguinal regions noting any palpable lymph nodes
- with the patient in the lithotomy position thoroughly examine external genitalia and perineum
- inspect:
    - pubic hair
    - mons pubis
    - external genitalia , perineum and perianal region
- separate labia,
    - inspect vaginal introitus - note the characteristics of any local changes such as erythema, abrasions, ulceration, warts or discharge in the introital region

If there are genital ulcers, collect specimen for genital ulcer as follows:
(Ask the laboratory technician to assist you. The details of this procedure are also given in the manual for field technician)

- Clean the ulcer with cotton wool dipped in sterile saline (remove any crust or dead skin).
- Gently hold the sides of the ulcer with the forefinger and thumb and press for a few seconds.
- Collect the exudates with swab stick by rolling over the ulcer, the most productive area being the moist area just inside the ulcer rim.
- Break the stem of the swab and keep it in the pre-labeled sterile screw-capped swab container. The length of the stem should be such that it fits into the container. Screw the container tightly.
- Keep the container in the small zip-lock bag and zip it.
- Place this zip-lock bag in cold thermocol box with gel packs.
- Log each ulcer swab sample into the form and indicate ulcer location in the laboratory submission form.

Genital Examination for Men:

- With patient in a standing position ask him to lower his pants and underwear
- Inspect skin from umbilicus to knees for rashes, scars and swellings and inspect pubic hair for pediculosis pubis.
- Examine inguinal region for enlarged lymph nodes or evidence of hernia
- Examination of genital area
    - penis – retract prepuce if uncircumcised, note visible urethral discharge, preputial or glans rash, abrasions or ulceration, subpreputial or meatal warts
    - Urethral Meatus – In the absence of visible urethral discharge, milk the urethra from base to tip to look for any covert discharge
    - Shaft – rashes, warts, ulcers etc
    - Scrotum – swelling or tenderness of testis or epididymis (epididymo orchitis); abnormal consistency of testis (neoplasm)
    - Perianal region - Either with patient lying in the left lateral position or bending over examine the perineum/anal/perianal region. Note for warts, ulceration, perianal haematomata or other swelling, discharge from the anus
    - Anus and rectum - Note discharge, warts, and ulceration. (see below)

Specimen collection for Genital Ulcer: as above in the female genital examination.

Diagnosis of STI:

- Urethral and vaginal discharge – if the participant has a current complaint of urethral discharge, a diagnosis of this is considered even if it is not visible on clinical examination. This is true for both males & females. Same is true for anal discharge in both & vaginal discharge in females.

- For the diagnosis of scrotal swellings it is important to rule out surgical emergencies. An important step is to check if the patient feels better after support to the scrotum. If yes, it is more likely due to STI.
- GUD – if recurrent, vesicular, painful multiple ulcers then it is in favour of herpetic ulcer, the treatment of which is palliative. Non-herpetic ulcers are single and curable. Often it is difficult to differentiate between these in which case it is better to make a diagnosis of non-herpetic ulcers & treat accordingly.
- Lower abdominal pain – usually there is a history of fever, vaginal discharge, dysparunia along with lower abdominal pain & on examination tenderness in the lower abdominal area & cervical motion tenderness on pelvic examination can be elicited. However since, internal examination is not being done in IBBA, diagnosis is made on the basis of history & findings of lower abdominal tenderness. It is important to rule out surgical causes & gynecological emergencies with careful history (including LMP) & external physical examination.
- Inguinal swellings: Any visible inguinal swellings

Treatment for STI:

Syndromic case management guidelines are based on symptoms reported by the participants and signs detected by the doctor on external examination. The common syndromes that participants could present with include:

- Urethral discharge
- Genital Ulcer
- Vaginal/Cervical discharge
- Scrotal swelling
- Lower Abdominal Pain
- Inguinal bubo

Diagnosis	***Treatment***	***Medications***
Ano-rectal Discharge, Urethral Discharge or Painful Scrotal Swelling	*1 (grey packet)*	*Cefixime 400 mg orally single dose AND* *Azithromycin 1 gram orally single dose*
Vaginal Discharge	*2 (green packet)*	*Cefixime 400 mg orally single dose AND* *Azithromycin 1 gram orally single dose AND* *Metronidazole 2gm orally single dose* AND* *Fluconazole 150 mg orally single dose*****
Genital Ulcerative Disease (non herpetic)	*3 (blue packet)*	*Benzathine penicillin 2.4 million units IM**** OR* *Doxycycline 100 mg BID orally for 15 days***** AND* *Azithromycin 2 gram orally single dose*
GUD (herpetic)	*4 (red packet)*	*Acyclovir 400 mg orally TID for 7 days*
Lower Abdominal	*5*	*Cefixime 400 mg orally single dose AND*

Pain	*(purple packet)*	*Doxycycline**** 100 mg BID orally for 14 days AND Metronidazole 400 mg BID orally for 14 days*
Inguinal swelling	*6 (yellow packet)*	*Doxycycline**** 100 mg BID orally for 21 days.*
Genital Wart	*7*	*Apply podophyllin – For this please refer the participant to the referral clinic*

** Caution in first trimester*
*** For pregnant women, replace Fluconazole with Clotrimazole pessary 500 mg intravaginally single dose*
**** For respondents seen to have ulcers during the IBBA, Doxycycline 100 mg BID for 15 days and Azithromycin 2 grams will be prescribed. They will be advised to collect the RPR test results from the referral clinic. All those found to be positive by RPR test will be considered to have been infected for unknown duration and will be advised to have 3 injections of Benzathine Penicillin at weekly intervals. This is true for even those seen with ulcers at the IBBA site.*
***** Doxycycline should not be given to pregnant women*
For more details on treatment in pregnant women see later.

Other important facts related to treatment:

- If the participant reports an ulcer or a sore which is not seen during physical examination, reassure the participant and refer her/him to the clinic for detailed examination. Do not start on treatment for ulcer if it is not seen. (However, if a discharge is reported but not seen, then treat for discharge). This is because many times the physician's perception of an ulcer is different from that of the participant and also because we are not doing internal examination under IBBA therefore we lack the exact information).
- If unable to differentiate between herpetic & non-herpetic ulcers treat for non-herpetic ulcers. Participants with non-herpetic ulcers would be given a stat dose of Azithromycin & started on Doxycyline 100 mg bd for 15 days. They would be advised to go to the referral clinic for getting their syphilis test results. At the referral clinic *preferable* treatment would be to give one shot of Benzathine Penicillin of 2.4 mega units. In this case, Doxycycline would be stopped at the referral clinic. (Alternative treatment is Doxycyline 100 mg bd for 15 days).
- All those with RPR positive would *preferably* be given three shots of Benzathine Penicillin of 2.4 mega units at weekly intervals. Alternative treatment is Doxycyline 100 mg bd for 30 days.
- With regard to treatment for syphilis the COGS guidelines (Clinical Operational and Guidelines Standards) recommended for Avahan STI services, are being followed for IBBA. As per COGS "Low VDRL/RPR titer (< 1:8) may be due to a biological false positive or a serofast low titer. Nevertheless, Avahan recommendations are to treat in the case of low titer reactive syphilis serology identified on the first syphilis screening in sex worker populations because of the high probability of exposure to syphilis, the high likelihood of complications in

untreated syphilis, and the increased HIV transmission associated with syphilis infection at the population level." The same will hold true for all groups being surveyed under IBBA. Thus, any RPR positive or Treponstika positive (in case of DBS) (irrespective of titers) will be treated for syphilis.

- All participants with ulcers should be advised follow up at the referral clinic after 7 days.
- If a female participant is diagnosed to have both vaginal discharge and lower abdominal pain, treat for LAP.
- The stat doses of medicines should be advised to be taken in front of the doctor at the survey site itself. Provisions would be made for drinking water and some refreshments. However, it is expected that this will be ensured by the doctor at the beginning of the day's work.
- Doxycycline will have to be dispensed to the participant as it is not a stat dose and should be advised to be taken after food.
- For stat dose of Azithromycin ensure the participant has taken some refreshments before as it is known to cause stomach discomfort and nausea.
- Participants given Metronidazole should be advised to avoid alcohol.
- Participants who are not prescribed antibiotics for STIs, should be given one tablet of B Complex once daily for 7 days.
- Participants diagnosed to have LAP, (after ruling out surgical & emergency gynecological conditions) should be given the full course of treatment & should be advised to attend the referral clinic after 3 days or earlier if the pain becomes worse.
- Participants diagnosed to have inguinal swellings, should be given the full course of treatment & should be advised to attend the referral clinic after 7 days.
- Participants with an inguinal sinus should be advised to attend the referral clinic on the same day.
- Participants with vaginal, urethral or anal discharge should be followed up in the referral clinic after 7 days.
- If a female participant complains of dysuria ask for features of vaginal discharge or LAP & treat for the same.
- **For pregnant women –**
    - No change in treatment 1 & 2 (for anal discharge & vaginal discharge)
    - In treatment 3 (for non-herpetic ulcers) do not give Doxycycline (Azithromycin & Penicillin are safe)
    - Acyclovir (treatment 4 for herpetic ulcers) is to be avoided. If very painful, it can be given but avoid.
    - Women who are suspected to be pregnant (missed periods) with LAP should be immediately sent to the referral clinic
    - Refer if they have inguinal swelling for diagnosis & erythromycin.
- Packaging of medicines –

For convenience the drugs have been packaged as treatment for individual syndromes and each packet has been color-coded. Thus, if a patient is diagnosed to have urethral discharge particular packet with the label of "urethral discharge" can be used for the participant.

Counselling of participants:

After specimen collection, the doctor will provide the following information to the study participants on the following:

- Ensure that the information obtained from the participants is confidential;
- Inform them that they will not be able to know their HIV test result and the urine result from the study;
- If they wish to know their HIV status – you will refer the respondent to a pre-selected Referral clinic from where someone would accompany them to a VCT center;
- They will be able to get the results of their syphilis test by going to the Referral clinic with the IBBA follow up card;
- Provide basic facts on HIV and STI including the nature and consequences of STIs;
- Provide information on safer sex, do condom demonstration and provide eight condoms to each participant;
- Provide information on the need for follow-up services at the Referral clinic;
- If with STI symptoms - explain the nature of STI, treatment provided including possible side effects, ensure treatment compliance, importance of *partner treatment* and to visit the Referral clinic for follow-up of STI management; and
- Ask if they have any questions and answer their queries.

Counselling on sexually transmitted infections

Steps for counselling a participant with STIs include the following:[1]

- Reassure your patient of confidentiality.
- Explain the findings and diagnosis and that the infection is passed through sexual intercourse.
- Explain the nature and consequences of STIs.
- Explain the treatment, name, and dosage of the medications, possible side effects of the drugs, and the importance of completing the full course of treatment.
- Explore with the patient the best way to tell his/her regular partners about the infection. If the patient is reluctant or worried about telling partners, explore alternatives, but do not push the patient into a potentially dangerous situation.
- Help the patient develop a plan for reducing risk in the future:
    - Help the patient explore options for safer sex.
    - Explain that the patient can make a choice that suits them now and change it as circumstances or preferences change.
    - Review the sexual activities mentioned by the patients and discuss the levels of risk of these activities.

[1] Adapted from *Counseling for STI/HIV prevention in sexual and reproductive health settings.* International Planned Parenthood Federation.

- Explain to the patients how to make their preferred sexual activities safer.
- Explore the good and bad points of each choice for safer sex in terms of STI/HIV prevention, enhancing relationships, partners' preferences, and feasibility. Discuss the possible consequences of their choices.
  - Promote and provide condoms (see appendix)
  - Ask about the patient's experience using condoms.
  - Provide information about condoms and demonstrate how to put on a condom.
  - If a patient has no experience using a condom, ask what he/she has heard about them, how they feel, and what the barriers are to using a condom.
  - When you understand the client's concerns, explore solutions.
- Encourage a follow-up visit to the Referral clinic to assess whether the patient has been correctly treated/cured and to provide additional support.

Clinical format
For Female Respondent

(Please fill all cells under the column "Response". If a wrong entry has been made strike it out & circle the correct response.
If question no. 2, 4 & 6 are not to be filled, please write not applicable. This will be if the answer to question 1, 3 & 5 is no).
Please do not fill the column "code box".

Identification Section:

I1	Participant's ID Number							
I2	Date							
I3	Age							
I4	Gender (Male 1 Female 2 Transgender 3)							

History Section

Q#	Question	Response	Skip	Code box
F01	Do you have any general medical problems?	Yes 1 No 0	→ F03	
F02	If yes, what? (Please write below)			
F03	Are you on any medications?	Yes 1 No 0	→ F05	
F04	If yes, what? (Please write below)			
F05	Are you allergic to any medicines?	Yes 1 No 0	→ F07	
F06	If yes, what? (Please write below)			
F07	Do you have any vaginal discharge at present?	Yes 1 No 0		
F08	Do you have any anal discharge at present?	Yes 1 No 0		
F09	Do you have any ulcers or sores on your genitals at present?	Yes 1 No 0		
F10	Do you have any ulcers or sores on your anus at present?	Yes 1 No 0		

F11	If currently has ulcer or sore, have they had the same symptoms before (probe for painful vesicular swelling, becoming sores)	Yes 1 No 0		
F12	Do you have fever at present	Yes 1 No 0		
F13	Do you have lower abdominal pain	Yes 1 No 0		
F14	Date of Last Menstrual Period (LMP) (_ _/_ _/_ _) Is the participant likely to be pregnant (This will affect the prescription)	Yes 1 No 0		

Examination Section:

Q#	Type of Examination	Response	Code Box
F15	Anaemia	Yes 1 No 0	
F16	Jaundice	Yes 1 No 0	
F17	Lower abdominal tenderness (without guarding or rebound)	Yes 1 No 0	
F18	Visible inguinal swelling	Yes 1 No 0	
F19	Inguinal lymphadenopathy	Yes 1 No 0	
F20	Vaginal discharge – white/curd-like	Yes 1 No 0	
F21	Vaginal discharge – watery	Yes 1 No 0	
F22	Vaginal discharge – purulent	Yes 1 No 0	
F23	Ulcer – single	Yes 1 No 0	
F24	Ulcer – multiple	Yes 1 No 0	
F25	Ulcer – Vesicular	Yes 1 No 0	
F26	Ulcer – tender	Yes 1 No 0	
F27	Ulcer – labia majora	Yes 1 No 0	
F28	Ulcer – labia minora	Yes 1 No 0	
F29	Ulcer – vaginal introitus	Yes 1 No 0	
F30	Warts – labia majora	Yes 1 No 0	
F31	Warts – labia minora	Yes 1 No 0	
F32	Warts – vaginal introitus	Yes 1 No 0	
F33	Anal – discharge	Yes 1 No 0	

F34	Anal – warts	Yes 1 No 0	
F35	Anal – ulcer	Yes 1 No 0	
F36	Anal – tear	Yes 1 No 0	

Syndromic Diagnosis

Q#	Type of Syndromic Diagnosis	Response	Code Box
F37	Vaginal Discharge	Yes 1 No 0	
F38	Anal Discharge	Yes 1 No 0	
F39	Non-herpetic genital ulcer	Yes 1 No 0	
F40	Herpetic genital ulcer	Yes 1 No 0	
F41	Non-herpetic anal ulcer	Yes 1 No 0	
F42	Herpetic anal ulcer	Yes 1 No 0	
F43	Visible inguinal swelling	Yes 1 No 0	
F44	Genital warts	Yes 1 No 0	
F45	Anal warts	Yes 1 No 0	
F46	Lower abdominal pain	Yes 1 No 0	

Treatment Section

Q#	Type of Treatment	Response	Code Box
F47	Cefixime 400 mg orally single dose + Azithromycin 1 gram orally single dose + Metronidazole 2gm orally single dose + Fluconazole 150 mg orally single dose *(vaginal discharge) (Treatment 2)*	Yes 1 No 0	
F48	Cefixime 400 mg orally single dose + Azithromycin 1 gram orally single dose *(anal discharge) (Treatment 1)*	Yes 1 No 0	
F49	Tab Doxycycline 100 mg BID for 15 days + Azithromycin 2 gram orally single dose *(non-herpetic genital or anal ulcer) (Treatment 3)*	Yes 1 No 0	
F50	Acyclovir 400 mg orally TID for 7 days *(herpetic genital or anal ulcer) (Treatment 4)*	Yes 1 No 0	

F51	Cefixime 400 mg orally single dose + Doxycycline 100 mg BID orally for 14 days + Metronidazole 400 mg BID orally for 14 days *(Lower abdominal pain) (Treatment 5)*	Yes 1 No 0	
F52	Doxycycline 100 mg BID orally for 21 days. *(inguinal swelling) (Treatment 6)*	Yes 1 No 0	

Lab Samples

Q#	Type of Sample	Response	Code Box
F53	Blood Sample	Yes 1 No 0	
F54	Urine Sample	Yes 1 No 0	
F55	Ulcer swab (if present)	Yes 1 No 0	

Referrals:
……
……
……
…….

Name of Editor: _____ Date of Editing: ____/____/_____

Name of Coder: _____ Date of Coding: ____/____/_____

Name of Data Entry Person: _____ Date of Data Entry: ___/___/____

Clinical format
For Male/Transgender Respondent

(Please fill all cells under the column "Response". If a wrong entry has been made strike it out & circle the correct response.
If question no. 2, 4 & 6 are not to be filled, please write not applicable. This will be if the answer to question 1, 3 & 5 is no).
Please do not fill the column "code box".

Identification Section:

I1	Participant's ID Number							
I2	Date							
I3	Age							
I4	Gender (Male 1 Female 2 Transgender 3)							

History Section

Q#	Question	Response	Skip	Code box
M01	Do you have any general medical problems?	Yes 1 No 0	→ M03	
M02	If yes, what? (Please write below)			
M03	Are you on any medications?	Yes 1 No 0	→ M05	
M04	If yes, what? (Please write below)			
M05	Are you allergic to any medicines?	Yes 1 No 0	→ M07	
M06	If yes, what? (Please write below)			
M07	Do you have any urethral discharge at present?	Yes 1 No 0		
M08	Do you have any anal discharge at present?	Yes 1 No 0		
M09	Do you have any ulcers or sores on your genitals at present?	Yes 1 No 0		
M10	Do you have any ulcers or sores on your anus at present?	Yes 1 No 0		

M11	If currently has ulcer or sore, have they had the same symptoms before (probe for painful vesicular swelling, becoming sores)	Yes 1 No 0		

Examination Section:

Q#	Type of Examination	Response	Code Box
M12	Anaemia	Yes 1 No 0	
M13	Jaundice	Yes 1 No 0	
M14	Visible inguinal swelling	Yes 1 No 0	
M15	Inguinal lymphadenopathy	Yes 1 No 0	
M16	Circumcised	Yes 1 No 0	
M17	Painful scrotal swelling	Yes 1 No 0	
M18	Urethral discharge	Yes 1 No 0	
M19	Ulcer – single	Yes 1 No 0	
M20	Ulcer – multiple	Yes 1 No 0	
M21	Ulcer – Vesicular	Yes 1 No 0	
M22	Ulcer – tender	Yes 1 No 0	
M23	Ulcer – glans	Yes 1 No 0	
M24	Ulcer – foreskin	Yes 1 No 0	
M25	Ulcer - penile shaft	Yes 1 No 0	
M26	Ulcer- non-penile	Yes 1 No 0	
M27	Warts – glans	Yes 1 No 0	
M28	Warts – foreskin	Yes 1 No 0	
M29	Warts – penile shaft	Yes 1 No 0	
M30	Warts – non-penile	Yes 1 No 0	

M31	Balanitis	Yes 1 No 0	
M32	Anal – discharge	Yes 1 No 0	
M33	Anal – warts	Yes 1 No 0	
M34	Anal – ulcer	Yes 1 No 0	
M35	Anal – tear	Yes 1 No 0	

Syndromic Diagnosis

Q#	Type of Syndromic Diagnosis	Response	Code Box
M36	Urethral Discharge	Yes 1 No 0	
M37	Anal Discharge	Yes 1 No 0	
M38	Non-herpetic genital ulcer	Yes 1 No 0	
M39	Herpetic genital ulcer	Yes 1 No 0	
M40	Non-herpetic anal ulcer	Yes 1 No 0	
M41	Herpetic anal ulcer	Yes 1 No 0	
M42	Scrotal swelling (tender)	Yes 1 No 0	
M43	Visible inguinal swelling	Yes 1 No 0	
M44	Genital warts	Yes 1 No 0	
M45	Anal warts	Yes 1 No 0	

Treatment Section

Q#	Type of Treatment	Response	Code Box
M46	Cefixime 400 mg orally single dose + Azithromycin 1 gram orally single dose *(Urethral or anal discharge, or painful scrotal swelling) (Treatment 1)*	Yes 1 No 0	
M47	Tab Doxycycline 100 mg BID for 15 days + Azithromycin 2 gram orally single dose *(Non-herpetic genital or anal ulcer) (Treatment3)*	Yes 1 No 0	
M48	Acyclovir 400 mg orally TID for 7 days *(Herpetic genital or anal ulcer) (Treatment 4)*	Yes 1 No 0	
M49	Doxycycline 100 mg BID orally for 21 days. *(Inguinal swelling) (Treatment 6)*	Yes 1 No 0	

Lab Samples

Q#	Type of Sample	Response	Code Box
M50	Blood Sample	Yes 1 No 0	
M51	Urine Sample	Yes 1 No 0	
M52	Ulcer swab (if present)	Yes 1 No 0	

Referrals:
……
……
……
…….

Name of Editor: _____ Date of Editing: ____/____/_____

Name of Coder: _____ Date of Coding: ____/____/_____

Name of Data Entry Person: _____ Date of Data Entry: ___/___/____

Chapter 4: System of referral for respondents after the survey

System of relay of syphilis test result:

All respondents in the IBBA who participated in the laboratory component of the survey are entitled to get the results of their syphilis tests and receive free medical treatment for syphilis. They are also entitled to reimbursement for transportation for getting their test results and any follow up treatment with the local Referral clinic. The doctor would advise the respondents on the same.

The IBBA team would have assessed the nearby clinic facilities in the district from where the participants would be able to get the syphilis test results, get detailed examination and followed up if required. At the time of being interviewed or examined the respondents would be given specific information about this designated clinic. The respondents would also be told the timings and the person to contact at that clinic. It is expected that the respondents having thus become aware of the interventions available in their vicinity and will be encouraged to visit these clinics at a later date as well.

Mechanism

- Respondents are provided with name(s) of the Referral clinic and the time he/she can approach to get his/her test result.
- The doctor will fill in the **IBBA follow up card** the date for collecting the test results and follow up at the local designated Referral clinic (2 days after blood sample taken – for example if the sample is taken on the 10th of the month – the results should be available at the Referral clinic on the 15th).
- The card will have the respondent's ID no. that is the same as that on the blood/DBS sample.
- The back of the IBBA follow up Card will have the names of the referral clinic, address and contact information for the respondent.
- The respondent presents this card at the Referral clinic to receive the test result anytime after 5 days.
- The results of the syphilis tests will be sent to the Referral clinic from the district laboratory.
- The results should reach the Referral clinic on a daily basis to ensure that the respondents can access their results in a short time period. The district laboratory will ensure that the test result list is sent to the designated Referral clinic within 5 days of receiving the blood sample.
- The test results will be confidential with each participant's test result being sent from the district laboratory in a sealed enveloped and only authorized staff of the referral clinic would have access to the information.
- Along with providing the test result the respondent should be given the option to utilize services that are available at the clinic including check up and treatment.
- The respondent need not register into the program, if he/she does not wish.

- After relaying the test result, the IBBA respondent card would be retained by the staff of the referral clinic.
- A list would be maintained at the Referral clinic to track how many respondents have appeared to collect their syphilis test result.
- Travel cost incurred by the respondent to collect his/her test result will be reimbursed.
- **The staff of the referral clinic should not try to track down the respondent to give the test result or for any other reason.**

IBBA Follow Up Card

Purpose of the card

- To assist referrals for individuals who have been seen by the IBBA doctor to the Avahan project clinics for detailed examination and further treatment if required.
- To provide information on ID numbers so that individuals can collect results of syphilis tests
- To provide information to Avahan project doctor on diagnoses & treatments given at IBBA site

Who receives the card?

- All individuals that participate in the biological component of the IBBA
- All individuals that visit the IBBA doctor, even if they do not participate in the biological component of the IBBA

FRONT SIDE

Referral Card

ID Number: _____

Needs to collect test result? YES NO
Date test results will be available: _____

Provisional Diagnosis:
Treatment: **Reason for referral**

Signature _____ Date _____

BACK SIDE

CLINIC INFORMATION

Name of clinic
Address
Phone number
Key contact person
Working days of the clinic
Timing of clinic

How to fill in the card

FRONT SIDE

- **ID Number –** The doctor should place the correct ID number sticker here
- **"Need to collect test results?"**
    - If the individual participated in the biological component by giving blood samples, the doctor should circle YES as the individual needs to collect the results of the syphilis test from the referral clinic
    - If the individual did not participate in the biological component, the doctor should circle NO as the individual will NOT need to collect the results of the syphilis test from the referral clinic
- **Date test results will be available**
    - If the individual needs to collect test results, the doctor should fill in the date which the test results will be available at the referral clinic. The date is 5 days AFTER the date of participation in the IBBA.
- **Provisional Diagnosis**
    - The doctor should provide information on the signs and symptoms of STI that were reported by the individual or seen by the doctor. This will help the doctor of the referral clinic to follow up with a detailed examination
- **Treatment**
    - If the respondent was given any type of treatment at the IBBA site, the doctor should provide information on the treatment that was given, dosage, and length of treatment. This will help the doctor from the referral clinic to follow up with a detailed examination.
- **Reason for referral**

Write down the reason why the participant is referred to the referral clinic

- **Signature, Date**
    - The doctor should sign the card and date it.

BACK SIDE

- The doctor should provide information to the individual on the referral clinics including where they are located, their timings, who to contact, etc. The doctor should refer the individual to the nearest clinic. The supervisor will inform the doctor which clinic should be used for referrals. The doctor should circle the names of the clinic where the individual can collect the result of the syphilis test

****NOTE:** If the individual declines to participate in the survey, the front side of the card should be crossed out and the individual should be informed about the Alliance clinics that are available. This card should be given to the respondent so that they know where the clinics are located and the timing of the clinics. (There will be no need to stick the ID no. in such cases) **

Clinical services at the Referral Clinic under the IBBA

- The doctor in the referral clinic should provide standard treatment for all respondents who test RPR positive according to Avahan Clinical Operating Guidelines and Standards (COGS) document. The treatment would include Injection Benzathine Penicillin 2.4 million units intra muscular (one dose per week for three doses) or Tablet Doxycycline 100 mg BD for 30 days. This is provided when the stage of syphilis is unknown or when it is late latent stage syphilis (after one year of infection)

- It is expected that the clinic doctor and counselor would counsel the respondent to come in for follow up visits and bring the regular sex partner for treatment also.

Referral for Voluntary Counseling and Testing services:

Respondents may be interested in the results of their HIV test but the HIV test results based on samples collected in IBBA cannot be given back to the respondents as they are anonymous. Thus, for those interested in HIV testing would be duly referred to the nearby VCCTC center in the district where they can avail the facilities for pre and post test counseling and testing and that they would be helped in this by the staff of the local referral clinic. Reimbursement for transportation to the VCCTC will be provided under the IBBA project. The doctor encourages the participants to avail of the services at VCCTC.

Before the respondents leave the premises it needs to be ensured that:

- All doubts pertaining to the tests or survey have been clarified
- They have been counseled on HIV/AIDS and STI issues
- They have understood where to collect the syphilis test results
- If they want to know their HIV status, they have been referred to the nearest VCTC
- They have collected the tokens/compensation where applicable.

Chapter 5: Infection control, waste disposal and PEP

Universal precautions should be implemented at all times by all staff, without regard for the patient's perceived level of infectivity. Training in universal precautions should be provided for clinical staff, housekeeping staff, and any other staff who come into contact with bodily fluids, waste, linens or spills.

Universal precautions include:

1. Proper hand washing
    - After touching blood, bodily fluids, secretions, excretions, and contaminated items
    - Immediately after removing gloves
    - Before contact with next patient

2. Use of gloves (protective barriers) to prevent contact with bodily fluids
    - For contact with blood, bodily fluids, secretions, and contaminated items
    - For contact with mucous membranes and non-intact skin

3. Safe handling and disposal of needles and sharps
    - Vacutainers should be used for drawing blood
    - Needles are for single use only, do not re-use.
    - Do not bend, break or recap needles
    - Destroy needles using the manual needle destroyer provided
    - Put the sharp objects in puncture-proof containers.
    - Locate containers within easy reach.
    - Replace containers when they are three-quarters full.

3. The other wastes contaminated with body fluids/blood should be put in the autoclavable bag and sent to the district lab for further disposal at the end of the day.

Proper waste management is the final step in infection control. Hazardous waste must be disposed of in a safe manner that eliminates any possibility of infecting clinic staff or community members.

Potentially infectious or toxic waste includes the following:

- Dressings and swabs contaminated with bodily fluids, blood or pus;
- Laboratory waste, including samples and used equipment;
- Patient care equipment, including gloves, needles, syringes and items used in direct contact with the patient;
- Chemical waste, such as laboratory reagents; and
- Pharmaceutical waste, such as expired drugs.

Heavy duty gloves should be used by anyone transporting waste to the site of disposal.

The details of waste disposal are given in the laboratory manual. It is important to remember that it is the responsibility of the field team to leave the survey site clean and not expose the community to risk of infection. Also, it is their responsibility to follow universal precautions to safeguard themselves and their colleagues.

Hepatitis B vaccination:

All health care workers participating in the IBBA will be provided Hepatitis B vaccination if not previously vaccinated.

Three doses of Hepatitis B will be provided at 0 and 1 month and at 6 months intervals if appropriate.

Chapter 6: Guidelines for Post-Exposure Prophylaxis (PEP)

IBBA is committed to the safety of all involved in the survey. For this all due precautions have been taken to ensure that all involved (including the community) do not get exposed to risk. In case of accidents which are expected to be rare, field supplies have been made to take immediate steps.

PEP is provided to health care providers where there is contact with potentially infectious materials. The exposure could be through needle stick injury, accidental contact while using sharp instrument or splash in the eye or mouth.

1. **Immediately following exposure:**
    a. Wash the areas exposed to potentially infectious fluids with soap and water.
    b. Flush exposed mucous membranes with water. If saline is available, flush eyes with saline.
    c. Do not apply caustic agents, including antiseptics or disinfectants, to the exposed areas.
2. Inform Medical Officer of the exposure as soon as possible.
3. The doctor would complete the Health Facility Occupational Exposure **Incident Report form** (see below) which includes date and time of exposure, exposure site(s), where and how the exposure occurred, if a sharp object was involved, type and brand of device, type and amount of fluid, severity of exposure (e.g., depth of sharp puncture), exposure source (infectious status, if known, if HIV-infected, stage of disease, viral load, history of antiretroviral therapy), counseling and post-exposure management, details on exposed HCW (existing medical status and Hepatitis B vaccination status)

    One copy of the incident report form should also be maintained at the field site.

4. At each state lab a nodal person for the clinical side would be designated and trained on PEP

5. The doctor at the field site should do the risk assessment in consultation with the state nodal person. The priority is to call the nodal person on the phone. Later, the Incident Report Form should be sent to the state nodal person at the state laboratory at the earliest, preferably the same day.

The evaluation of exposure for potential transmission of HIV is based on:

a. Type and amount of bodily fluid/tissue:
    - Blood
    - Fluids containing blood
    - Semen

- Vaginal secretions
- Cerebrospinal fluid
- Synovial fluid
- Pleural fluid
- Peritoneal fluid
- Pericardial fluid
- Amniotic fluid

b. Type of exposure:
   - Percutaneous injury
   - Mucous membrane exposure
   - Non-intact skin exposure
   - Bites resulting in blood exposure

c. Infectious status of source:
   - Presence of HIV antibody
   - Presence of HbsAg
   - Presence of HCV antibody

d. Susceptibility of exposed person:
   - Hepatitis B vaccine and response status
   - HIV, HBV, and HCV immune status

6. Determine if the exposure is low risk of high risk for HIV infection

Low Risk:

- Exposure to small volume of blood or fluid contaminated with blood from asymptomatic HIV-positive patient with low viral load
- Percutaneous exposure with a solid needle
- Any superficial injury or muco-cutaneous exposure

High Risk:

- Exposure to large volume of blood or potentially infectious fluids
- Exposure to blood or blood-contaminated fluids from an HIV-infected patient with a high viral load
- Injury with a hollow needle
- Deep and extensive injuries
- Confirmed ARV drug resistance in the source patient

7. To those with a high or low risk classification PEP and follow-up (including testing) should be strongly recommended by the doctor.

8. Contact of intact skin with blood etc, is considered to be of no risk for HIV infection. However, in a situation of breakage of vials where the worker is exposed to spills and is worried, the doctor should explain the risk of exposure (which is almost nil). The detailed follow up, testing and side effect of drugs should also be explained to her/him. If the exposed worker wishes for PEP despite appropriate counselling, it should be given.

9. If the HCW accepts the offer of PEP and follow-up, PEP will be commenced immediately and they would be referred to the nearest VCCTC for HIV testing.

10. The affected HCW will attend the designated VCCTC for counselling and testing at the first opportunity (within 24 or 48 hours of the exposure), and is expected to get the remaining drugs of antiretroviral therapy from the VCCTC. Associated haematological and biochemical indices (full blood count and liver and renal function tests) will be determined on the specimen obtained from the HCW for HIV testing.
11. The State nodal person will be responsible for managing follow-up of the HCW and for ensuring that the testing and treatment is as per the recommended practices.

12. The doctor should note the ID no. of the source in the incident report format. The blood sample from the source would be tested as soon as possible at the state laboratory and the result communicated to the state nodal person. However, even if it is negative for HIV, the treatment should not change as the source is from a group with ongoing high risk behaviour and could be in the window period at the time of the accident.

Usually if the source person is HIV negative, baseline testing or further follow-up of the exposed healthcare worker is not considered necessary. However, under IBBA, as we are dealing with groups that are vulnerable to HIV infection with on-going high-risk behaviour, they might be in the window period and not yet sero-converted. Hence, PEP would be offered to the exposed person based on the risk assessment.

13. The confidentiality of the exposed healthcare worker will be maintained.

Confidentiality of the source person will be maintained at all times.

Treatment provided for PEP

Regimen for Risk Category	
Risk Category	**ARV Prophylaxis**
Low	Zidovudine 300 mg twice a day x 28 days plus Lamivudine 150 mg twice a day x 28 days *(Note: One combination tablet twice a day)* *Under IBBA all exposures are considered to be of high risk category.*
High	Zidovudine 300 mg twice a day x 28 days plus

	Lamivudine 150 mg twice a day x 28 days plus Indinavir 800 mg three times a day x 28 days Alternative to Indinavir: Efavirenz 600 mg QD or Nelfinavir 1250 mg BID *(NOTE: Combination tablet twice a day may replace Zidovudine + Lamivudine)*

1. Start ARV medications within 1-2 hours of exposure if possible. If a delay occurs, initiate PEP regardless of the interval. Currently, there is no defined interval after which PEP is not effective.

2. PEP is to be administered for 28 days. First dose is given at the field site after consideration of rapid test results and the remaining could be given at the district VCCTC or through IBBA.

3. Follow up during PEP:

Perform recommended serology after exposure:

2 weeks	Full blood count Liver and renal function tests
6 weeks	HIV serology
3 months	HIV serology
6 months	HIV serology

4. Offer counseling to person who has been exposed to HIV infection:
   - Assure maintenance of confidentiality
   - For healthcare workers, inform them of the probability of infection from accidental exposure (CDC statistics):
   - 0.3% from percutaneous injury from HIV-infected source
   - 0.03% from muco-cutaneous exposure from HIV-infected source
   - Inform them of the benefits and possible adverse effects of ARV prophylaxis
   - Counsel them on prevention with sexual partners until HIV infection has been ruled out

5. Toxicity of ARVs:
   1. Adverse symptoms with ARVs, such as headache, nausea, and diarrhea, are common.

2. Management without changing the PEP regimen is recommended (e.g., prescribing analgesic, antimotility, or anti-emetic agents).

At the state level –

a. The exposed person should be called for additional counseling by the nodal person
b. Follow up should be done under the care of the nodal person to ensure completion of PEP, to monitor side effects and to ensure that HIV testing is done at the recommended intervals

Incident Report

State _____ District _____ Field _____ Name of supervisor _____

1. Name and position of exposed person: _____
2. Date and time of exposure: _____
3. Where and how exposure occurred (describe): (if sharp object was involved, describe type of device)
   _____
   _____
4. Type and amount of fluid exposed to: _____
5. Severity of exposure (e.g., depth of sharp puncture): _____
6. Risk definition (circle one) Low risk High risk
7. For exposure source:

   a. HIV status: (circle one)
   Negative
   Unknown (test pending)
   Date of test:
   Place of test:
   Positive
   Unknown (refuses test)

   b. If HIV-infected, describe stage of disease, history of treatment:

   c. Hepatitis B status: (circle one)
   Vaccinated
   Unknown
   Date of HBsAg test:
   Place of test:
   History of or active Hepatitis B infection
   Unknown (refuses test)

8. For exposed healthcare worker:

   a. Current medical status: _____
   b. HIV serostatus: _____
   c. Hepatitis B vaccine status: _____

9. Management and counseling of exposed person:

   a. Laboratory tests performed: _____
   b. Medications: _____
   c. Counseling given: Yes No

10. Exposure reported to: _____

Name and position of reporting person: _____
Signature: _____
Date: _____

Chapter 7: Management of drug supply at the field

For syndromic treatment of the participants drugs have been provided under IBBA.

List of drugs supplied

A) Drugs available at the field site:

S. No.	*Drugs for STI**
1	Tab Azithromycin 1gm
2	Tab Cefixime 400 mg
3	T Metronidazole 400 mg
4	Tab Fluconazole 150 mg
5	Clotrimazole pessary 500 mg
6	T Acyclovir 400 mg
7	Tab Doxycycline 100 mg
	Drugs for PEP
8	Tab. Ziduvudine 300 mg + Tab Lamivudine 150 mg
9	Tab Indinavir 800 mg
	General drugs
10	Tab Paracetamol
11	Tab B complex
	For STI counseling
12	Condoms (for distribution to participants)
13	Penis model (for demonstration)

*In many districts drugs for STI would be available in packets – one packet for each individual syndrome.

B) List of drugs available at the Referral clinic:

The referral clinic would be administering the Benzathine Penicillin. Supplies (needles, syringes etc) required for has been given to the referral clinic along with the supplies for management of anaphylaxis. This includes:

S. No.	*Drugs*
1	Inj Benzathine Penicillin 2.4 M Units (vials of 1.2 M units)
2	Tuberculin syringe & needle for test dose (26G)
3	Alcohol swabs
4	Syringe (5 ml with needle)
5	Needle 21 G of one & a half inch size
6	Sterile water for injection
7	Tab Chlorpheniramine 4 mg
8	Aq adrenaline (epinephrine) 1:1000 dilution for inj
9	Inj Pheniramine Maleate
10	Inj Hydrocortisone 100 mg
11	Ambu bag
12	Oropharyngeal airway
13	Inj N saline (500 ml)
14	IV tube
15	Scalp vein 22 G
16	Leucoplast

Management of drug supplies at the field

At all times drugs for about 20 participants should be available at the field site. This is slightly on the higher side and would take care of extras required for losses etc.

At all times maintain a supply for about 3 days or as suggested by the supervisor of the team. This is roughly worked out to 10 doses each of treatment 1 & 2 and 5 doses each of treatment 3, 4, 5 and 6.

The replenishment of supplies will be done from the district laboratory and the following request form should be sent:

REQUEST FORM FOR DRUGS

(Please use this form if STI drugs are in packets)

Date_____

Field team _____

Name of the supervisor_____

Name of the doctor _____

Date when supplies last received _____

S. No.	Name of the Item	Opening stock	No. of tablets received with the last request	No. of tablets consumed in the interval	No. of tablets on hand (closing stock)	No. of tablets requested	No. of tablets received**
1	Treatment 1(Urethral discharge)						
2	Treatment 2 (Vaginal discharge)						
3	Treatment 3 (GUD)						
4	Treatment 4 (non-herpetic GUD)						
5	Treatment 5 (LAP)						
6	Treatment 6 (Inguinal swelling)						
7	Tab. Ziduvudine + Tab Lamivudine						
8	Tab Indinavir						
9	Condoms						
10	Tab Paracetamol						
11	Tab B Complex						

Name & Signature of the doctor _____

Name & Signature of the supervisor _____

Instructions:

- Please write nil where required instead of leaving the cell blank
- The opening stock is same as closing stock at the time of last filling the form
- At the time of requesting the drugs do not fill the last column
- Please fill in duplicate
- Send one copy to the district and retain one as office copy with you
- **After receiving the supplies enter the quantity received in the last column in the office copy with you.

Chapter 8

Organization of work place for clinical examination in the field

At the beginning of each day it is advisable to ensure that conditions are appropriate for examining the participants. A list has been given in the "Manual for field level laboratory component of IBBA". This is the abridged list for the clinical component.

A) Requirement for examination:

1. A cot
2. A lamp
3. A screen to ensure privacy. Even if a single room has been provided for the doctor, it is good to use the screen to separate the examining area. The participant would be more at ease.
4. Soap
5. Water for washing hands before and after each examination
6. Condoms for distribution
7. Model of penis for demonstration of correct use of condom
8. Clinical format for recording the clinical findings (use of 15 formats in a day is expected to be the maximum).
9. IBBA follow up cards (15 in a day would be considered as maximum number)

Male doctors should ensure that a female worker is present with them while carrying out the examination. Ask the participant if she would want someone else to be there.

B) Requirement for administering the medicines:

1. Drinking water for the participant to take the medicines
2. Refreshments so that they do not take Azithromycin/Doxycyclin on empty stomach.

C) Requirement of medicines

As advised earlier, at all times maintain a supply for about 3 days or as suggested by the supervisor of the team. This is roughly worked out to –
Treatment 1 – 10 doses
Treatment 2 – 10 doses
Treatment 3 – 5 doses
Treatment 4 – 5 doses
Treatment 5 – 5 doses
Treatment 6 – 5 doses

Appendix

Condom Education Guidelines

Male Condoms and Prevention of STIs, including HIV[2]

The surest way to avoid transmission of sexually transmitted infections (STIs), including HIV, is to abstain from sexual intercourse or to be in a long-term mutually monogamous relationship with a partner who has been tested and is known to be uninfected. For persons whose sexual behaviors place them at risk for STIs, correct and consistent use of the male latex condom can reduce the risk of transmission of STIs, including discharge, genital ulcer diseases, and HIV, and the risk of unplanned pregnancy.

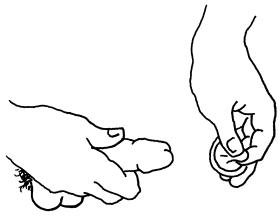
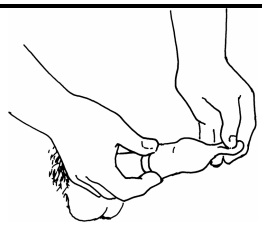
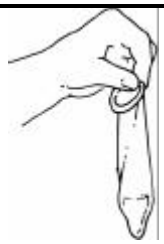
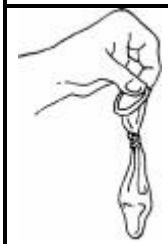
However, no protective method is 100% effective, and condom use cannot guarantee absolute protection against any STI or unplanned pregnancy. Furthermore, condoms lubricated with spermicides may increase the risk of HIV transmission. To achieve the maximum protective effect of condoms, they must be used correctly and consistently. Incorrect use can lead to condom slippage or breakage, thus diminishing their protective effect. Inconsistent use (i.e., failure to use condoms with every act of intercourse) can lead to STI transmission or pregnancy because transmission and/or conception can occur with a single act of intercourse.

Studies have shown that latex condoms are highly effective in preventing HIV transmission when used consistently and correctly. These studies looked at uninfected people considered to be at very high risk of infection because they were involved in sexual relationships with HIV-infected people. The studies found that even with repeated sexual contact, 98–100% of the people who used latex condoms correctly and consistently did not become infected.

Detailed instructions on the correct use of male condoms follow. Condom use should be demonstrated to the patient using a penis model or banana.

[2] Adapted from CDC materials by Family Health International, 16 April 2004.

Instructions for Use of Male Condom[3]

	
1. Remove the condom from the package carefully, to avoid tearing.	2. Squeeze the air out of the tip of the condom.
	
3. Unroll the condom onto the erect penis.	4. After ejaculation, withdraw the penis from the vagina while the penis is still erect. Hold on to the rim of the condom while withdrawing to prevent it from slipping off and the semen spilling into the vagina.
	
5. Remove condom from penis, and tie a knot in it to prevent spills or leaks. Dispose of condom safely (where it cannot cause any hazard)	

[3] World Health Organization. 2005. *Sexually Transmitted and Other Reproductive Tract Infections. A Guide to Essential Practice.*