



Community based interventions to
improve **HIV** outcomes in youth:
A cluster randomised trial in **Zimbabwe**
(**CHIEDZA**)



MANUAL OF OPERATIONS

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List of Abbreviations and Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Aminotransferase
ANC	Antenatal care
ART	Antiretroviral Therapy
AZT	Zidovudine
ATZ	Atazanavir
BBT	Blood based test
BP	Blood Pressure
BD	Bis die (Refers to medication given Twice per day)
BV	Bacterial Vaginosis
CAPS	CHIEDZA Adolescent Peer Support
CBO	Community-Based Organisation
CHW	Community Health Worker
COC	Combined Oral Contraceptive
CrAg	Cryptococcal Antigen
(e)CRF	(electronic) Case Report Form
CT	Chlamydia <i>trachomatis</i>
CTX	Cotrimoxazole
EC	Emergency Contraception
EFV	Efavirenz
ELISA	Enzyme-Linked ImmunoSorbent Assay
DAIDS	Division of AIDS
FAQ	Frequently Asked Question
FBC	Full Blood Count
FDC	Fixed-dose combination
FSW	Female Sex Worker
FP	Family Planning
FTC	Emtricitabine
GC	Gonococcus (<i>Neisseria gonorrhoea</i>)
GCP	Good Clinical Practice
GDPR	General Data Protection Standards
GUID	Globally Unique IDentifier
Hb	Haemoglobin
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HSV-2	Herpes Simplex Virus-2
HTC	HIV Testing and Counselling
IEC	Information, Education and Counselling
IM	Intramuscular
IV	Intravenous
3TC	Lamivudine

LARC	Long Acting Reversible Contraceptive
LFA	Lateral Flow Assay
LGBT	Lesbian, Gay, Bisexual or Transgender
LMP	Last Menstrual Period
LTFU	Lost to Follow Up
MHM	Menstrual Hygiene Management
MOHCC	Ministry of Health and Child Care
MSM	Men who have Sex with Men
NRTI	Nucleos(t)ide Reverse Transcriptase Inhibitor
NVP	Nevirapine
OD	Omne in Die (Refers to medication given Once a Day)
OI	Opportunistic infection
PEP	Post Exposure Prophylaxis
PI	Protease Inhibitor
POP	Progestogen Only Pill
PO	Per Oral
PID	Pelvic Inflammatory Disease
PMTCT	Prevention of Mother-to-Child Transmission
PREP	Pre-Exposure Prophylaxis
PSZ	Population Services Zimbabwe
PV	Per Vaginal
RCT	Randomised Controlled Trial
RDT	Rapid Diagnostic Test
RIT	Ritonavir
SJS	Stevens Johnsons Syndrome
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
TB	Tuberculosis
TDF	Tenofovir
TDS	Ter Die Sumendus (refers to medication given three times per day)
ULN	Upper Limit of Normal
VL	Viral Load
VMMC	Voluntary Medical Male Circumcision
YAG	Youth Advisory Group
YAZ	Youth Advocates of Zimbabwe
WHO	World Health Organization

Glossary of Terms

ART MOHCC books: Popularly known as the ‘green books’ and refer to the booklet used by MOHCC to record HIV testing, care, and treatment information of an individual registered for HIV care in the national HIV care programme

CHIEDZA centre: Community venue at which the CHIEDZA services will be delivered

Client: People aged 16-24 years old accessing CHIEDZA health services. May also refer to their partners who may not be in this age range

Client-held record: Record of contacts with health service providers that is maintained by the client. It is usually in the form of a brown note-book (brown book) and the provider makes a brief note of the problem and treatment given at each contact. The record includes any kind of service or treatment provided and may also include results of important tests e.g. HIV test, blood pressure, CD4 count etc.

Cluster randomised trial: Type of randomised controlled trial in which groups of individuals (as opposed to individuals) are randomised. The “group” can be defined as a school, a clinic, a geographically demarcated area etc. that contains individuals

Intervention: An action taken to improve health outcomes. In the context of the CHIEDZA trial, it refers collectively to the package of services that are described in this manual

Intervention Team: Members of the team including nurse, community health worker, youth worker and driver, who will be responsible for CHIEDZA’s service provision and activities

ITHAKA: Mobile application or platform used to support clients to perform HIV self-testing and to report results to the provider

Key population: Populations of specific concern because of the high risk of HIV exposure (FSW or MSM) or discriminated groups (e.g. LGBT populations or those with disability)

Partner Health Facility: Health facilities that are closest to a CHIEDZA centre, partnered to CHIEDZA for client referrals, and for accessing certain treatments such as ART and STI treatments

Post Exposure Prophylaxis : is any preventive medical treatment started after exposure to an infectious agent in order to prevent the infection from occurring. In the context of this manual, PEP refers to treatment given to prevention acquisition of HIV infection

Randomised controlled trial: Type of scientific (often medical) experiment which aims to test if a new intervention is better or worse than what is being done currently (standard of care). Individuals participating in the trial are randomly allocated to either the group receiving the intervention under investigation (intervention group) or to a group receiving standard care (control group)

Red-flag sign: sign that signals significant risk of danger or harm to individual or to others and require an urgent response from intervention team

Research Team: BRTI and LSHTM staff who will be responsible for maintaining the CHIEDZA protocol’s integrity. This includes coordinating study activities, ensuring that study data is captured appropriately, ensuring that regulatory necessities are up-to-date

SIMPRINTS: Software that enables fingerprints to be converted to and identify with a unique Identification number

STI Screening: Conducting tests to check if a client has an STI regardless of whether s/he has any symptoms

Syndromic STI management: A client is offered treatment according to national guidelines for all possible causes of a particular STI symptom or group of symptoms, No test is conducted to identify the organism that could be the cause of the symptom(s)

Youth: Defined in this manual as those aged 16 to 24 years

Youth Advisory Group: A group of youth selected to advise the project on intervention development and delivery. Each intervention province will have its own Youth Advisory Group

Overview of the CHIEDZA trial

It is well recognised that youth are at high risk of acquiring HIV infection. Youth who are living with HIV are less likely to have been tested for HIV and those who are identified as being HIV-positive have lower rates of HIV viral suppression once they start antiretroviral therapy for treatment of HIV infection, compared to adults and younger children. Therefore, youth are a high priority for interventions to improve HIV-related outcomes.

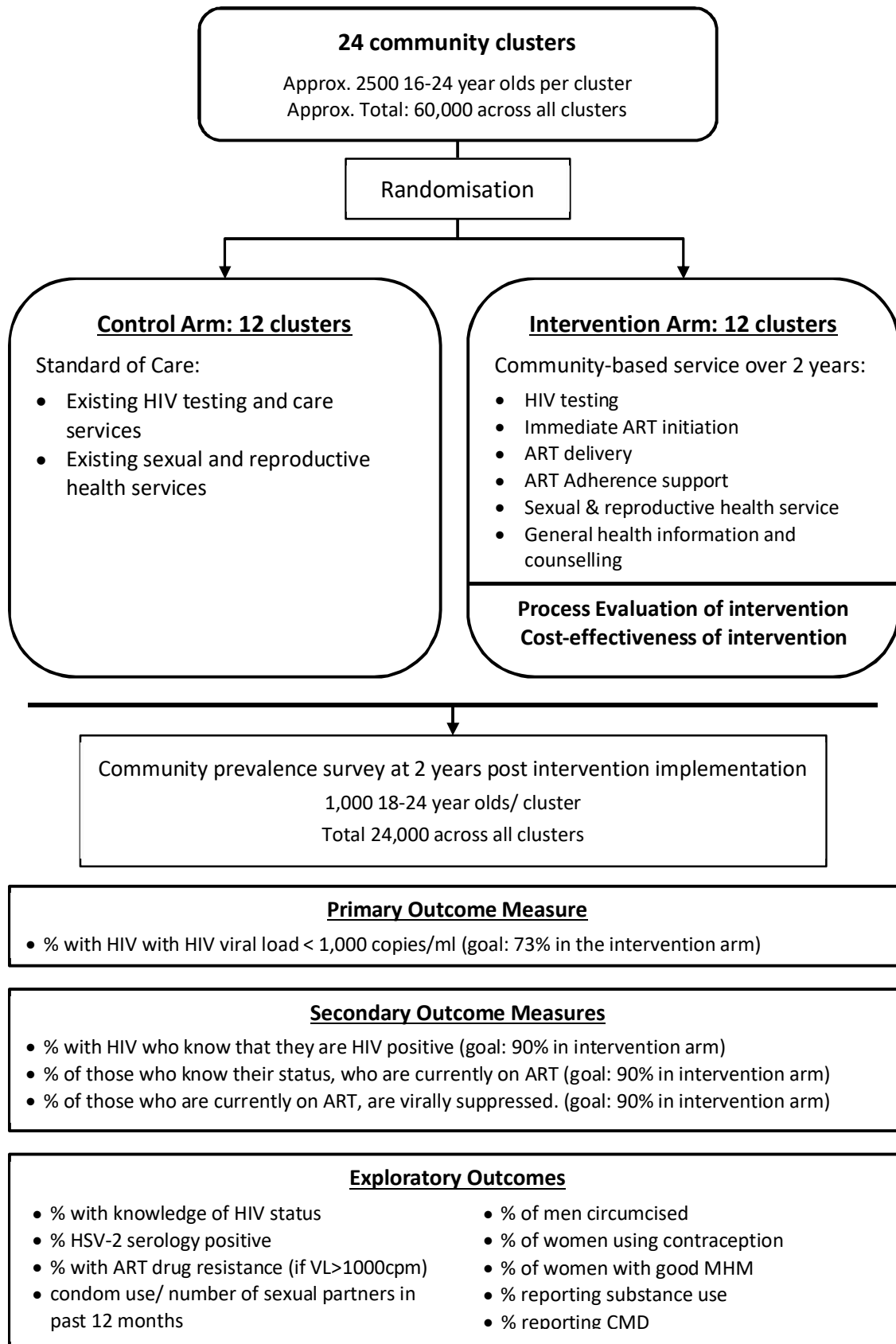
The CHIEDZA Trial is a pragmatic cluster randomised controlled trial to investigate whether providing an integrated package of services including HIV testing, care and prevention, sexual health and reproductive health and general health information and counselling in community-based settings to those aged 16 to 24 years, improves HIV viral suppression at *population* level. To have an impact at population level will require not only the intervention itself to be effective but also high level of uptake and coverage.

Importantly, usage of health facilities by youth is low because personal, social, legal and structural barriers, and their access to key services is therefore limited. Therefore community-based services may increase access and coverage of services. Also, integrating HIV services with other services likely lead to higher acceptability and greater potential for scalability. An important barrier to youth accessing services is healthcare provider attitudes and therefore a key component of this intervention is training and mentorship of the intervention teams to provide youth friendly services.

The trial will be conducted in three provinces of Zimbabwe: Harare, Bulawayo and Mashonaland East. Twelve randomly selected clusters (a geographically defined area with an average of 2500 youth as estimated from the 2012 Zimbabwe National Census) will receive the intervention (the integrated package of services). A further 12 clusters (called control clusters) will not receive the intervention. After two years of intervention delivery, a community-based survey will be conducted in all 24 clusters to determine if there is a difference in proportion of youth with HIV who have a suppressed viral load.

The services will be delivered in a community-based setting by teams that will include nurses, community health workers, counsellors and youth workers. and will collaborate and work closely with health facilities and community-based organisations to deliver the services. The services will be delivered from community centres and the teams will also conduct mobilisation and outreach activities within the intervention communities.

Figure 1: Flow chart of the CHIEDZA trial



Purpose of the manual

This manual is a guide for delivering the CHIEDZA intervention and is divided into three sections:

Section 1: Describes the intervention, the flow of clients through the intervention and data collection and management

Section 2: Details of *how* to deliver each service component

Section 3: Discusses safety considerations for staff, training and community engagement and outreach

The purpose of the manual is:

- 1) To guide the intervention team in implementing and delivering the intervention
- 2) To serve as a “live” record of any changes made in the intervention
- 3) To develop a reference repository of common questions and issues raised by clients

The manual is a dynamic document, and any changes over the lifetime of the study will be documented. Any updates in the study affecting the study procedures should be communicated to the PI. Any updates to procedures affecting data management must be communicated to the study Data Manager and to the PI as soon as possible. The record of changes will be maintained in Appendix 1.

The manual should be read with the CHIEDZA protocol and substudy protocols.

Acknowledgements

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SECTION 1

1. CHIEDZA Intervention

This chapter describes the principles underlying the CHIEDZA intervention, the content of the intervention, as well as how, by whom and where the intervention will be delivered.

1.1 Principles underlying the CHIEDZA Intervention

Youth need access to a variety of health services, including services that are considered taboo by communities such as reproductive health services or HIV services. Youth often avoid going to health clinics and accessing services because of inconvenient hours or location, unfriendly and judgemental staff, and lack of privacy and confidentiality. As a consequence, youth often seek services only when they become sick or because of an acute illness or problem. This means they do not benefit from services that may improve their health, prevent future illness and enhance their well-being.

There are two main principles underlying CHIEDZA:

- 1) Research has shown that youth may prefer receiving services outside healthcare settings. This was confirmed by our formative research and hence CHIEDZA will be delivered in community-based settings. This may address the issue of youth not accessing services as they avoid going to health clinics.
- 2) Special efforts must be made to attract, serve, and retain young clients. This can be done if services are made youth-friendly i.e.
 - i. Attract young people to them
 - ii. Create a comfortable and appropriate setting, and
 - iii. Meet young people's needs.

Researchers have found that youth-friendly services generally share the following main traits:

- Providers are trained to communicate with youth in a respectful and non-judgmental manner
- The service has policies of confidentiality and privacy for youth
- The service has convenient hours and location for youth, and a nonthreatening environment
- The service is affordable
- Youth participate in developing policies and implementing services through an advisory board, as peer educators, and in other roles

The CHIEDZA intervention aims to provide a package of health services delivered to youth (aged 16-24 years) in a community-based setting. While the intervention package will be delivered in the community, it will be delivered in partnership and collaboration with health care facilities and other community-based stakeholders serving youth. Importantly, the intervention is configured to be youth-friendly: details of the characteristics of a youth-friendly service are shown in the panel below.

Characteristics of a Youth-Friendly Service

Programmatic Characteristics

- Youth are involved in program design
- Both boys and girls are welcomed and served
- Unmarried clients are welcomed and served
- Group discussions are available
- Parental involvement is encouraged but not required
- Affordable fees/ free services are available
- A wide range of services is offered or necessary referrals are available
- An adequate supply of commodities is available
- Drop-in clients are welcome, and/or appointments are arranged rapidly
- Waiting times are short
- Information and Educational material is available on-site
- Services are well promoted in areas where youth gather
- Linkages are made with schools, youth clubs, and other youth-friendly institutions
- Alternative ways to access information, counselling, and services are provided

Service Provider Characteristics

- Staff are trained in adolescent issues
- Respect is shown to young people
- Non-judgemental attitude: DO NOT TELL YOUTH OFF
- Provider is NOT prescriptive and Choices are offered
- Privacy and confidentiality are maintained
- Adequate time is given for client-provider interaction
- Peer counsellors are available

Service Characteristics

- Convenient hours
- Convenient location
- Adequate space
- Sufficient privacy
- Comfortable surroundings

Youth Perceptions of the Program

- Privacy is maintained at the facility
- Confidentiality is honoured
- Youth are welcome regardless of marital status and sexual orientation
- Boys and young men are welcome
- Service providers are attentive to youth needs; feedback is sought from youth on how to improve service

SOURCE: Adapted from PHN Center FOCUS on Young Adults project, 2000

1.2 Services within CHIEDZA intervention

The table below list the menu of services that will be available through CHIEDZA.

Table 1.1: Health services provided by the CHIEDZA intervention

For all clients	
HTC	<ul style="list-style-type: none"> • Choice of HIV testing methods: <ul style="list-style-type: none"> ○ Screening for HIV using OMT done by provider ○ Self-testing at CHIEDZA centre using OMT ○ Provision of self-test kit to test at home using online platform • HTC for sexual partners • Confirmatory HIV testing using a rapid BBT
Sexual and reproductive health	<ul style="list-style-type: none"> • Age-appropriate risk reduction counselling • Provision of condoms • MHM • Counselling for contraception and provision of a choice of contraceptive products (EC, depot, COC, POP, condoms) • Syndromic STI management (and GC/CT screening) • Expedited referral for VMMC • Expedited referral for cervical screening • Pregnancy testing
General health	<ul style="list-style-type: none"> • Provision of IEC • General health counselling • Risk-reduction counselling • Referral to specific services (mental health, sexual assault, substance use) • General toll-free helpline
For HIV-positive clients	
Linkage to care	<ul style="list-style-type: none"> • Referral to PHC for HIV care • Registration for HIV care with CHIEDZA centre*
HIV care and treatment	<p>If registered for HIV care with CHIEDZA:</p> <ul style="list-style-type: none"> • CD4 count at diagnosis • TB screening at diagnosis • CrAg testing (if CD4 count < 100cells/μl) at diagnosis • ART initiation at community level • Community-based ART delivery-individual or through CAPS • Care and treatment according to national guidelines • Viral load and CD4 count testing according to national guidelines
ART adherence support	<ul style="list-style-type: none"> • Regardless of whether registered for HIV care with CHIEDZA • CAPS groups (facilitated monthly support groups) • Defaulter tracing • Regular contact via SMS

*automatically registered with the national HIV programme

1.3 CHIEDZA Sites and centres

The CHIEDZA centres are community halls, centres or venues within intervention clusters. The CHIEDZA services will be delivered from these centres and the centres will be refurbished by the project to enable two functions: i) to be an attractive social space for youth and ii) provision of services. Certain items will be left at the centre and others will be carried by the intervention team to the cluster they are working in (Table 1.2).

Each intervention team will travel to clusters (with the required intervention materials) in an intervention van. The van will also be used for moonlighting and outreach activities.

The centre will have an open “social” area with games, pool tables, music, chairs for social interaction and edutainment. This area will be designed to look welcoming and warm and should attract youth to the service. This area is also where some social events may be held on a regular basis.

There will be 4 tents that will serve as private consultation booths. Booths 1 to 3 will provide all the services, so that it is not possible to identify what service a client is accessing when they enter a particular booth. Therefore, all CHIEDZA services will be offered in Booths 1 to 3 without distinction to type of service (one stop shop). Booth 4 will be used for i) clinical examination, ii) self-testing, iii) extended/special counselling by counsellor, or iv) a “quiet” space.

The consultations in the booths will largely be provided by the CHWs. The nurse and counsellor will also do general consultations, but they will also be responsible for provision of specific services across all booths –see Section 1.4.3 and 1.4.4). Therefore, a CHW in any booth may ask the nurse to perform a specific service that only a nurse can provide or refer a client to the counsellor.

At the start of each day, the team will set up the centre as follows:

- 1) IEC materials laid out
- 2) The television will show selected edutainment videos and music system set up
- 3) Consultation booths (tents) set up
- 4) Booths 1-3 should have a small table and chair and the commodities, forms and registers required to provide the service and document data (see Table 1.2 and relevant Sections in Manual of Operations)
- 5) Booth no 4 will have a tablet put up for self-testing using the digital self-testing platform (ITHAKA) and will also have an examination couch
- 6) Furniture- beanbags, chairs, tables, mats, sports and games equipment laid out.
- 7) Items for service provision (tablets, commodities, medication, consumables, registers) to be available for access by each consultation booth.

It is important to note that these centres are also used by the community for other activities and are not exclusively used for the intervention. Therefore, it is important that at the end of the intervention day, the centre is left in a condition that enables it to be used by others.

Table 1.2: Checklist of items required for the intervention

On site			
Equipment	Documents	Other	
BP machine	Protocol	Banner	
Weight scales	Manual of Operations	Posters	
Television		Graffiti wall	
DVD player			
Pool Table			
Football and nets			
Dart boards			
Chairs and Tables			
Bean bags			
Condom demonstration kit			
Carried by intervention team			
Equipment	Commodities	Consumables	Medication
Tents	MHM products	Sharp bins	Cotrimoxazole
PIMA Machine	HIV OMT kits	Gloves	ART packs
Tablets and cases	HIV BBT kits	Needles and vacutainers	Antibiotics for STI treatment
Telephone handsets	CD4 cartridges	Lancets	Amoxicillin tablets
Foldable examination couch	CrAg kits	Sputum jars	Paracetamol
Gene Xpert machine	Condoms	Toilet roll	Ibuprofen
Public address system	IEC	Stationery	Contraceptive injections
	Paper forms, menu cards, logs, registers		Contraceptive pills
	GC/CT Gene Xpert cartridges		
	Urine collection kits		

1.4 Intervention team

The intervention team will be responsible for delivery of the CHIEDZA intervention. The intervention team will work closely with the research team who will be responsible for ensuring the valid data collection, adherence to the protocol and the evaluation of the intervention process.

There will be three intervention teams, each managed by a team coordinator. Each intervention team will consist of a nurse, a counsellor, 4 CHWs and 2 youth workers. The intervention team will be trained in i) delivery of youth-friendly services and management of logistics ii) process of intervention delivery iii) principles of counselling iv) engaging the target population and communities v) data collection during service provision, and vi) research ethics and Good Clinical Practice. Specific training will be provided contingent with specific roles e.g. in-depth training on counselling (counsellors); training on HIV treatment (nurses).

Ongoing mentorship and training will be provided and the team will be expected to participate actively in problem-based learning during the weekly team meetings.

1.4.1 Responsibilities of all team members

Members of the intervention team should:

- Work as a team, shift tasks and triage as appropriate, to ensure the most efficient and effective delivery of services
- Maintain a clean and tidy and well-organised working area and ensure that commodity supplies are maintained
- Understand and have thorough knowledge of the project and the intervention procedures as laid out in the protocol and the Manual of Operations respectively
- Understand the principles of and provide youth friendly services
- Be familiar with the boundaries of the clusters they work in and the local cluster landmarks as this will be critical for determining residential eligibility of participants and for outreach and moonlighting services
- Be familiar with the PHCs (and appropriate hospital clinics if relevant) in the clusters they work in. The team should have introduced themselves to the clinical staff working in the health facilities and should make every effort to maintain ongoing communication and share information about the intervention activities at regular intervals.
- Be familiar with the CBOs, NGOs and other stakeholders providing health and other services for youth in the clusters they work in
- Maintain an updated list (including name, contact details, and type of service provided) of CBOs, NGOs and other stakeholders providing health and other services for youth in the clusters they work in.
- Maintain an up-to-date list of relevant referral organisations for the clusters they work in
- Keep the resources and IEC as up-to-date as possible and identify additional IEC resources and channels to keep the intervention as active and as youth-focused as possible
- Create and maintain a programme of social activities in the clusters they work in as a means of engaging with and attracting youth to the CHIEDZA service
- Seek advice from the team coordinator should they come across any situation they don't feel comfortable handling.
- Data recording and maintaining documentation as per the manual of operations
- Attend debrief meetings and training
- Be responsible for their safety and the safety of clients

While the team will as a whole be responsible for intervention delivery and there will be overlap of roles, there will be certain tasks that will be the primary responsibility of specific team members. These are laid out below.

1.4.2 Role of CHW

- Offer different methods of HTC and perform HTC including confirmatory HIV testing using BBTs
- Family planning consultations (except initial consultations)
- Provision of condoms and condom use demonstrations
- Menstrual hygiene management
- Screening for GC/CT
- ART adherence counselling
- Referral to appropriate services (e.g. VMMC, cervical screening, sexual assault, mental health)
- Referral to nurse or counsellor for specific services
- General health consultation
- Entering data on services accessed and other data as per manual of instructions
- Facilitating CAPS groups
- Ensuring adequate supplies (commodities, consumables)
- Supervision of youth workers
- Outreach and moonlighting

1.4.3 Role of nurse

- Roles performed by CHW

The following tasks will be performed only by the nurse:

- Diagnosis of STIs and treatment prescription
- Initial consultation with a client who tests HIV-positive
- Initiate ART
- Sign off on all ART prescriptions
- Initial consultation for family planning prescriptions
- Working with the counsellor to support clients with specific health issues
- Supervision of CHWs
- Liaising with PHCs to get relevant medication supplies
- Maintaining registers for reporting to donors and to the national programme

1.4.4 Role of counsellor

- Roles performed by CHW

The following tasks will be performed predominantly by the counsellor

- Counselling for specific health problems following referral from nurse, CHW or youth worker
- Dealing with red flag issues as a priority (sexual assault, mental health problems, violence, substance use and so on) in consultation with the nurse and the team leader. Clients with red flag issues should be seen immediately and should not be asked to return the following week.

1.4.5 Youth worker

- Work in the CHIEDZA Centre reception area and perform client eligibility screening
- Manage the orderly flow of clients in social area to health booths, according to the order in which they attend (based on sequential numbering on the menu cards)
- Serve as CHIEDZA champions and mobilise peers in the clusters
- Explain the services to clients in the common social area
- Organise and run social activities
- Maintain order in the social area and encourage clients to access services
- Ensure that attendees to the centre access services and do not exclusively use social area
- Condom use demonstration and encourage clients to take condoms from social area
- Escort clients to services that the client may have been referred to
- Perform outreach and moonlighting activities with CHW
- Perform tasks set by CHWs, counsellor and nurse

1.5 Service delivery

There will be three intervention teams covering a province each (Harare, Bulawayo and Mashonaland East)-see Appendix 2 for list of clusters and cluster maps. Each province has 4 clusters and the intervention team will rotate around the 4 clusters in their allocated province once a week (Table 1.3). The team should be at a particular cluster on the same day of the week over the two-year intervention period.

The team will spend Saturdays facilitating CAPS groups. The team will facilitate CAPS groups on Saturdays. Up to a maximum of 3 CAPS groups will be held on Saturdays and more than one group can be held at the same time. The team should hold CAPS groups in a particular cluster on the same Saturday (1st, 2nd, 3rd or 4th Saturday) of each month.

Each Friday, the team will meet at the BRTI office (for the Harare and Mashonaland East teams) or the Bulawayo OPHID office (for the Bulawayo team) for weekly team meetings. The meetings will be serve as debrief sessions where any challenges identified will be discussed, any changes to the intervention discussed and formally recorded and training held. The team meetings may be reduced in frequency to bi-monthly meetings as the intervention progresses.

The services will be delivered by the intervention team at the CHIEDZA centres. The CHIEDZA centres will open at 1100 and provide consultations from 11.30hrs to 1900, with the last client consultation slot at 1830hrs. The intervention team will be expected to be on site by 1100hrs to set up.

Table 1.3: Monthly team rotation schedule

	MON 1100-1900	TUES 1100-1900	WED 1100-1900	THURS 1100-1900	FRI 0800-1030	SAT 1000-1400
WEEK 1	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Team Meeting	CAPS CLUSTER 1
WEEK 2	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Team Meeting	CAPS CLUSTER 2
WEEK 3	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Team Meeting	CAPS CLUSTER 3
WEEK 4	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Team Meeting	CAPS CLUSTER 4

1.6 Frequently Asked Questions

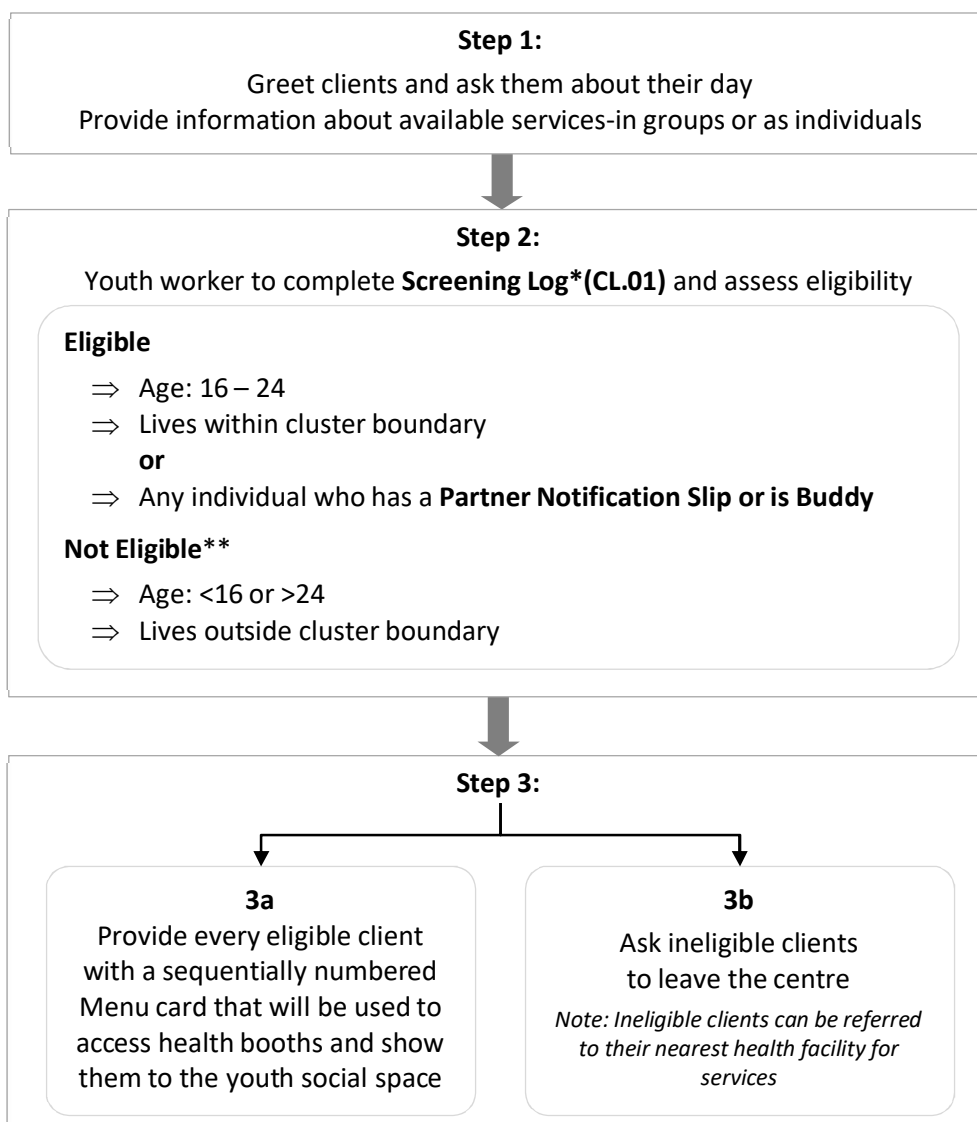
2. Flow of clients through the CHIEDZA centre

This chapter provides information about the client flow in each CHIEDZA centre. See Section 1.3 for how a CHIEDZA centre will be laid out.

2.1 Client Flow through social area

This section describes the flow of activities in the social and reception area of each CHIEDZA centre. Youth workers will be responsible for eligibility screening, managing this area and for controlling client traffic to the health booths. **One of the** youth workers will perform screening. See Section 3 on how to complete the Screening Log (CL.01). **Clients should be gently discouraged from being at the CHIEDZA centre if they do not wish to access services (see Section 2.3.2).**

Figure 2.1: Flow of clients through the social area



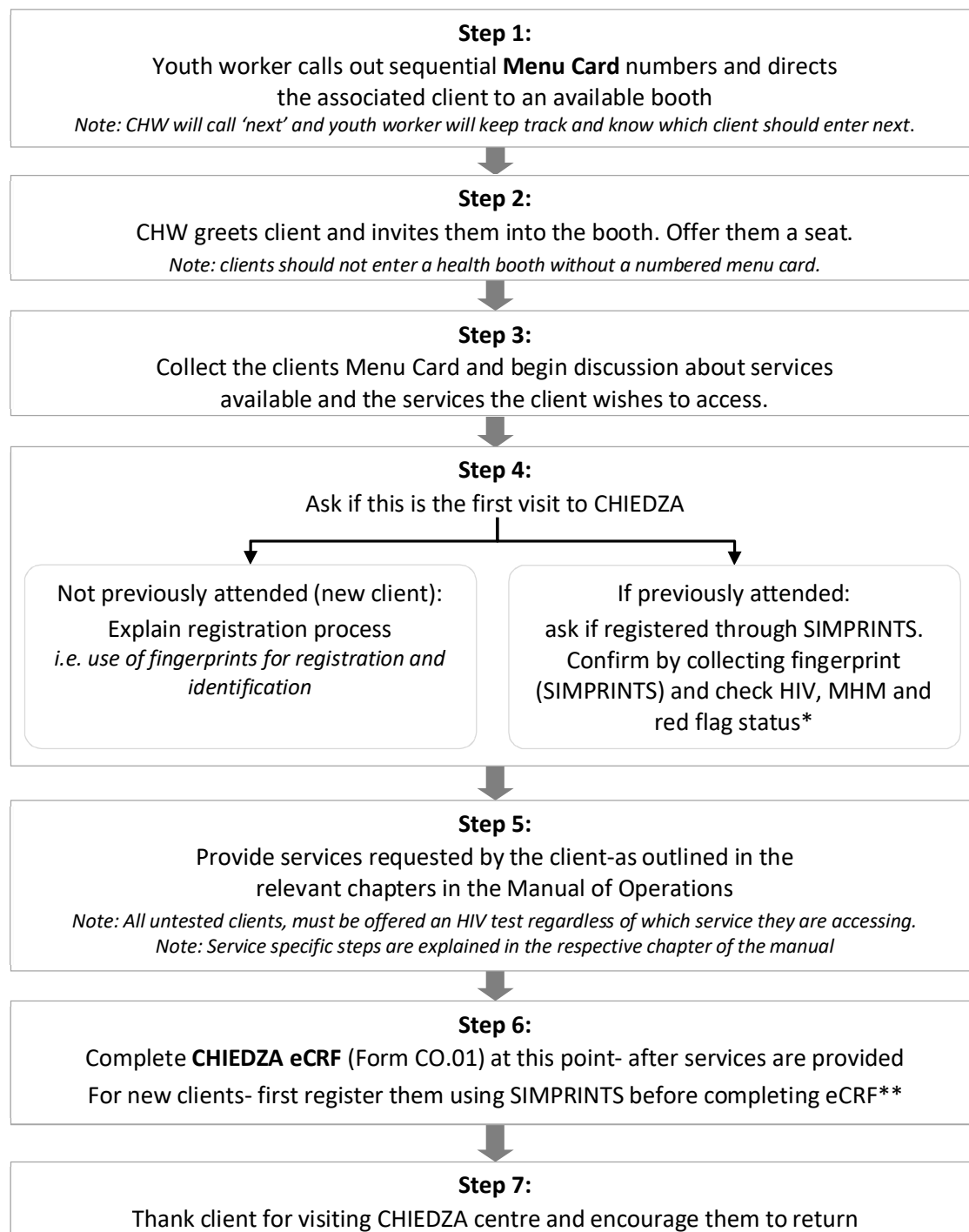
*Details on how to complete a Screening Log are in Section 3

**These exclusion criteria DO NOT apply to those with Partner Notification slips or to Buddies.

2.2 Health service booths consultation flow

This section describes the flow of service provision in the CHIEDZA service booths.

Figure 2.2: Health service booths consultation flow

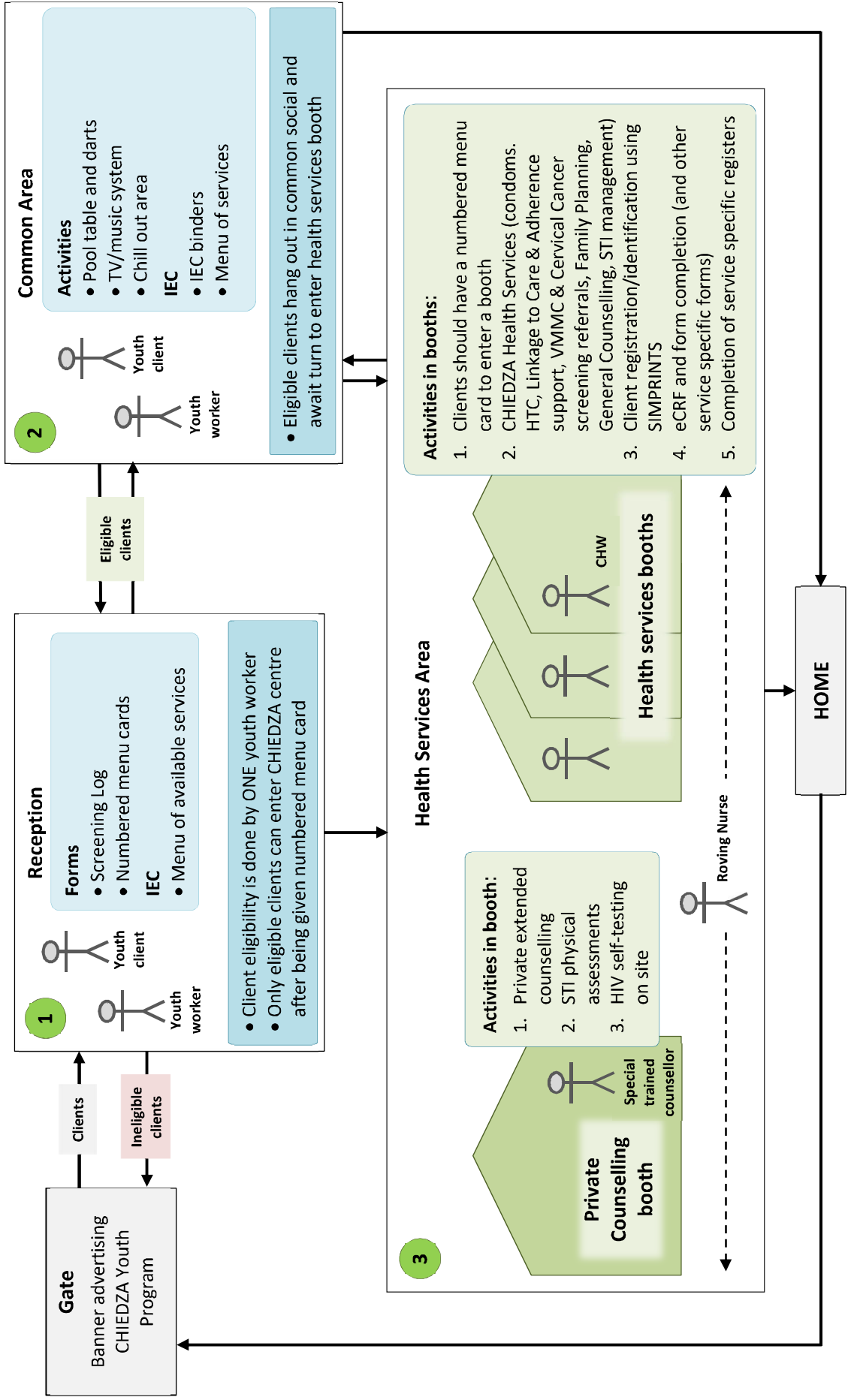


**if client has previously refused to provide fingerprints- use paper register to check previous attendance*

***if clients refuse registration with fingerprints, register them using manual IDs provided by data team*

If a number is called and the client does not want to access a service, the menu card should be returned to the youth worker.

Figure 2.3: Flow of clients through CHIEDZA Centre



2.3 Procedures

2.3.1 How to deal with ineligible clients

Only eligible clients should enter the CHIEDZA centre

- Gently but firmly inform ineligible youth that they cannot enter the youth centre on CHIEDZA days. Direct them to the nearest health facility or other youth health services – use the CHIEDZA referral directory as needed.
- If an eligible client comes to the centre with an ineligible companion, the ineligible client can wait outside and access outdoor CHIEDZA entertainment or sport activities.

2.2.2 How to deal with clients in the social area

Client traffic into CHIEDZA centres will change based on multiple factors including how much awareness there is of CHIEDZA within the study communities, time of day, and so on. It is the responsibility of the youth workers to pay attention to these changes and respond accordingly.

- Engage with clients in the social area as time and workload permits.
 - Describe CHIEDZA and respond to any questions that the clients may have about the health booths, IEC or any materials in the social area.
- Monitor and track client movement to the health booths; call out menu card number and direct associated clients to available health booths.
- For clients who continually come to the centre and only access the social area without entering the health booths; gently explore reasons for not accessing the health booths and explain the rationale for CHIEDZA's health service provision model. If a client comes to CHIEDZA approximately four times (estimate) and does not access the health services booth, inform the client that they cannot come to CHIEDZA just for the social scene and not access CHIEDZA services.

2.3.3 General consult with CHIEDZA client

Clients should not enter a health booth without a numbered menu card/Buddy card or Partner Notification Slip

Try to keep the consultations prompt. Should aim to have a consult that is on average 20-30 minutes. If there is a complicated problem that is likely to require counselling or a deeper exploration of an issue, refer to a counsellor.

- Greet client and ask them about their day
- Ice-breaker and create rapport e.g. ask them something about themselves
- Ask if they have accessed a CHIEDZA service previously and had their fingerprint
 - If yes: check whether they have registered using a fingerprint. If they have previously registered with a fingerprint, collect fingerprint and check HIV,

MHM status and if any red flag comes up. If attended previously but did not register with a fingerprint, check ID register for IDs.

- If no (i.e. new client), explain the CHIEDZA fingerprint biometric collection and registration process. Specifically mention that CHIEDZA is an anonymised service and the fingerprints will be converted to an ID no so it will not be possible to identify any individual through the ID no. The fingerprints will be maintained confidentially and will not be available for **anyone** to access.
- Ask if they have a specific request
 - If yes: address that request
 - If no: move to next step

Note: pay attention and respond as appropriate to any red flag status that may have come up in client's profile

- Explain about services available using the menu card as a guide.
- Specifically, discuss HIV testing. Discuss HTC proactively with all clients: we are aiming for opt-out testing which is defined as HIV testing unless specifically reject it.
- Discuss options for HTC and perform HTC procedures based on the choice client has taken.
- If client refuses HTC, gently explore reasons for refusal and discuss and address their concerns and mention why HTC is important. However, do not coerce clients to undergo HTC. Respect their refusal if they still decide to not test. Offer them the option to come back.
- Proactively offer GC/CT screening (males and females) and TV screening (females only)
- Provide the other services that the client needs. If the client needs a service that can be provided by a nurse, call the nurse in. If the nurse is busy, check how long s/he will be. If it is going to be for a while, you may provide the other services and ask the client to wait until the nurse is free.
- Ask if they need anything else, and judge whether they might need a counsellor depending on their issue. If a client needs or asks to see the counsellor about a specific matter, call the counsellor in. If s/he is busy, give other services and ask the client to wait outside for the counsellor. Let the counsellor and nurse know that the client is waiting.
- If a client refuses the offer of a counsellor, s/he should be provided with information about relevant organisations through the established referral pathways (Chapter 13).
- Offer a pack of condoms to the client and give information about the toll-free helpline (see Section 12.2).
- End the consultation.
- Once service provision is complete the CHIEDZA Form (Form CO.01):

- If the client has already visited, complete the Form (which will be open as a SIMPRINT ID will have been collected at the start of the consultation)
- For the new client, register client by collecting a fingerprint and this will generate a unique ID number (through SIMPRINTS). Then complete the CO.01 Form.
- For those who decline fingerprints, complete a form using an ID number that is generated manually.
- See Section 3 on data collection and completion of Forms, and Appendix 3 for Forms and Registers
- Each client will be given a brown book in which the service they access will be recorded. This is to be held by the client to ensure continuity of care if the client presents elsewhere. Every time the client presents to CHIEDZA, the brown book should be filled in to record the service/treatment provided.

2.3.4 Counselling consult

Clients should enter the specialised counselling booth or have a specialist counselling session, **only** after being referred from a health booth. In the health booth, a client will mention or request counselling and either be referred to the Booth 1 (or the counsellor will be asked to come into the health booth to do the session)

- Greet client and ask them about their day
- Ice-breaker and create rapport e.g. ask them something about themselves
- Ask if the client has a specific counselling request
 - Explore, discuss and address that request and provide counselling
 - If required, refer the client to the appropriate organisation and record details in “Referral Register”
- Ask if client needs anything else. If not, offer the client a pack of condoms, give them the toll-free helpline contact details and end the consultation
- Record reason for requesting counselling in “Counselling Register”.
- It will be the responsibility of the counsellor to facilitate referrals and to follow-up on any referrals as required

2.3.5 Consult with those with Partner notification slips

Collect the Partner notification slip- this will specify if the individual is a contact of someone with an STI / someone with a positive HIV test.

Do not register (i.e. using SIMPRINTS) those who come with the slip

- See Section 4.3.1 for someone who presents with a contact slip from an HIV-positive client.
- See Section 8.4.1 for someone who presents with a contact slip from a client with an STI.

2.3.6 Consult with those with a buddy card

Do not register (i.e. using SIMPRINTS) those who come with a the buddy card.

Complete the HIV Cohort follow-up form- Form CH.02

2.4 Frequently Asked Questions

3. Data Collection and Management

CHIEDZA data management follows Good Clinical Data Management Practices wherever possible and is compliant with GDPR.

This chapter describes the activities and methods used to collect, validate, and process data obtained by the study and other study-related documentation. This chapter also describes study-specific data management roles and responsibilities and data flow. It serves as a guideline and reference document for persons involved in all study-related data collection and management processes.

3.1 Key Personnel

Table 3.1: Key data personnel

Name	Role
Rashida A Ferrand rashida.ferrand@lshtm.ac.uk	Principal Investigator: Overall trial management and oversight
Vicky Simms Victoria.Simms@lshtm.ac.uk	Statistician: Oversight of data management, data cleaning and analysis
Ethel Dauya Harare Province Coordinator edauya@brti.co.zw	Team coordinators: Oversight of day to day running of the study in respective provinces, including data collection activities
Chido Dziva Chikwari Bulawayo Province Coordinator chido.dziva.chikwari@lshtm.ac.uk	
Ethel Dauya Mashonaland East Coordinator edauya@brti.co.zw	
Mandi Tembo tembom91@gmail.com	MHM substudy Lead: Responsible for overseeing the running of the MHM substudy, including data collection activities
Tsitsi Bandason Data Manager Email: tbandason@brti.co.zw	Development of data collection and management tools, data management operations, database maintenance & and training and oversight of data management team.
Joyce Chen Project Manager Email: joyce@simprints.com	Oversight of SIMPRINTS operations
Faizan Diwan VP Data & Customer Success Manager Email: faizan@surveycto.com	Oversight of Survey CTO operations
Luke Shankland Lyanne Mapani Email: luke@avirohealth.com Email: lyanne@avirohealth.com	Oversight of ITHAKA operations

3.2 Data Management Systems

3.2.1 Data Collection Platforms

Data collection is done using two mobile platforms: Survey CTO and ITHAKA:

1. Survey CTO is a secure and scalable mobile data collection platform based on Open Data Kit. Survey CTO can integrate with biometric fingerprint technology (SIMPRINTS) that will be used by the project for client identification. Survey CTO will be used for collection of intervention data (as well as for data collection in the population based survey to ascertain the trial outcomes). It will also be used for data collection of the HIV cohort accessing care through CHIEDZA (HIV cohort).
2. ITHAKA is an interactive mobile platform developed by Aviro (South Africa) aimed at providing guidance and support for HIV testing. The ITHAKA platform will be used for collecting OMT data.

3.2.2 Data Storage

1) Biometric Data

- i. All fingerprint templates, GUIDs (and GPS Coordinates: for population-based survey), sex, date of birth and initials will be saved on the **SIMPRINTS** Cloud Data Server.
- ii. Access to the server will be limited to **SIMPRINTS** personnel and only GUIDs will be automatically transferred to the Survey CTO Server.

2) CHIEDZA data

- i. All CHIEDZA data will be collected using Survey CTO eCRFs and data will be saved on the SurveyCTO Cloud Server
- ii. Access to the Server will be limited to Survey CTO and CHIEDZA data management personnel
- iii. Data for each eCRF will be downloaded from the server as CSV (MS-DOS) files
- iv. All CSV files for each eCRF dataset will be imported into CHIEDZA Microsoft SQL Server for local storage
- v. The SQL Server database will have one table per eCRF

3) HIV OMT Data

- i. HIV Screening data will be saved on the AVIRO Cloud Server
- ii. Specified variables will be downloaded from the server as CSV (MS-DOS) files
- iii. CSV file will be imported into CHIEDZA Microsoft SQL Server for local storage and study purposes
- iv. Access to the data will be limited to specified AVIRO personnel and CHIEDZA data management personnel

3.2.3 Training of staff

The study teams will be trained on completing Forms; any questions regarding data collection will be addressed to team coordinators and to the Data Manager.

3.2.4 Items for data collection

At the beginning of each day, the CHIEDZA team should have the following in place for data collection:

- Fully charged tablets
- Fully charged Fingerprint scanner
- Study eCRFs on tablets and paper CRFs
- Paper logs
- MOHCC ART care books
- CHIEDZA and MOHCC Registers
- Referral Slips
- Menu cards, CAPS and Buddy cards
- Cluster Record Book

Blank paper copies of logs and CRFs should be stored in the study van in the event that tablets fails. Paper forms should be requested from the data team at least 24 hours before they are required. See Appendix 3 for List of Forms and Registers

3.3 Client screening and identification

3.3.1 Screening of clients for eligibility

Eligibility can be determined using the paper version or the **eCL01 Screening Log**.

The paper version will be used alongside the tablet version (to keep track of order of clients)

Figure 3.1: CL01 (paper version)

CL.01 CHIEDZA Trial					
SCREENING LOGSHEET					CLUSTER NO _____
(Eligible clients are only those aged between 16-24years and reside in Cluster Area or Partner or Buddy)					
No.	Age	First Visit (Y/N)	Reside within Cluster (Y/N)	Comment Type Client (C), Partner (P) or Buddy (B)	Eligible (Y/N)
1					

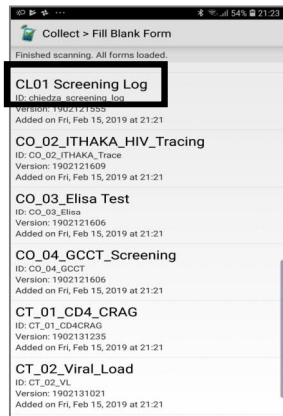
All clients screened for the CHIEDZA study will be assigned a unique screening identification number (SPID) for identification in the waiting area before registration or accessing services. The screening number will only be valid for the day. A client will be assigned number sequentially at screening (001-100).

Open **Survey CTO app** on tablet and open **eCL01 Screening Log** and start adding client. For each attendee determine the age, visit type, residence, client status and enter the information on the **paper CL01 Screening Log**.

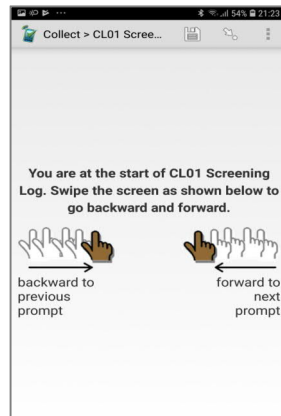
Assign each eligible client an SPID. Stop adding clients when the last client for the day has been added on **eCL01 Screening Log**

Figure 3.2: Screening Clients for Eligibility using eCL01

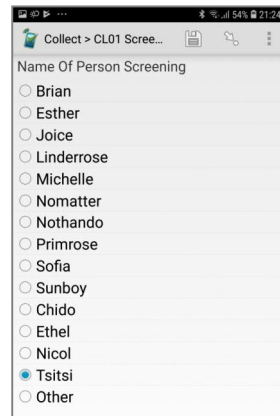
1. Select the eCRF



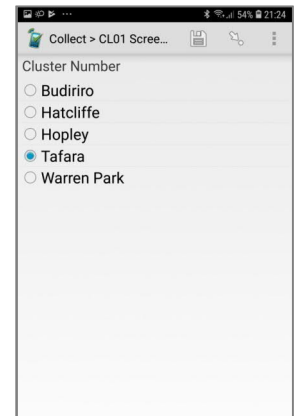
2. Swipe Forward



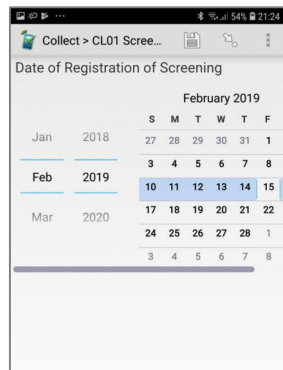
3. Select Your Name



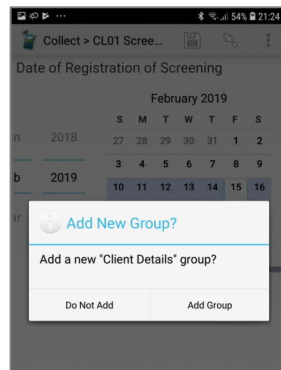
4. Select Your Cluster



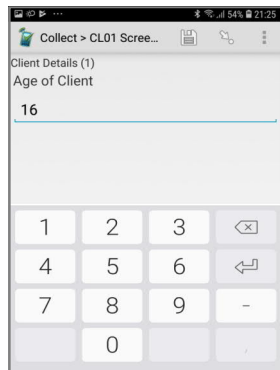
5. Select Date



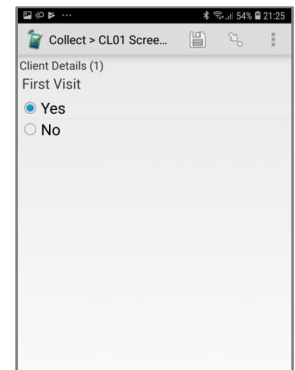
6. Add Group



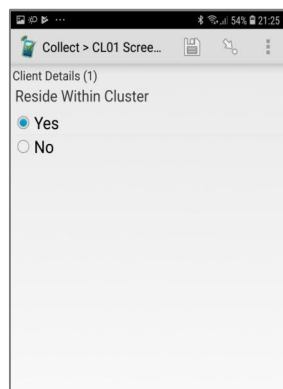
7. Enter Client Age



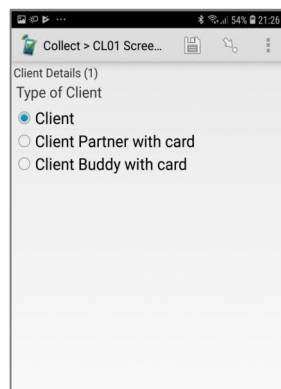
8. Enter Type of Visit



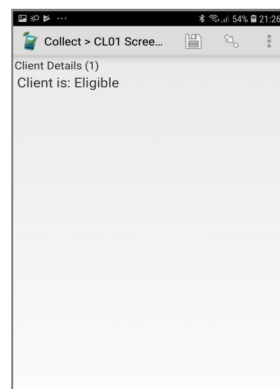
9. Indicate if Client Resides within Cluster



10. Indicate if Type of Client



11. Client Eligibility is Indicated



12. Add the next client or do not add if it is the end of the day or no more clients.

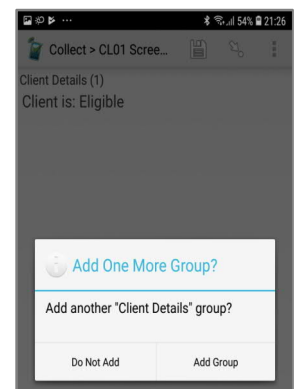
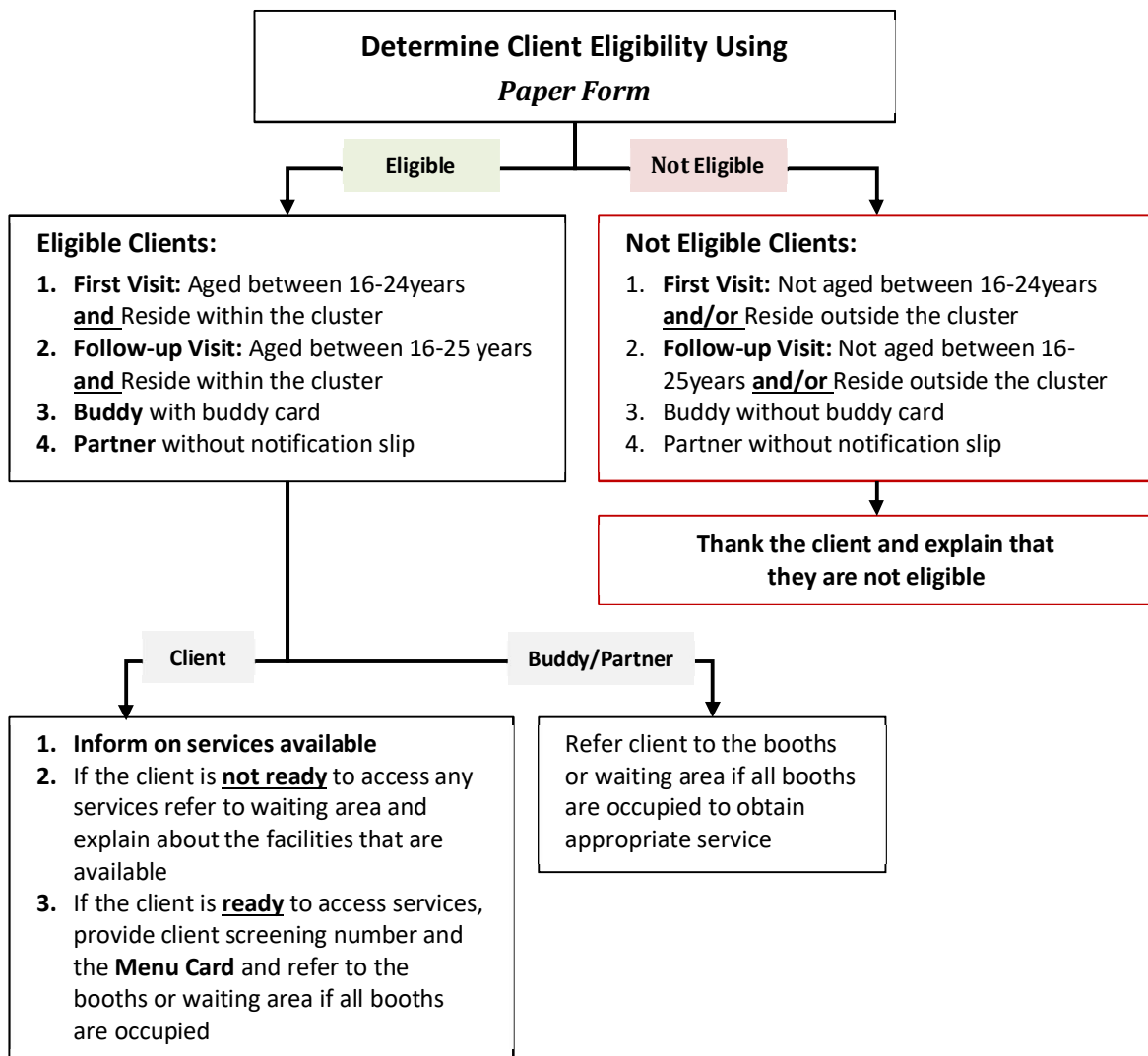


Figure 1.3: Screening clients for eligibility using paper form



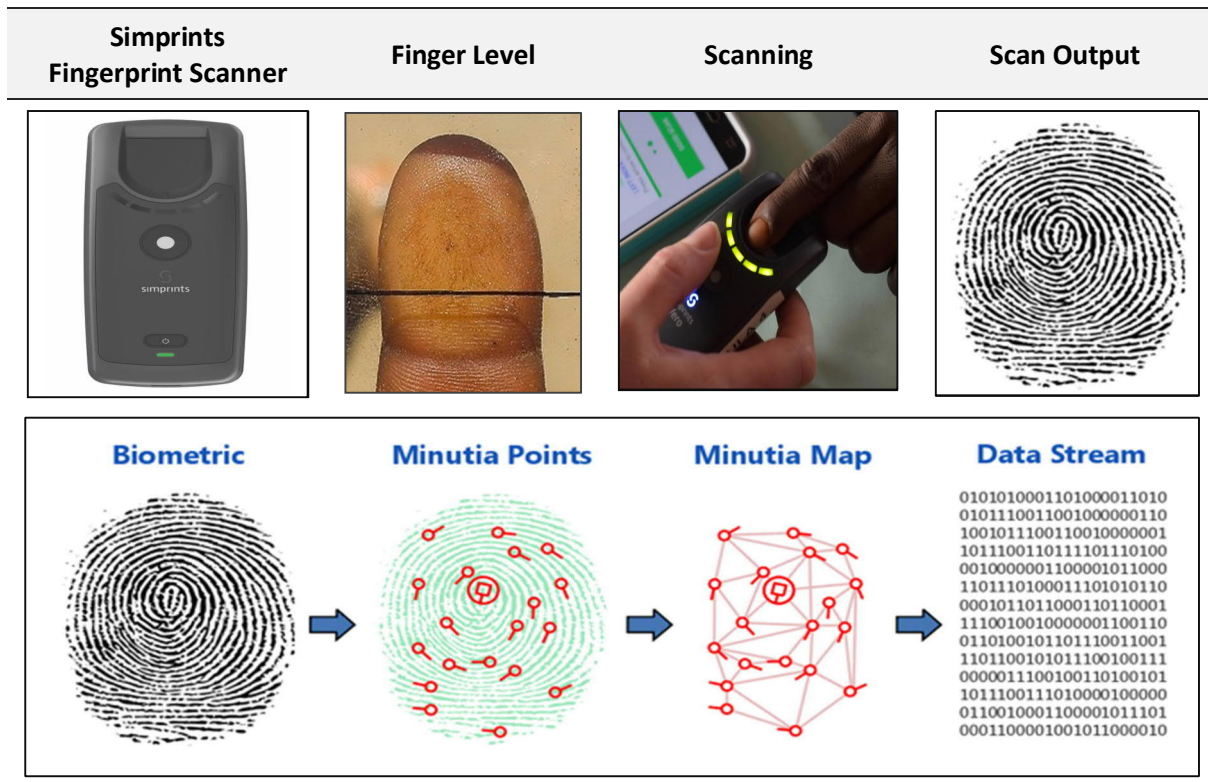
3.3.2 Registration and identification of CHIEDZA clients

3.3.2.1 Use of biometrics

Clients attended to in the CHIEDZA booth are registered and identified using the SIMPRINTS biometrics system. Clients will be registered using four different fingers: Left Thumb, Left Index, Right Thumb and Right Index fingerprint. The SIMPRINTS software converts the fingerprint into a GUID e.g. **ec1c17b9-185c-4d6e-8e42-05728b7e77aa** (Figure 3.4). The GUID generated from these fingerprints is the unique identifier for the client.

For identification, the fingerprint/GUID of the client should be obtained. The software shows 5 clients that provide the best match and the correct client should be identified using date of birth, sex and initials of client.

Figure 3.4: Generation of GUID from a fingerprint



3.3.3.2 Manual registration and identification

Clients who decline to provide a fingerprint will be assigned a unique client ID number to identify them. This will be used in conjunction with date of birth, sex and initials to ensure that the client ID number is unique. This will consist of two key components and take the format: **CMZZZZZ**

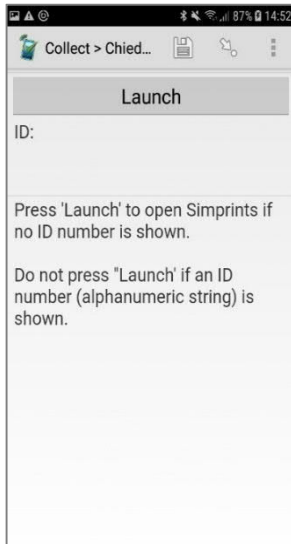
- **CM**= To identify the ID as a CHIEDZA client ID
- **ZZZZZ**= Unique 5-digit client number, assigned sequentially to eligible clients (00001-99999)

The CHIEDZA client ID numbers range from **CM0001- CM99999**.

Figure 3.5: Client registration using SIMPRINTS

1. Enrolment with Fingerprints

Press 'Launch' to open Simprints



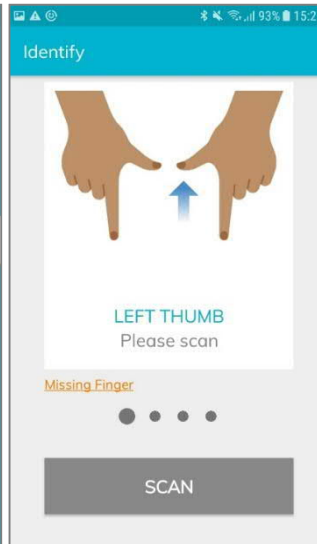
2. Consent

If agree to consent, press 'agree'. If disagree, then do a **Manual Enrolment**.



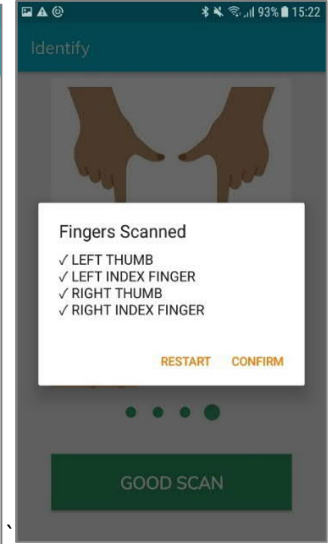
3. Scan fingers in order

Left Thumb, Left Index, Right Thumb, Right Index



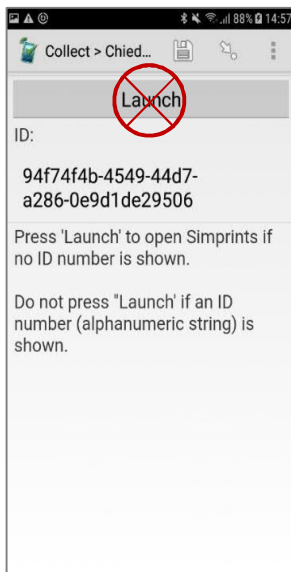
4. Confirm

Confirm or restart if doubtful of correct scanning.



5. Swipe forward

Do not press 'Launch' if ID is shown.



6. Swipe forward



7. Confirm enrolment

Select 'Yes'

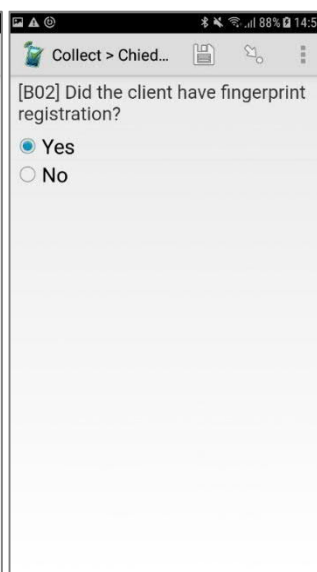
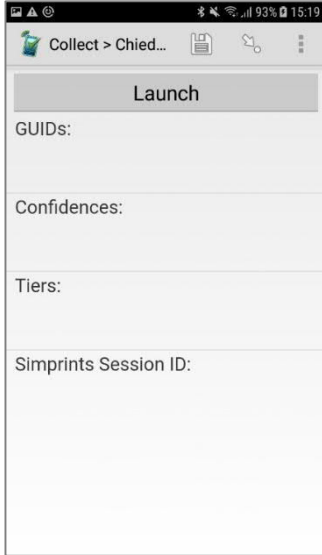


Figure 3.6: Client identification using SIMPRINTS

1. Identification with fingerprints

Press 'Launch' to open Simprints



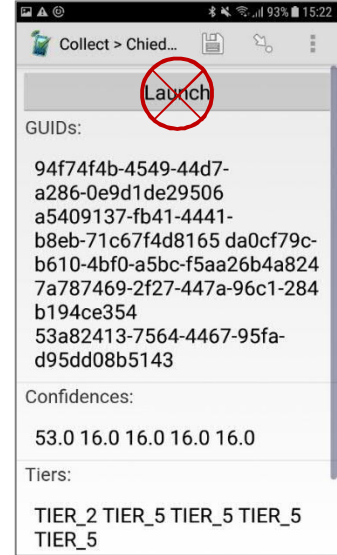
2. Simprints workflow

Perform **Simprints workflow** (i.e. **Step 2 to 4 of Enrolment**). If client disagrees then go to **Step 2 of Manual Identification**.



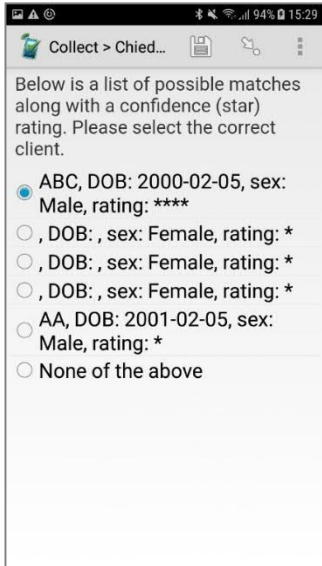
3. Swipe forward

Do not press 'Launch' if GUIDs are shown.

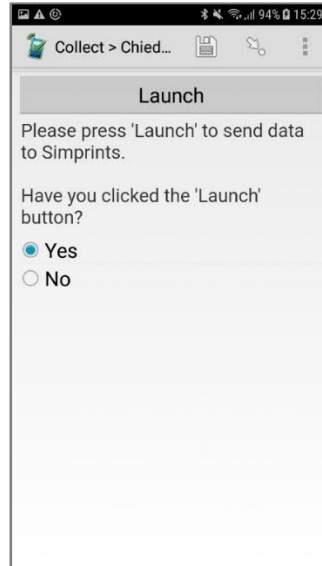


4. Select correct client

If cannot identify client, swipe backward and go to **Step 1** to try again. If still cannot identify then select 'None of the above' and go to **Step 4 of Manual identification**



5. Press 'Launch' then 'Yes'



6. Confirm successful identification

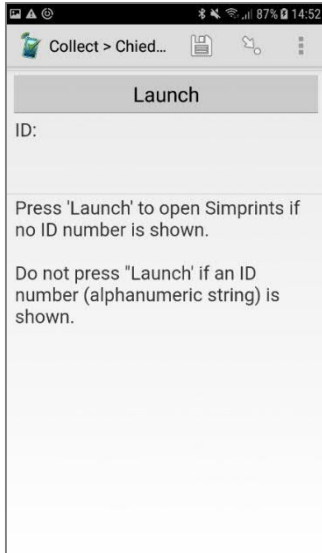
Select 'Yes'



Figure 3.7: Manual client Registration

1. Manual Enrolment

Press 'Launch' to open Simprints



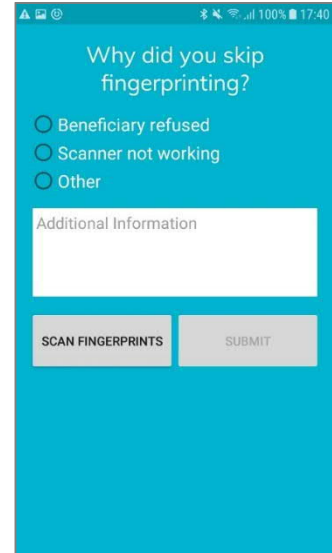
2. Refuse consent

If disagree to consent, ask why and correct any misunderstandings. If client still disagrees, then press 'decline'.



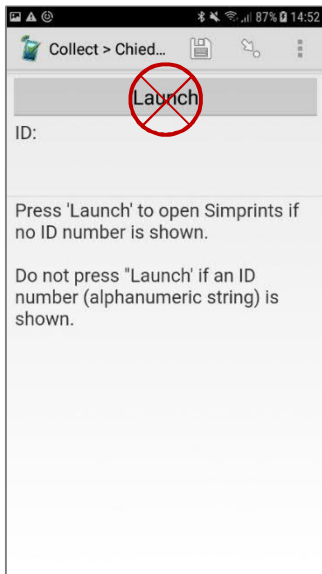
3. Refusal form

Select reason and give additional detail, then press 'Submit'. If accidentally arrived at this screen, press 'Scan Fingerprints' and go to **Step 2** in **Enrolment workflow**.



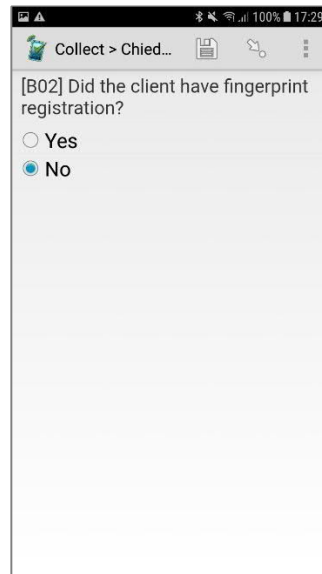
4. Swipe forward

Do not press 'Launch'



5. Confirm refusal

Select 'No'.



6. Enter Manual Study ID

Record the manual PID, date of registration, date of birth, sex and initials in the cluster Record book.

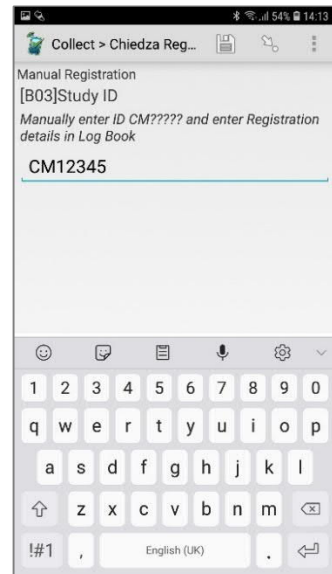
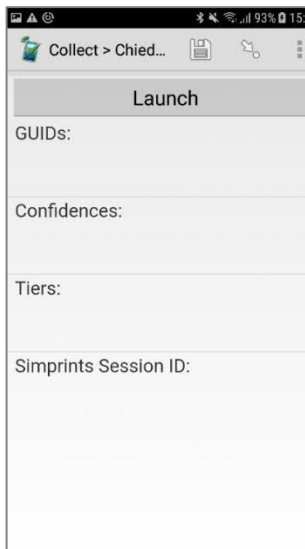


Figure 3.8: Manual client identification

1. Manual Identification

Press 'Launch' to open Simprints



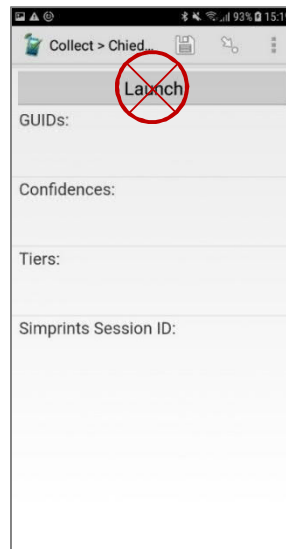
2. Simprints refusal

If disagree to consent, ask why and correct any misunderstandings. If still disagree, then press 'decline' and fill refusal form.

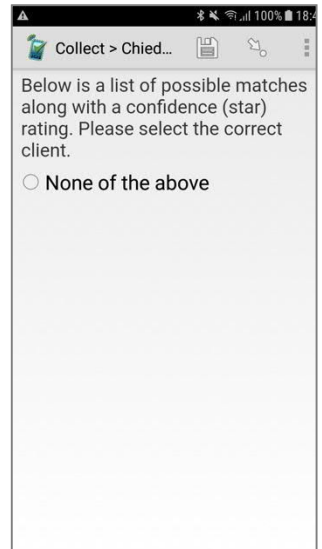


3. Swipe forward

Do not press 'Launch'.

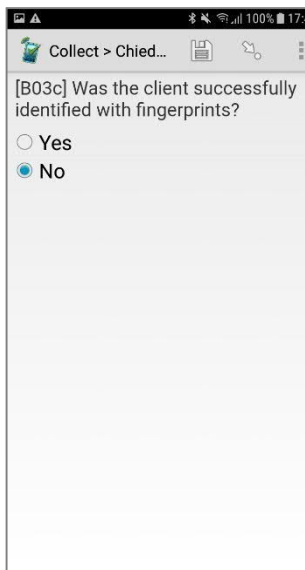


4. Select 'None of the above'



5. Unsuccessful identification

Select 'No'



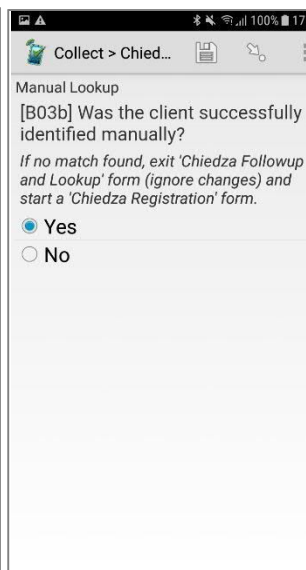
6. Enter Manual ID

Search for Manual ID in Log Book



7. Confirm manual identification

If successfully identified, select 'Yes', otherwise exit the form and start 'Chiedza Registration Form'



3.3.3. ITHAKA Client Identifier

Each OMT kit will have a OMT kit number with the format **CHZZZZZ** which will be the unique identified for the OMT test and which will need to be entered onto ITHAKA platform every time the test is reported. The OMT kit numbers will be pre-stuck on the kits to ensure there is no duplication of kits numbers used.

3.3.3. Registration of HIV-positive clients

3.3.3.1 Clients who access HIV care through CHIEDZA

A CHIEDZA client who enrolls for HIV care through CHIEDZA will be given a HIV Cohort ID number. Participant study numbers consist of two components and take the format: **DZZZZ**

- **D** = To identify the participant as an HIV cohort client ID
- **ZZZZ** = Unique 4-digit for HIV Cohort assigned in chronological order upon determining eligibility and enrolment into HIV cohort (0001-9999)

The HIV Cohort ID numbers range from **D0001-D9999**.

CAPS member Identifier

Each enrolled HIV Cohort Client can join a CAPS group and be given a CAPS card (Figure 3.9).

The CAPS membership number will use the same HIV cohort ID number i.e. **DZZZZ**.

HIV Cohort Client 'Buddy' Identifier

Each enrolled HIV Cohort Client can appoint one person as their treatment 'buddy' and be given a buddy card (Figure 3.10).

The 'buddy' will have the same ID as the HIV Cohort Client with a B at the end i.e. **DZZZZB**.

The HIV Cohort Participants 'Buddy' ID numbers will therefore range from **D0001B-D9999B**.

3.3.3.2 Clients who do not access HIV care through CHIEDZA

If HIV-positive individuals who are not accessing HIV care from CHIEDZA but are cluster residents and aged 16-24 year, they will be eligible to access CAPS groups and have a buddy attend CAPS groups with them.

They will be given a CAPS membership card with a CAPS number that has a prefix P (instead of a D) and numbers will range sequentially from **P0001-P9999**.

The Buddy membership card will have the name number but with a suffix B (**P0001B-P9999B**).

Figure 3.9: CAPS membership card

CAPS MEMBERSHIP CARD

Number: D (Cohort)

Number: P (non-cohort)

Cluster:

Harare Province 0779 620 908,
Mashonaland East Province 0716 318 730
Bulawayo Province 0716 318 734

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Figure 3.10: Buddy Card

Wangu/Skeem Sami

Number: D B (Cohort)

Number: P B (non-cohort)

Cluster:

Harare Province 0779 620 908,
Mashonaland East Province 0716 318 730
Bulawayo Province 0716 318 734

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3.4 Completion of CRFs and Data Collection Flow

The appropriate CRFS should be completed at the specified time points.

Laboratory and tracing CRFs should be completed on the paper version of the eCRF until results are received or tracing is completed respectively.

Table 3.2: General CHIEDZA CRFs

CRFs and Logs to Be Completed at each visit		Platform	Screen	Enrol/ Reg	Weekly
<i>A=All Clients, C=Eligible clients only, D=HIV Cohort Clients Only</i>					
Logs	CL.01 Screening Log	CTO	A		
	CL.02 Attendance Log		C		
	CL.03 eCRF Dispatch Log		C		
	CL.04_Form Transportation Log	Paper			
Menu	Menu Card	Paper	C		
Forms	Incident Reporting Form	Paper			
	Referral Form	Paper			
	Debrief Form	Paper			
Slips	Partner Notification Slip	Paper			
	GC/CT Screening Slip	Paper		C	C
Registers	MOHCC HIV-Self Testing Register	Paper			
	MOHCC STI Register	Paper			
	MOHCC Family Planning Register	Paper			
	CHIEDZA Referral Register	Paper			
	CHIEDZA Counselling Register	Paper			
CRFs	CHIEDZA YAZ Helpline Register	Paper			
	CO.01_Reg_Follow_Services eCRF	CTO		C	C
	CO.02_IHAKA Tracing Form eCRF	CTO			
	CO.03_ELISA Form CRF/eCRF	Paper/CTO			
Apps	CO.04_GC/CT Form CRF/eCRF	Paper/CTO		C	
	ITHAKA APP	ITHAKA		C	C

Table 3.3: HIV Cohort CRFs

CRFs and Logs to Be Completed at each visit		Platform	Enrol	Time post-enrolment											
<i>D=HIV Cohort Clients Only</i>				Monthly	2w	1m	3m	6m	9m	12m	15m	18m	24m		
CHIEDZA HIV Cohort															
Logs	MOCC ART Book (Source document for clinical care)	Book	D		D	D	D	D	D	D	D	D	D		
	CHL.01 Locator Form	Paper	D												
	CHL.02 PIMA Logsheets	Paper													
Registers	CAPS Register			D											
Forms	CAPS Session Form	Paper													
	CH.01_Initial Form eCRF	CTO	D												
CRFs	CH.02_Follow-up Form eCRF	CTO			D	D	D	D	D	D	D	D	D		
	CH.03_Unscheduled visit Form eCRF	CTO													
	CH.04_Cohort Exit Form eCRF	CTO													
	CH.05_Death Form eCRF	CTO													
	CH.06_Tracing Form CRF/eCRF	Paper/CTO													
	CH.07_Caps Enrolment Form eCRF	CTO													
	CT.01_CD4 Count and CRAG Form CRF/eCRF	Paper/CTO	D												
	CT.02_HIV Viral Load Form CRF/eCRF	Paper/CTO						D		D			D		
CT.03_GeneXpert TB Screening Form CRF/eCRF	Paper/CTO														

**Client can enrol into CAPS at enrolment or any point during HIV care*

3.4.1 First CHIEDZA visit for general services

Ask client if it is their first visit.

Explain all the services available on the menu card and about SIMPRINTS registration.

Determine client initials, date of birth, sex and current HIV status of client (if they are not aged between 16-24 years, they are ineligible to access services).

If consent to finger print check, check if client was not previously registered using fingerprints (Figure 3.6). If not identified proceed as new client first visit but if identified proceed as follow-up visit (Item 3.4.2).

If do not consent to fingerprint, check if client was not previously registered using cluster log book based on registration date, date of birth and initials. If not identified proceed as new client first visit, but if found proceed as follow-up visit (Item 3.4.2).

Enter client initials, date of birth, sex and current HIV status of client (if they are not aged between 16-24 years, they are ineligible to access services).

If appropriate, offer an HIV test (see Section 4).

Determine preferred testing mode including screening HIV Test through ITHAKA.

Provide all other services required (see below procedures for various services).

Determine if client consents to fingerprint.

If consents, register on SIMPRINTS (Figure 3.5). If declines to provide fingerprint, register manually (Figure 3.7).

Complete **CO.01_Chiedza Registration and Services** Form.

3.4.2 Subsequent CHIEDZA visit for general services

Determine client initials, date of birth.

Ask client if this is a follow-up visit. If it is:

Open **CO.01_Chiedza Registration and Services** Form

If consent to finger print check, determine if client was registered using fingerprints. If so, identify client using fingerprint (Figure 3.6).

If registered manually, check for Client ID number in cluster log book based on registration date, date of birth and initials.

Use this number to identify client (Figure 3.8).

Check if they require HIV test and offer if needed. If tested at previous visit update the current HIV status.

Offer other services.

Complete the **CO.01_Chiedza Registration and Services** Form.

3.4.3 Registration into HIV cohort

If the client opts to access HIV care and treatment through CHIEDZA enrol them into a cohort as follows:

Complete a locator form for the participant **CHL.01 Locator Form**

Complete **MOHCC ART Care Book**

Complete **CH.01_First Visit** Form

Complete **CT.01_CD4 Count and CRAG** paper CRF and place in the participant file with result slip from PIMA machine attached and then complete eCRF version of the same

If client is suspected to have TB, take sputum sample and complete paper **CT.03_Sputum** and send to the lab with specimen (Place in the participant file when results are received and then complete eCRF version of the same). If client cannot expectorate sputum, complete Referral form and ask client to have a Chest X-ray.

3.4.4 Follow-up HIV care visits

Complete **MOHCC ART Care Book**

Complete **CH.02_Follow-up** Form

Complete **CT.02_Viral Load** paper Form at **6, 12 and 24** months visit after initiation of ART and send with specimen to the lab (Place in the participant file when results are received and then complete eCRF version of the same)

If a client makes an unscheduled visit, complete **CH.03_Unscheduled visit** Form

If the client misses a scheduled visit, trace using **CH.06_Tracing** paper Form. Place CRF in the participant file when follow-up is completed and then complete the eCRF version of the same

If a client dies, complete **CH.05_Death** Form

If a client exits the cohort, complete **CH.04_Cohort Exit** Form

3.4.5 Procedures for specific services

HIV OMT: Any OMT kit used or given out should be recorded in the **MOHCC HIVST register**. The outcome of the test (result (reactive or non-reactive) or result not returned) should be recorded when known.

HIV BBT: Any BBT conducted should be recorded into the **MOHCC HIV register**.

ELISA test: If an ELISA test is required, collect specimen and complete paper **CO.03_ELISA** Form, and send to the laboratory. Complete electronic version of the same Form on Survey CTO when results are received. The OMT kit number **CHZZZZ** should be put on the form to identify the client.

GC/CT screening: If client agrees to have a GC/CT test, give them a **GC/CT Screening Slip**. The client should choose a pseudonym that should be written on the slip, and the Sample number.

Figure 3.11: GC/CT screening slip

I am called: _____

Centre:

Sample Number:

If you have a question about your result, call or whatsapp:

 Harare Province 0779 620 908, Mashonaland East Province 0716 318 730
Bulawayo Province 0716 318 734

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Complete paper **CO.04_GC/CT** Form and send to the laboratory. The form should have pseudonym, client's telephone number, sample number and whether client has been treated for GC/CT already recorded. A client will be considered to have been treated already if s/he has received syndromic treatment for urethral discharge, epididymo-orchitis, cervical infection or PID (if treated for bubo, that constitutes treatment for CT only).

The laboratory will send the CO.04 Form with the results to the data team. If the client has a positive test results AND has not been treated, the data team will send the positive result to the relevant team to follow-up client for treatment. In addition, complete consent form to request storage of unused urine and tick whether consented given on the CO04_GC/CT Form, so the laboratory is aware whether urine should be stored.

Enrolling into HIV cohort: If client agrees to access HIV care through CHIEDZA, assign a cohort ID number (section 3.3.3.1) and see Section 3.4.3.

STI treatment: If Client is provided STI treatment, complete the **“Ministry of Health and Child Care STI Register”**

Partner Notification: If client is treated for an STI or tests HIV positive, counsel the client and give **Partner Notification Slip**. Give as many slips as the client asks for. Tick the appropriate reason for partner notification (Figure 3.12).

Figure 3.12: Partner Notification slip

Visit the Chiedza Centre for Advice

Centre:

Issue Date: / / Date attended: / /

Centre is open on _____

VDS UDS PID EPOR GUD HCT BUB CTS GCS TV






Harare 0779 620 908, Mashonaland East 0716 318 730 Bulawayo 0716 318 734

Key

- VDS: Vaginal Discharge Syndrome
- UDS: Urethral Discharge Syndrome
- EPOR: Epididymo-orchitis
- GUD: Genital Ulcer Disease
- HCT: HIV test positive
- BUB: Bubo
- CTS: Chlamydia trachomatis positive
- GCS: Gonococcus positive
- TV: Trichomonas vaginalis Positive

Making a referral: If referring the client to an external service register. The provider making the referral is responsible for follow-up for the outcome of the referral and documenting the outcome in the referral register.

Counselling Register: Whenever a client is referred to the CHIEDZA counsellor, s/he will document the reason for referral and outcome into the counselling register.

3.5 Completion of MOHCC Registers

There are 3 MOHCC registers that will require completion (see Appendix 3 for MOHCC Registers). This is to enable reporting of activities to the National Programme.

3.5.1 MOHCC HIVST Register

This register should be completed every time an OMT kit is used (regardless of the choice of method of HIV testing the client opts for). This register will provide accountability and outcomes for OMT kits. There are 24 variables in the register.

- Variable 5 and 7: leave BLANK (for confidentiality)
- Variable 12 and 13: Leave BLANK (12 is always community based; 13: pre-test information is always given)
- Variable 19-23: LEAVE BLANK
- Variable 6: enter the OMT kit number **CHZZZZ**
- Variable 11: Enter YES if both individuals who attend are eligible for CHIEDZA. CHIEDZA does not provide OMT kits to partners unless 1) both partners are eligible or 2) the index of the partner tests HIV-positive.
- Variable 15: Enter 1 if the OMT is being provided to a partner. Enter 9 otherwise.
- Variable 17a: Enter YES for “Client tested on site” if client tests in a booth or tested by provider. Otherwise enter NO. Enter YES for “Client has an assisted self-test” if client tested by provider. Otherwise enter NO.
- 17b: Enter YES for “Disclosed result to provider” if client tested by provider or if client tests in booth and returns to tell provider the OMT result. Enter test result if known. Otherwise this will be completed by the Data team who have access to results through the ITHAKA platform. Where a result is not known “INACTIVE” should be completed.

- Variable 18 applies only to those who have a reactive OMT. Variable 18a and b: This can be filled in either by the CHIEDZA team (if answer known) or retrospectively by the Data team who have access to results through Form CO.01.

3.5.2 MOHCC HIV Test Register

This register should be completed every time a BBT is done.

Variables 10,11, 12, 21: Leave BLANK

Variable 13: Put L

Variable 23: Enter 8

Variable 24: Leave BLANK

3.5.3 MOHCC STI Register

This register should be completed every time an STI treatment is given.

There are 21 variables in the register

Variables 3,4,8, 11,12,13,21: Leave BLANK

Variable 10: Candida is not being reported

Variable 17: Enter "YES" for client

Variable 18: Enter "YES" for partner (i.e. individual attending with PN slip)

3.6 Data Validation and Processing

Data quality will be checked at several stages of the data management process.

3.6.1 Completing CRFs

Trained study personnel will be responsible for ensuring CRFs are completed as per protocol and that they accurately reflect the source data and that all relevant sections are completed. The team coordinator (or member of the study team as per the delegation log) will check that all the required Forms are completed.

3.6.2 Uploading and verification of CRFs

At the end of each day, the team coordinator (or member of the study team as per the delegation log) will check that the number of eCRFs on tablets corresponds to the number of clients seen and have been finalised. The Survey CTO will automatically check if all required fields have been checked and the eCRF cannot be finalised without all fields being completed.

3.6.3 Local SQL database checks

A series of data checks will be run on the local SQL database by the data manager. These will include basic checks of the validity of the data and that all required CRFs are completed.

A further series of data checks will be run by the trial statistician (during the data cleaning process). These will include some range and date checks, checks of the validity of the data and checks for consistency across fields and CRFs. Any queries generated will need to be clearly documented and resolved. This will be managed by the data manager and team coordinator with the assistance of the relevant study staff.

SECTION 2

4. HIV Testing and Counselling

HTC is one of the key services offered by CHIEDZA, and all clients should be encouraged to undergo HTC. HTC will be provided by a CHW or a nurse.

All forms of HTC will be voluntary and adhere to the “5Cs” guiding principles (Consent, Confidentiality, Counselling, Correct and accurate HIV test results, and Connections to HIV prevention care and support services).

HTC should be offered at every consult if the client has not had a test in the past year or has had exposure more recently. If a client declines HTC at CHIEDZA, explore reasons and advise on alternatives like testing at health facilities.

OMT will be used as the screening test. If an OMT is reactive, confirmatory testing using a BBT will be required performed according to Zimbabwe national guidelines (see Section 4.4.2). This has to be done by a provider (CHW or Nurse) and not as a self-test.

HTC will be offered in different ways to maximise uptake and acceptability i.e. provider-delivered HTC and HIVST.

4.1 Modes of delivery of HTC

4.1.1 Provider-delivered HTC

- A client can opt for a provider to perform the screening HIV test using the OMT at the CHIEDZA centre. This can be done either by the CHW or a nurse with verbal consent of the client.
- A digital platform called ITHAKA should be used by the CHIEDZA provider to record the HIV test result (Section 4.1.2.1).

4.1.2 HIV self-testing

HIVST is a process in which an individual who wants to know his or her HIV status collects his/her own specimen, performs the test and interprets the result him/her self, often in private. HIVST may increase uptake of HTC as it is done at the convenience of the client, at their chosen time and in their chosen location, and without having to have anyone present. HIVST will be possible through two routes:

- A client will be able to self-test in a private booth at a CHIEDZA centre using an HIV OMT kit given to them by a CHIEDZA provider
- A client will be able to take an OMT kit and test away from the CHIEDZA centre.

These two options will require the client to use a digital platform called ITHAKA to:

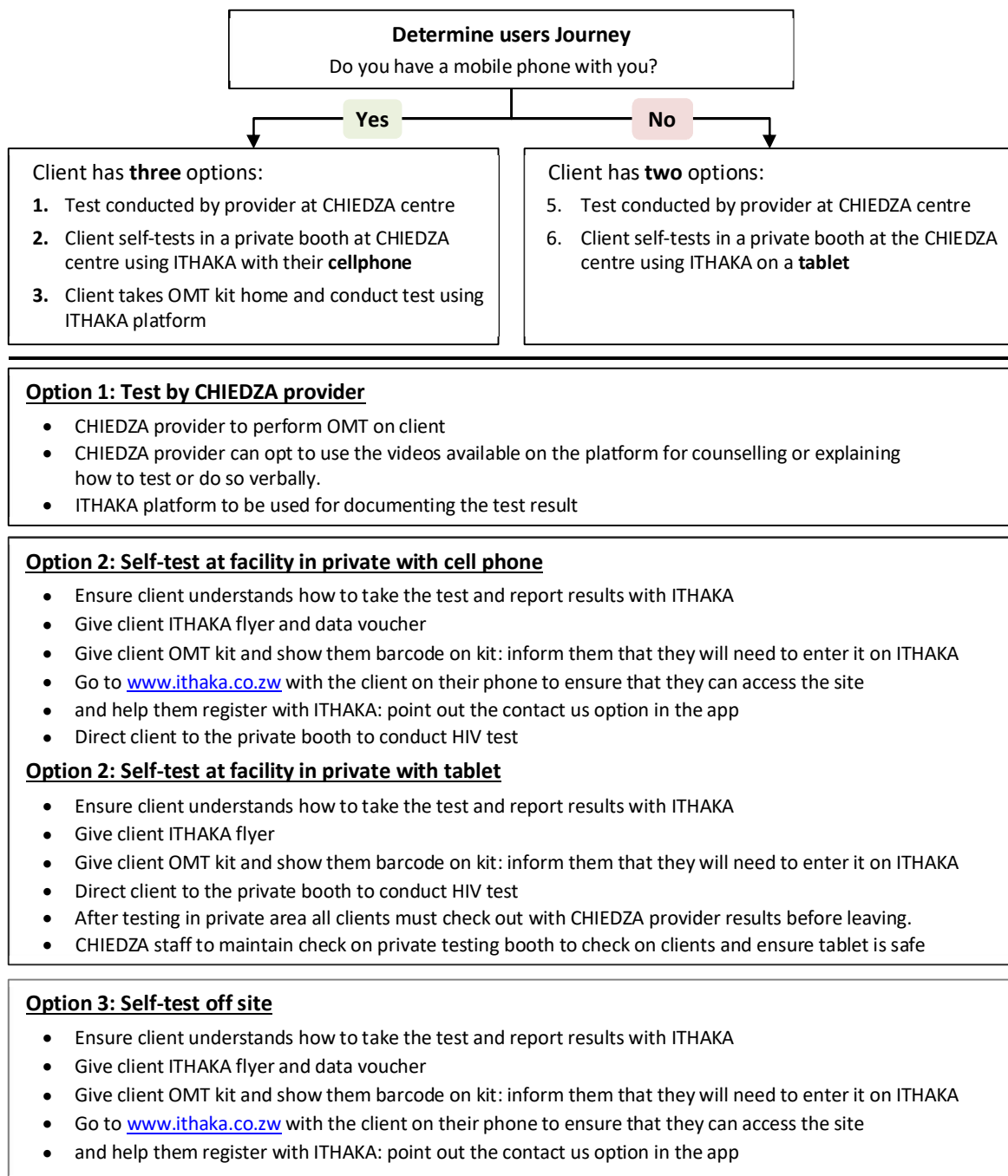
- i. receive pre- and post-test counselling
- ii. receive instructions for performing and interpreting the test
- iii. report their test result

Clients who use the ITHAKA platform will give consent by accepting the terms and conditions of use of the platform when they register to use the platform.

4.2. ITHAKA Platform for HTC

ITHAKA is a mobile application/platform that can be accessed via a web browser. The platform will be made available to clients who wish to undertake HIVST, and will guide them through HIVST with videos of pre- and post- testing counselling and how to conduct an oral self-test. The platform will send those who test HIV non-reactive SMS reminders to re-test after 6 months; those who test HIV-reactive will be reminded to go for confirmatory testing. Importantly ITHAKA will be used by clients to self-report their HIV test result to providers. ITHAKA is free for use by all clients. A flyer and a voucher (for internet access) will be given to clients to be able to access the ITHAKA platform.

Figure 4.1: Options for HIV testing



4.2.1 Provider-delivered HTC option

- Give pre-test counselling (Section 4.3.1).
- Create an ITHAKA account with client to record HTC test results
- In the CHIEDZA eCRF (Form CO.01), enter the client's OMT kit barcode
- Perform OMT (see section 4.4.1). While waiting 20minutes for the test result, offer other services/counselling as appropriate.
- Read result after 20mins and give result to client.
- If the OMT is negative, give appropriate post-test counselling (see section 4.3.2) centred on HIV prevention and other services including referrals
- If OMT is reactive, perform confirmatory testing using a BBT (see section 4.4.2).
 - If the confirmatory HIV test is positive, give post-test counselling (see section 4.3.2) and link to care and treatment (see Chapter 5)
 - If confirmatory test if negative, collect a blood sample to send to the laboratory for an ELISA test, as this is considered discordant to the OMT (see section 4.4.2).
- Enter results on the ITHAKA platform and on CHIEDZA eCRF (CO.01).
- Complete client-held brown book and give client an HIV results slip if they request one.

Note, in the rare case where an individual declines OMT but prefers to have a BBT, move straight to BBT.

4.2.2 HIV self-testing

- Explain to the client that they can self-test either in the booth, or take the test kit away with them (only if they have a cell phone)
- Ask client is s/he has a phone number- this is required for the client to receive a One-Time-PIN to create a personal profile on ITHAKA. Clients who do not have phone numbers are not eligible to take self-test kits out of the CHIEDZA centre.
- Explain ITHAKA platform to the client and how it can be used to get counselling, instructions on using OMT and to report results. Mention that there is a helpline provided in the platform and that if they report a reactive result, they will be contacted by the CHIEDZA team on the phone number they have entered to create their profile
- Ensure client understands the process and refer them to the testing instructions that come with the OMT kit. **Point out the barcode on the kit** (this will need to be entered on the ITHAKA platform when they want to self-test).
- Give client an OMT kit.
- If the client has no cell phone but wants to self-test, they can go to the private booth with their OMT kit where the ITHAKA platform will be already downloaded on the tablet and they can create a profile using a phone number that will be provided to them.
- If a client has a cell phone, they can test in a private booth or take the kit away with them from the CHIEDZA centre.

- If client reports a reactive HIV results into ITHAKA or lets the provider know that s/he has tested HIV reactive in the booth, confirmatory testing can be done on the same visit (Section 4.4.2)

4.2.2.1 Follow-up of clients who self-test

Client who enters HIV test result into ITHAKA:

If client **enters** a reactive HIV results into ITHAKA, the CHIEDZA team will automatically get an email to prompt them to contact the client to attend for confirmatory testing.

- Contact the client using the phone number client entered into ITHAKA. The outcome of tracing of a HIV-reactive result recorded on ITHAKA by a client who has opted for self-testing should be recorded on Form CO.02.
- Ask the person who answers the call i) if s/he has visited the CHIEDZA centre previously, what they accessed at the centre and what pseudonym they used in their ITHAKA profile (to confirm identity). Invite them to return to the centre for confirmatory HIV testing.
- If there is a negative response after follow up calls, the client will be considered LTFU. Negative response includes:
 - No answer after repeatedly calling
 - Person who answers denies visiting the CHIEDZA centre, using services including ITHAKA and does not know the pseudonym.
 - Client refuses to come back to CHIEDZA centre or go to a PHC after four follow-up calls that include counselling.
- Note: Clients do have the option of contacting CHIEDZA directly (via the helpline) or may attend the CHIEDZA centre spontaneously for confirmatory HIV testing either soon after reporting the results or at a later date after initially refusing to attend.
- Complete Form CO.02.

Client who does not enter HIV test result into ITHAKA:

S/he is considered LTFU. Such a client may attend CHIEDZA at a later date. At that point, when s/he enters their fingerprint via SIMPRINTS, the eCRF (Form CO.01) will flag up the incomplete OMT. This will warn the provider that the client has previously taken an OMT test kit but did not test.

- Offer the client provider-delivered testing.
- The client will not be eligible for HIVST due to previous failure in completing HIVST.
- The outcome of the **previous OMT** kit should be LTFU.
- When performing HIV testing now - enter a new barcode (for the OMT kit being used to perform the test now)

Figure 4.2: Provider delivered HIV testing flow chart

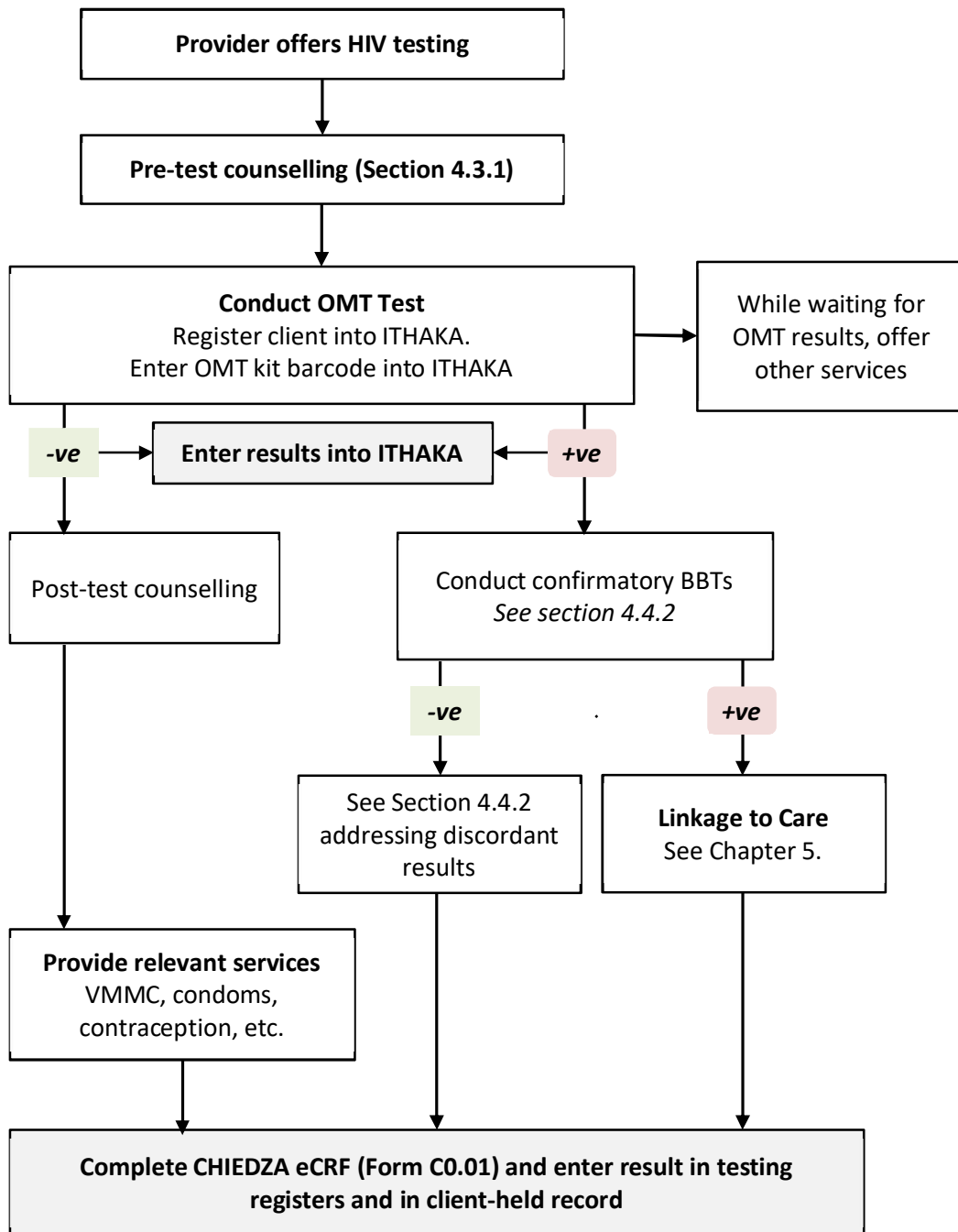
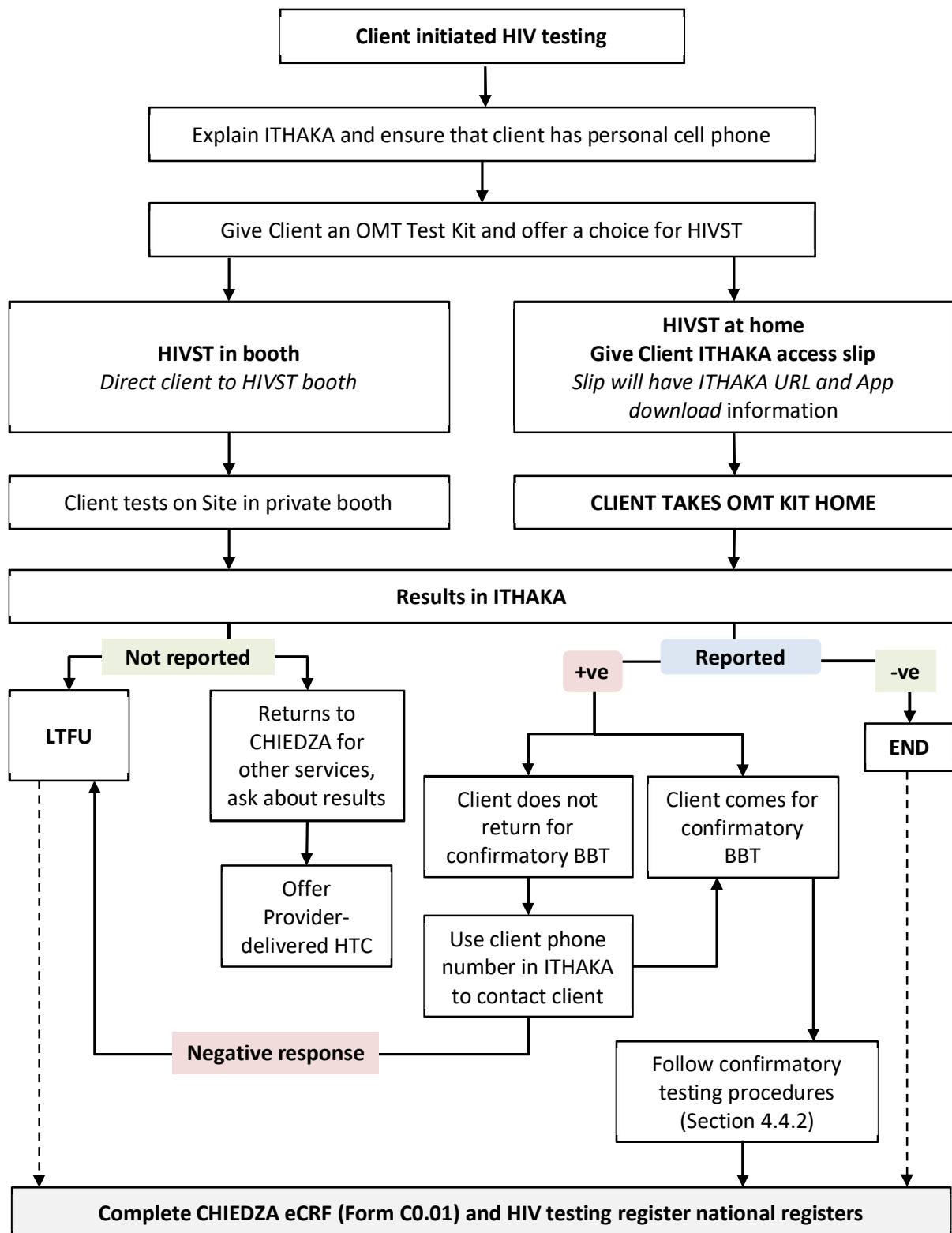


Figure 4.3: HIV Self Testing Flowchart



4.3 Partner notification

If a client tests HIV-positive, offer HIV testing to the partner. Give the client a **Partner Notification** slip to attend the CHIEDZA centre for HTC. There is no limit to the number of Partner Notification slips that can be given. The HCT code should be entered for “HIV” on the partner notification slip so the provider is aware why the partner has presented.

Partners do not have to be resident of the cluster or be aged 16-24 years to access HTC.

4.3.1 Testing of partners

Partners will be defined as those who present with a partner notification slip.

Collect the Partner Notification slip- do not lose this- each slip must be returned to the data office.

Offer HTC: Partners cannot access HIVST- they will only be eligible to receive provider-delivered HTC using the same procedures as that for CHIEDZA clients- i.e. OMT followed by BBT for confirmation if the OMT is reactive.

Record the HIV test result in the HIV testing register.

If the partner tests HIV-negative, provide appropriate post-test counselling.

If the partner tests HIV-positive, provide post-test counselling and refer to a PHC for onward HIV care. The partner will only be eligible for HIV care through CHIEDZA if 1) aged 16-24 years and 2) residing in the cluster.

4.4 Counselling for HIV testing

The aim of counselling is to provide sufficient information to clients and to support them in adequately understanding the testing process and possible consequences of being tested as well as their right to defer testing.

Counselling for HIV is a confidential dialogue between the youth client and a service provider guided by the individual circumstances, age and developmental stage of the youth. The process should enable the young person to:

- make informed personal decisions about HIV testing
- know their HIV status
- cope with the implications of a positive or negative result
- cope with related stressors.

4.4.1 Pre-test counselling

Pre-test counselling helps the client to make a personalised risk assessment; encourages risk reduction; and assists in making an informed choice about HIV testing.

PRE-TEST sessions should help clients to:

- Understand the basic facts of HIV
- Understand the benefits of HIV testing
- Understand the confidentiality of their results and any information they share
- Assess their own risk of acquiring HIV with an emphasis on risk reduction
- Understand prevention options including encouragement of partner testing
- Understand HIV testing procedures and possible results
- Explore support systems and disclosure mechanisms
- Understand range of options and services available to them
- Understand the implications of HIV test result and how to cope with result
- Give consent for HIV testing and to understand that it is voluntary

In addition, during pre-test counselling for HIVST the provider should:

- Explain to the client about HIVST and make sure client understands that HIVST
 - is a screening test that needs to be confirmed by a BBT
 - is a crucial part of HIV testing in CHIEDZA
 - An OMT can be **falsely non-reactive** if a client is taking ART
- Explain to the client about ITHAKA's role in the HIV testing journey
 - The HIVST results will be recorded and tracked on the ITHAKA platform

4.4.2 Post-Test Counselling

The post-test discussion is an individual session between the client and the provider, following the definitive test result. The aim of the discussion is to prepare the client to receive the HIV test result and to address all concerns they may have about the test result.

The HIV test result will be positive or negative or inconclusive or discordant. Tailor the post-test counselling:

- to the experience and understanding of the client and
- according to the result of the HIV test.

Regardless of result (positive, negative, discordant or inconclusive result), the provider should discuss risk reduction and provide emotional support.

Negative HIV test result:

A negative test result is either the nonreactive HIV screening test and occasionally an OMT may be false positive (i.e. confirmatory testing may yield a negative result) (see Section 4.4.2).

The provider should:

- Allow the client to respond to the result
- Explain to the client that if they were likely exposed to HIV in the last three months or less, the test result may be negative although the client is HIV positive due to the “window period”.
- Recommend that s/he gets another HIV test in six months’ time.
- Emphasize the need to maintain a negative HIV status by discussing the ways that HIV can be transmitted and ways to prevent HIV transmission.
- This is also an opportunity to discuss other relevant health services. Important to discuss:
 - VMMC
 - Correct and consistent condom use
 - Regular HIV testing
 - Partner HIV testing
 - PEP / PrEP
 - Screening and treatment of other STIs
 - Family planning
 - Cervical cancer screening
 - Harm reduction services (if relevant)
- Encourage the client to ask questions.

Positive HIV test result:

A positive HIV Test result refers to the definitive positive BBT result (see Section 4.4.2).

If a client has a reactive screening HIV test result, then:

- Describe and explain to the client what a reactive HIV test result is (see Section 4.4.1)
- Allow the client to respond to the result and provide support based on response.
- Explain the next step of the process is to perform the BBT to get a definitive HIV result. Then proceed to conduct a BBT (see section 4.4.2).
- Only after a definitive positive result from the BBT then provide the information and counselling as below.

Information and counselling to provide to clients who test HIV positive

- Explain the test result, taking into consideration the mental and emotional status of the client. Emphasize the client's right to confidentiality. Particularly mention the excellent prognosis on treatment and that PLWH can have a normal quality of life and life expectancy
- Support the process of anticipatory grief: give the client time to consider and respond to the result- some people take a lot of time to absorb and understand the results and its implications. Be sensitive to their emotions and help them cope with the emotions that arise
- Discuss immediate concerns and help client identify and decide who in her or his social network may be available to provide immediate support. Individualise planning with client on how, when and to whom to disclose HIV status (family, partner, peers, others). Offer couples counselling as appropriate
- Assess the risk of suicide, depression and other mental health consequences of an HIV diagnosis
- Provide clear information on ART, its benefits for maintaining health and reducing the risk of HIV transmission. Emphasize the importance of taking treatment and staying in care
- Provide information on how to prevent transmission of HIV, including information of the reduced transmission risk when virally suppressed on ART; provide male condoms and guidance on their use
- Give clear description of where and how to obtain treatment and care and what care will look like, and options available (SECTION 5.0). Make an active referral to enroll into care for a specific time and date either at CHIEDZA or at a health facility of the client's choice (if client decides to enroll in ART care there). NOTE: enrolment into CHIEDZA can be done on the same day if client wishes (see SECTION 5.0)
- Encourage and offer HIV testing for sexual partners, children and other family members of the client. This can be done individually, and in CHIEDZA a note will be provided for couples testing, index testing or partner notification
- Assess the risk of intimate partner violence and discuss possible steps to ensure the physical safety of clients, particularly young women, who are diagnosed HIV-positive
- Provide additional referrals for counselling, support and other services tailored to both the situation in which infection happened and the developmental age of the individual, for e.g. STI screening and treatment, contraception, ANC, substance or alcohol abuse etc.)
- Encourage and provide time for the client to ask questions about any issues they may have

Source: adapted from WHO 2015 Consolidated guidelines on HIV testing services 2015

4.5 How to perform and interpret HIV tests

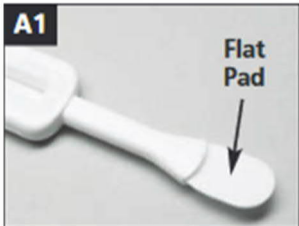







This section describes:

- 1) How to perform the screening test: OMT (Orasure®)
- 2) The algorithm for performing confirmatory testing using BBTs

4.5.1 HIV Screening using OMT (Orasure®)



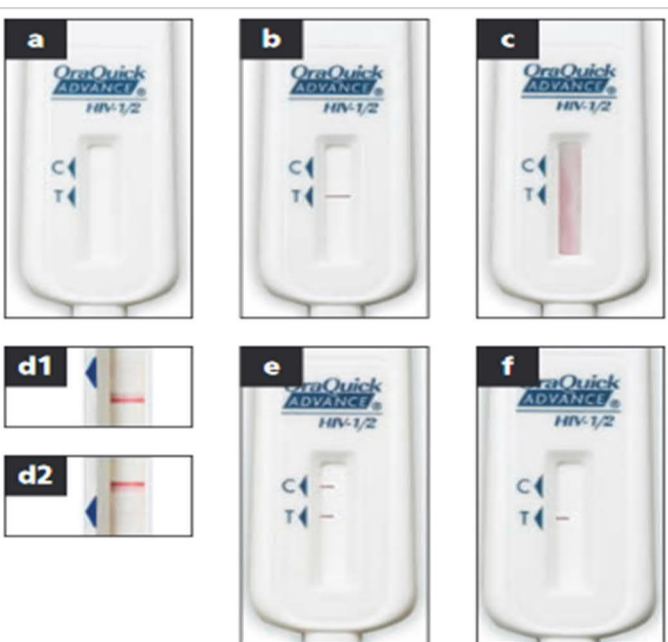
Ensure prior to testing that client has not had anything to eat or drink and has not chewed gum for at least 15 minutes. Should wait at least 30 minutes prior to testing if client has used any oral care products (mouthwash or toothpaste).

Figure 4.4: Performing OMT

1. Remove the device from the pouch but DO NOT touch the Flat Pad

2. Check that an Absorbent Packet is included with the Device. If no Absorbent Packet is present, discard Device and obtain a new test kit.

3. Place the flat pad above the teeth against the outer gum.

4. Gently swab all the way around outer gums, both upper and lower, once only, using the Flat Pad. DO NOT swab the roof of mouth, inside of cheek or tongue. Both sides of the Flat Pad may be used.

5. Insert the Flat Pad of the Device all the way into the vial. Make sure that the Flat Pad touches the bottom of the vial. (picture A5/A6).

6. The Result Window on the Device should be facing towards you.

7. Start timing the test. DO NOT remove the Device from the Vial while the test is running

8. Pink fluid will appear and travel up the Result Window. Pink fluid will gradually disappear as the test develops


Read the results after 20 minutes but not more than 40 minutes in a lighted area

Figure 4.5: Interpreting the OMT results

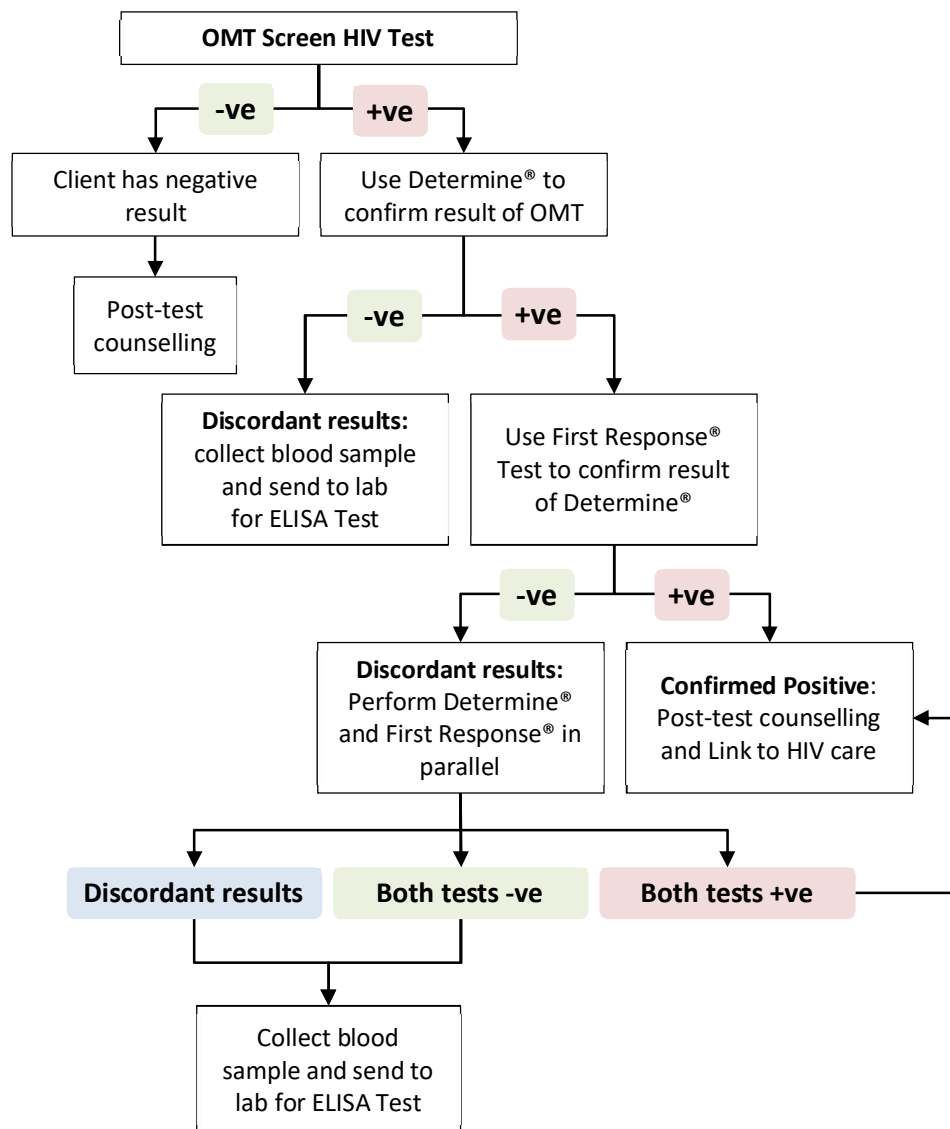
<p>Non-Reactive</p>	<p>The test result is interpreted as NON-REACTIVE for HIV-1 and HIV-2 antibodies if:</p> <p>Reddish-purple line appears next to the triangle labeled “C” and NO line appears next to the triangle labeled “T”</p>	
<p>Reactive</p>	<p>The test result is interpreted as REACTIVE for HIV-1 and HIV-2 antibodies if:</p> <p>Complete reddish-purple line appears next to the “T” triangle AND to the “C” triangle, no matter how faint these lines are.</p>	
<p>Invalid</p>	<p>Test is INVALID if:</p> <ul style="list-style-type: none"> • NO reddish-purple line appears next to triangle labeled “C” (picture a/b) • Red background in Results Window makes it difficult to read result after 20 minutes (picture c) • If any of the lines are NOT inside the “C” or “T” triangle areas (picture d1/d2) • Any partial line on one side of “C” or “T” triangle areas picture e/f) 	

4.5.2 Confirmatory HIV testing using BBTs

In CHIEDZA, blood-based rapid diagnostic testing will be used for confirming a reactive OMT. All reactive OMTs MUST be confirmed by a BBT, based on Zimbabwean national guidelines using a serial testing algorithm.

The BBTs used in the national programme will be used by CHIEDZA. As these do change occasionally, check what is being used.

Figure 4.6: Flowchart for confirmatory HTC using BBTs



4.5.2.1 Interpretation of BBTs

Invalid test:

An invalid test is one which has not worked either because of an error in performing the test or some problem with the test kit.

If a test is invalid, repeat the test using another kit. If an OMT was invalid, repeat using a different OMT. If a BBT is invalid, repeat using another kit of the same BBT that was invalid

Discordant HIV test result:

A discordant test result is when two tests that were performed correctly give different results. This is not the same as an invalid test. If there is a discordant test result, collect a blood sample from the client and send to the laboratory for an ELISA test which is a highly accurate test.

Explain to the client that it is not possible to be certain about a test result as occasionally a test can be falsely positive or negative, and that a blood sample will be required to give an accurate result. **Do not second guess the HIV test result if there is discordancy between tests.** It is important to be clear to the client that the final result will only be available once the laboratory test has been done.

4.5.2.2 Performing an HIV ELISA

The ELISA HIV test is the definitive HIV test and is done in a laboratory.

Collect 5mls of blood in a yellow-topped tube and send to the local laboratory at room temperature. The sample should be delivered to the laboratory within 4 hours of the sample being collected with Form CO.03.

4.6 Frequently Asked Questions

5. Linkage to HIV Care

Linkage to care occurs when there is a first clinical visit after an HIV diagnosis. It is critical to the HIV care continuum as it sets the pace for ART initiation, retention in care and viral suppression. This section describes the steps that will be taken to link HIV diagnosed clients to care.

5.1 Procedures

All clients who have a confirmed HIV positive result should be linked to care as quickly as possible. These clients will present with various stages of acceptance and readiness for this initial clinical visit to get them onto treatment.

Linkage to care can be provided by a CHW or a nurse.

- Present the HIV care choices available to the client
 - Receive HIV Care at CHIEDZA or at the health facility
 - Join CAPS group (regardless of where they choose to access their HIV care)

In all cases (wherever clients access care), clients who reside in the cluster and are HIV positive can join CAPS groups

- If clients are pregnant, they will not be eligible to access HIV care at CHIEDZA until after their pregnancy as the service does not have the capacity to provide ANC. However, they will be eligible to receive care from at CHIEDZA (should they wish to) after pregnancy.
- Clients who are already on ART and have MOHCC green books already can choose to access ART at the CHIEDZA provided they were previously accessing HIV care at clinics linked to the cluster. If they are accessing care in a clinic outside the cluster or not linked to the cluster, they will not be eligible to receive care at CHIEDZA.

All outcomes of linkage to care should be entered into the HIV testing register

5.1.1 Care at CHIEDZA

- Give an appointment for the first visit (it may be on the day you link them to care)
- See Chapter 6 for procedures for the first appointment: Register the client into the CHIEDZA HIV cohort by completing Initial Assessment Form (Form CH.01)-the client will be given a CHIEDZA HIV cohort number that will be linked to their SIMPRINTS ID no.
- Record client's phone number and address in the Green Book and in locator Form (Form CHL.01). If client does not attend for the first clinical visit, call the client. If after 4 attempts to call there is no response, ask the youth worker to conduct a home visit to encourage client to attend.

5.1.2 Care at healthcare facility

- Offer clients the choice of either the clinic in the cluster or a PHC facility of their choice- Mention that CHIEDZA has a relationship with the clinic in the cluster and that the CHIEDZA staff can facilitate registration.
- Provide the client with a referral letter to the facility of choice.
- Offer to support the client to link to care at the clinic. This will be done in two ways:
 - 1) If client agrees, the youth worker will accompany the client to the clinic and help the client get registered and ensure they have a date for the first clinical visit. This will only be an option for clients who opt to register for HIV care at the clinic within the cluster.
 - 2) For clients who choose to link to care at a non-cluster clinic, CHIEDZA staff will call the clinic ahead of time to let them know that the client will be attending the clinic to register. If feasible, arrange a time.
- Ask the client for their phone number and address so that they can be followed up to check whether they have linked to care. Offer to escort client on the appointed date (if client has selected a health facility within the cluster).
- Ring client to check they have attended for their first clinical visit (if CHIEDZA staff did not accompany client to clinic). If they have attended, record which clinic they have registered at in HIV testing register. If not attended, see Section 5.1.3).

5.1.3 Refusal of linkage to care services

Refusal to link to care can take several forms:

- Clients may refuse outright to have appointment made
- Clients may have appointment made but not attend
- Clients may give false contact details

Every effort should be made to continue counselling and to link to care

5.1.3.1 Clients who upon diagnosis refuse to link to care outright:

Provide additional post-test counselling to explore the reasons why they do not want to link to care

Where feasible, address the reasons for not wanting to link to care, link/refer to other support services etc.

Record phone number and address so that they can be followed up. Follow up weekly to provide more counselling and support to link the client to care

If the client eventually agrees to link to care offer them community-based CHIEDZA care or facility-based care. Follow above procedures.

Never coerce a client- sometimes it takes time and you may find that a client presents later. **Always leave an “open door” for the client.** Give the client the toll-free helpline number and offer to be available whenever the client is comfortable to attend. Sometimes it can take time for the client to come to terms with diagnosis and to accept the need for care.

A client who after multiple follow up attempts, continues to decline or stops responding will be considered LTFU. This should be recorded in the HIV testing Register.

5.1.3.2 Clients may have appointment made but not attend

Follow up weekly to provide more counselling and support to link the client to care

Where feasible, address the reasons for not wanting to link to care, link/refer to other support services etc.

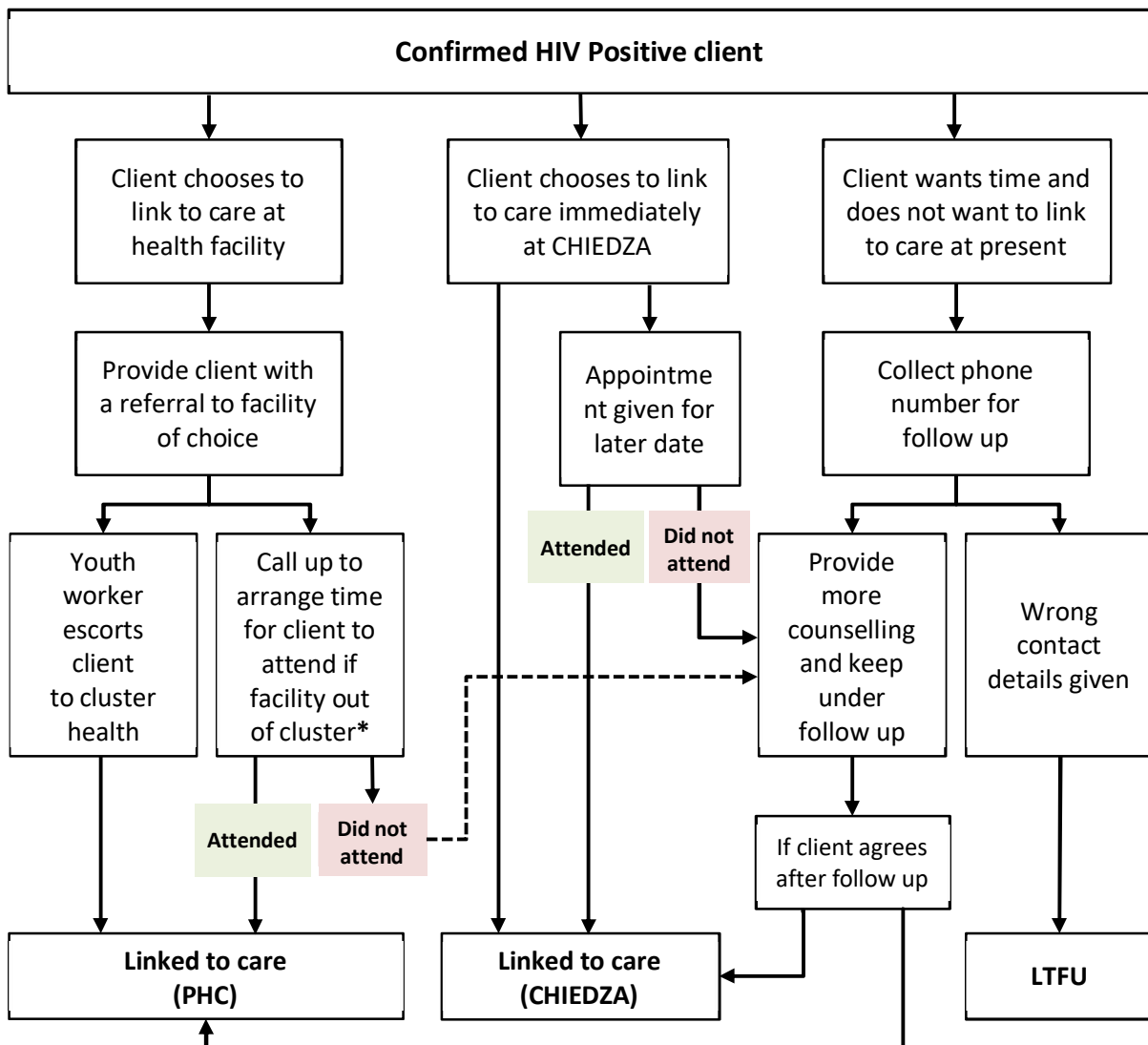
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A client who after multiple follow up attempts, continues to decline or stops responding will be considered LTFU. This should be recorded in HIV testing register.

5.1.3.3 Clients who provide false contact details:

Considered LTFU on realisation. This should be recorded in the HIV testing register.

Figure 5.1: Linkage to care procedures



*Ascertain whether attended or not through calling client

5.2 Frequently Asked Questions

6. HIV care and treatment

The following chapter describes how to i) conduct an initial assessment of a client who tests HIV-positive, ii) conduct follow-up visits iii) prescribe ART, for clients who opt to receive HIV care and treatment through CHIEDZA.

The initial assessment should be performed by a nurse. Follow-up appointments and unscheduled visits can be dealt with by a CHW in collaboration with the nurse. CD4 counts and TB screening can be done by a CHW or a nurse, but a CrAg test and taking a sample for viral load must be done by a nurse. All drug prescriptions must be signed off by the nurse.

6.1 Initial Assessment

The following should be covered in the initial assessment:

- Give client a CHIEDZA HIV ID number and a national programme registration number. The CHIEDZA HIV ID no will be linked to the SIMPRINTS ID number. Start a MOHCC ART Record (“Green Book”) and a client-held record (brown note book).

CHIEDZA will keep and store the GREEN BOOKS of clients accessing HIV care through CHIEDZA. The Green book and client-held record should be co-completed at every consultation

- Complete Cohort Registration form (Form CH.01): medical history, previous ART exposure, social history. Also complete the Green Book and client-held record.
- Complete Locator form (Form CHL.01)
- WHO Disease Staging (see Table 6.1)
- Manage any acute infection – Amoxicillin 500mg tablets will be available at the CHIEDZA Centre. If other treatments needed, refer to PHC.
- Screening for TB (Section 6.5.1)
- CD4 count testing (Section 6.5.2)
 - If CD4 count <350 cells/ μ l, start cotrimoxazole prophylaxis (960mg twice daily or three times a week)
 - If CD4 count <100cells/ μ l, perform CrAg testing (Section 6.5.3)
- Pregnancy testing if appropriate.
- Blood pressure
- Make a referral for cervical screen (women)
- HIV and ART education
- Address partner HIV testing /partner notification (if not done)
- Discussion: encourage and answer questions. Issues such as disclosure of status to others, testing of sexual partners, relationships, issues with schooling or work, prognosis etc. may arise. Answer honestly and if you do not know the answer, tell the client you will find out and get back to them. The client may need special

counselling to help them adjust to their diagnosis. Refer to the counsellor if the client agrees.

- Give information (and information sheet) about CAPS groups (see Section 7.7).
- Discuss the possibility of a treatment supporter or a treatment “buddy” (see Section 7.5). This would be someone the client identifies who will support the client in different ways: accompany them to CAPS or follow-up visits, pick up refills on their behalf if the client is unable to attend, support them, and so on.
- Assess eligibility for starting ART. The “Test and Treat” approach is being used in the project which means that there is no CD4 or WHO Staging criteria to start ART.
- ART should be started if the screening tests (TB/CrAg) are negative and the client is ready and prepared to take ART.
- If not ready, give follow-up appointment in 1 or 2 weeks and start ART when ready. For some clients, it may take time to become ready. Keep clients under follow-up and keep addressing their concerns.
- If sample for TB screening sent, ask client to return in one week for TB screening results and decision about whether to start ART. If client is CrAg-positive, refer for investigation and ask client to return in one week to assess whether eligible for ART.
- See Section 6.4 on ART initiation

Table 6.1: WHO HIV Disease Staging in adolescents and adults

Clinical Stage 1
<ul style="list-style-type: none">• Asymptomatic• Persistent generalized lymphadenopathy
Clinical Stage 2
<ul style="list-style-type: none">• Moderate unexplained weight loss (<10% of presumed or measured body weight)• Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis)• Herpes zoster• Angular cheilitis• Recurrent oral ulceration• Papular pruritic eruption• Fungal nail infections• Seborrhoeic dermatitis
Clinical Stage 3
<ul style="list-style-type: none">• Unexplained severe weight loss (>10% of presumed or measured body weight)• Unexplained chronic diarrhoea for longer than 1 month• Unexplained persistent fever (intermittent or constant for longer than 1 month)• Persistent oral candidiasis• Oral hairy leukoplakia• Pulmonary tuberculosis• Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)• Acute necrotizing ulcerative stomatitis,• Gingivitis or periodontitis• Unexplained anaemia (<8 g/dl), neutropaenia (<0.5 x 10⁹/l) and/or chronic• Thrombocytopenia (<50 x 10⁹/l)
Clinical Stage 4
<ul style="list-style-type: none">• HIV wasting syndrome• Pneumocystis (<i>jirovecii</i>) pneumonia• Recurrent severe bacterial pneumonia• Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month's duration or visceral)• Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)• Extrapulmonary tuberculosis• Kaposi sarcoma• Cytomegalovirus infection (retinitis or infection of other organs)• Central nervous system toxoplasmosis• HIV encephalopathy• Extrapulmonary cryptococcosis, including meningitis• Disseminated nontuberculous mycobacterial infection• Disseminated histoplasmosis• Lymphoma (cerebral or B-cell non-Hodgkin)• Symptomatic HIV-associated nephropathy or cardiomyopathy• Recurrent septicaemia (including non-typhoidal Salmonella)• Invasive cervical carcinoma

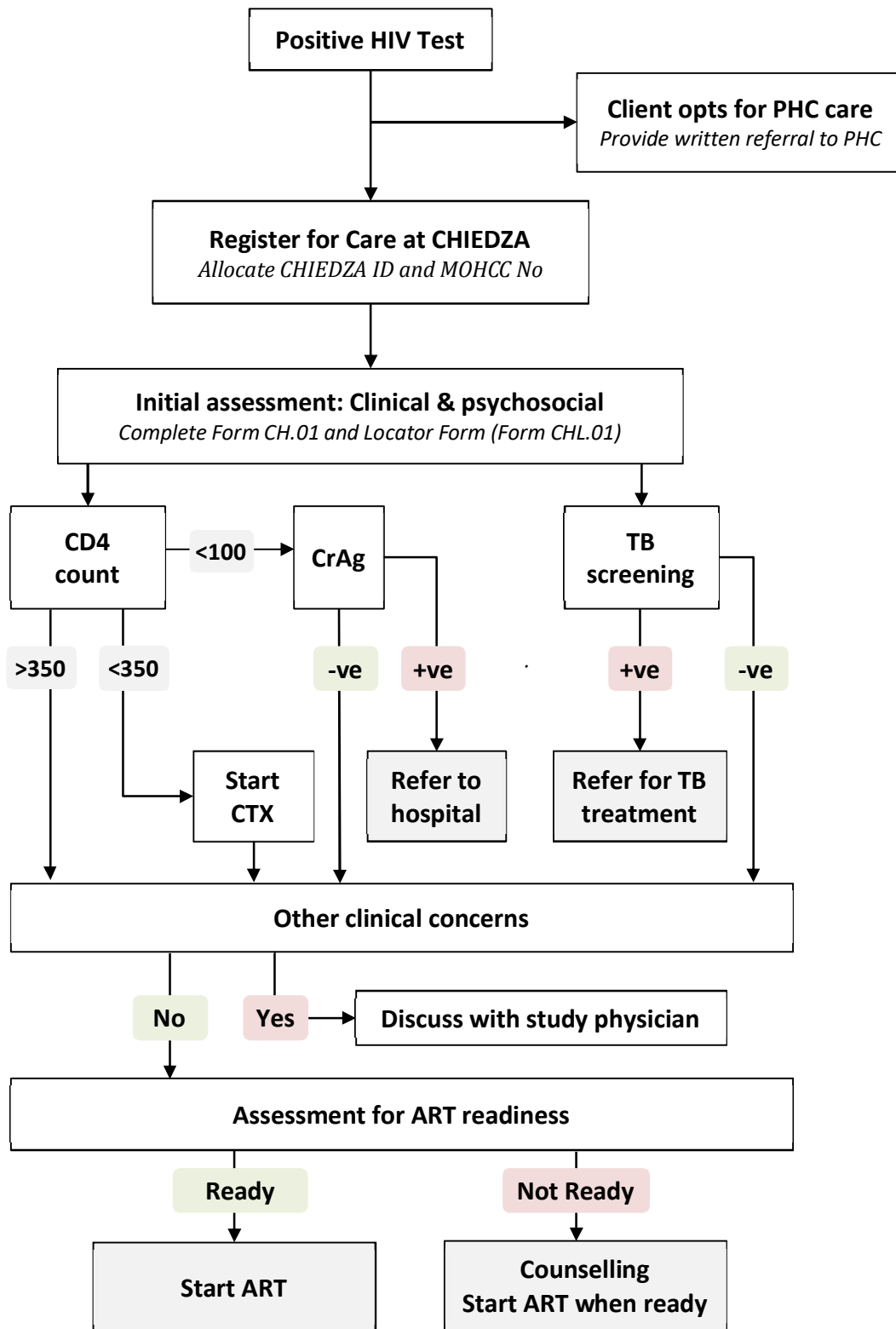
Basic facts about HIV and ART

- HIV attacks and destroys the “immune system”. This is a set of billions of cells that fight infection and diseases. It is like an army set up to protect the body. HIV attacks a specific set of cells of the immune system or a set of soldiers of the army called “CD4”.
- We can measure how strong the immune system is by measuring the number of CD4 cells- this is called the CD4 count. If HIV is left untreated, it will destroy CD4 cells and the CD4 count will drop. A normal CD4 count is usually >500
- ART is a combination of at least three drugs that suppresses multiplication of HIV. If HIV multiplication is stopped, it can no longer destroy the immune system. Therefore, taking ART daily as instructed leads to HIV not being able to multiply and therefore STOPS the immune system from being damaged.
- If you take ART, you will not get infections and will have a NORMAL life and will remain healthy. However, ART does not cure or eradicate HIV from the body.
- The amount of HIV in the body can be detected using a test called “viral load”. If the treatment is working, the virus count will be very low or what we call “undetectable”. This is a level <50. If the Viral load is >1000, then there is a problem with treatment.
- **U=U: If your viral load is undetectable i.e. <50copies/ml, you cannot pass on HIV when you have sex.** However, you should use condoms as you can still pass on and get other STIs.

Instructions about taking ART

- You do not need “special food” or avoid any foods or alcohol to take ART. Have a normal diet. Avoid alcohol excess.
- You do not need to eat extra if you take ART. You may feel hungrier initially but your body will adjust.
- There is nothing you need to avoid doing because you take ART. Doing exercise is good and you should remain as active as you can.
- You should take your ART at round the same time every day. However, it does not need to be the exact time to the minute or to the hour. So, do not start worrying if you are 1-2 hours late or early. The most important thing is not to miss a dose.
- Do not take any medications or herbs or any other treatments without checking with your nurse first. Some medications or treatments may affect how ART works.

Figure 6.1: Flow chart on assessment of client diagnosed with HIV



6.2 Routine follow-up visits

Clients should be followed up approximately 3 monthly for assessment and drug refills although if there are issues, it may be prudent to see them more frequently.

Once a client is stable on ART, a buddy or another appointed individual may come to collect drug refills on the client's behalf

However, you must aim to see the client at least twice a year and certain tests and examinations must be performed within specified periods. This visit should not be done during CAPS group session.

Ensure that you have discussed Treatment buddies and CAPS enrolment and that the client's decision about both has been recorded on the follow-up forms.

6.2.1 Client attendance

As with any other CHIEDZA visit, the client will provide a fingerprint and a CHIEDZA eCRF (Form CO.01) will be completed if the client attends.

- Complete the HIV cohort follow-up form (Form CH.02), Green Book and client-held record for **all** visits.
- Address the following as appropriate at any follow-up visit:
 - HIV prevention: condoms
 - HIV testing of partners
 - Provide support for disclosure
 - Pregnancy testing (females)
 - Assess mental health status
 - Psychosocial support and referrals as required

The client will have two types of visits: 1) refill visit or 2) review visit.

6.2.1.1 Refill visit

Check if any significant issues. If not, give ART refill and end consultation

6.2.1.2 Review visit

This should ideally happen at 2 and 4 weeks post-ART, and 6, 12, 18 months post ART. For those not starting ART, a 2 week visit post-registration and then visits *at least* three times a year- and more frequently if any clinical or psychosocial problems. It is anticipated that most clients will be initiated on ART soon after registration (provided no contra-indications)

On review visits:

- Assess symptoms and manage incident infections
- Assess ART drug side-effects and toxicity and manage (if taking ART)
- Assess adherence to ART and re-motivate client to continue (if taking ART).
- Measure Weight and BP on every review visit

- Measure CD4 count 12 months after registration and after starting ART (if these dates are <3 months apart do not repeat) stop cotrimoxazole if CD4 count >500cells/ μ l
- Measure HIV VL (Section 6.5.4) at 6 months, 12 months and 24 months after initiating ART. Call client with result and ask client to re-attend if VL >1000copies/ml.
- Refer for annual cervical screening (females)

**Allow 2 months in either direction of the allocated date
for CD4 count, VL measurements**

6.2.1.3 Transfer out clients

For clients who move from the cluster, complete a referral form to transfer the client out to a facility closer to their new residence. Detailed clinical history including the OI number should be put in the referral form to facilitate the transfer. The client's green book should be returned to the cluster PHC.

6.2.2 Proxy attendee

The follow-up visit can be made by the client or the client can allocate a buddy or someone else to pick up their drugs on their behalf.

The refill drugs will be given to the individual attending on behalf of the client if the CHIEDZA team is satisfied that they have been sent on behalf of the client (e.g. they should bring the buddy card).

If the proxy attendee brings the buddy card, they can see the CHIEDZA team directly and do **NOT** have to provide a fingerprint using SIMPRINTS. Therefore, the client visit will not be recorded on the CHIEDZA recording system but will be recorded through the cohort follow-up form.

6.3 Unscheduled visits and acute events

Clients may present to the CHIEDZA centre outside their scheduled appointment for several reasons including: Counselling, run out of medication, acute illness

Form CH.03 should be completed to document reason for attendance and how the problem was addressed and the outcome of attendance.

If the client did make a visit to other health facilities between appointments at CHIEDZA, this will be recorded retrospectively on the Follow-up form (Form CH.02).

Record the "final diagnosis" on the Unscheduled Visit Form (Form CH.03) as accurately as possible- avoid non-specific terms such as "headache" or "loose stools". Check with study physician if you are unsure what to record

6.3.1 Red flags

If client presents with “red flag” signs, refer to hospital. **If in doubt, discuss with study physician.** Red flag signs include:

- High Fever (Temperature >38°C) and “unwell”
- Hypotension (systolic BP < 100mgHg) and /or tachycardia (Pulse >100/min)
- Signs of respiratory distress: e.g. tachypnoea (respiratory rate >24/minute), indrawing of intercostal muscles, nasal flaring, accessory muscle use)
- Reduced level of consciousness or confusion
- Severe headache, especially if accompanied by blurred vision
- Neurological deficit
- Severe diarrhoea
- History of overdose
- Suicidal ideation (refer to acute psychiatry services)

6.4 Prescribing ART

Zimbabwe National treatment guidelines should be followed. ART drugs will be obtained from the National ART programme, which uses FDCs.

If there is an acute shortage or stockout in the PHC, CHIEDZA will where possible, attempt to access drugs to other sources to ensure that the client’s drug supply is not interrupted.

The guide below is not meant to be comprehensive and assumes some prior knowledge and experience of HIV management and ART prescription.

If ever in doubt, consult the study physician

Always give ART in a CHIEDZA bag to maintain confidentiality.

Complete Green Book. Transcribe ART prescriptions to national programme registers.

CHIEDZA will keep and maintain GREEN books of clients accessing their ART at CHIEDZA centers. The Green books will be taken to partner health facilities once a month to update client information into national programme

6.4.1 Initiating ART

ART is indicated regardless of CD4 count or WHO Stage.

ART should be started only when the client is assessed as being prepared and ready (see above).

If the client has a co-infection, treatment of the co-infection should always be prioritised over starting ART. Consult the study physician about when to start ART in relation to treatment of the co-infection i.e. if ART can be started at the same time as treatment of the co-infection.

Start ART ONLY when client ready and no clinical contra-indication

Do not start ART on the same day as starting cotrimoxazole. If the client is prescribed cotrimoxazole, ask client to return in 1-2 weeks to start ART. This is to avoid overlapping toxicities.

Do a treatment plan with client before initiating ART (see Section 7.1).

When initiating ART, give a two-week supply (maximum 3 weeks if client not able to attend at two weeks) only and ask the client to return in 2 weeks to assess for side-effects, drug toxicity.

6.4.2 ART prescription

Table 6.2: ART regimens

Adopted from National Guidelines for Antiretroviral Therapy for the Prevention and Treatment of HIV in Zimbabwe (2016)

Indication	Drug and dose	No of pills	FDC name [§]
First line	TDF 300mg + 3TC 300mg + EFZ 400mg OD	1 pill OD	Tenolam E
If on TB treatment	TDF 300mg + 3TC 300mg + EFZ 600mg OD	1 pill OD	Tenolam E
Pregnant / breastfeeding	TDF 300mg + 3TC 300mg + EFZ 600mg OD	1 pill OD	Tenolam E
If not tolerating EFZ*	TDF 300mg + 3TC 300mg + ATZ 300mg / RIT 100mg OD	2 pills OD	Tenolam OD + Atazanavir/Rit OD
If not tolerating TDF	AZT 300mg BD + 3TC 300mg BD + EFZ 400mg OD	2 pills bd 1 pill OD (pm)	Zidolam BD + Efavirenz OD
2nd line [‡]	AZT 300mg + 3TC 300mg + ATZ 300mg / RIT 100mg OD	2 pills bd 1 pill OD (pm)	Zidolam BD + Atazanavir/Rit OD

* Efavirenz may also be replaced by nevirapine (dose 200mg BD- no “step up” dosing required) but replacing with PI is preferable because of risk of SJS and significant risk of hepatotoxicity at high CD4 counts with NVP (Note: NVP should NOT be used in females with CD4 counts >250 cells/μL or men with CD4 count >400 cells/μL)

‡ When changing regimen due to assumed failure, do not change one drug only. At least 2 drugs of the regimen should be changed

§ Brand names of FDCs: Tenolam E= Tenofovir + Lamivudine + Efavirenz; Tenolam=Tenofovir + Lamivudine; Zidolam= Zidovudine + Lamivudine

Table 6.3: DAIDS Grading of side effects

Parameter	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 potentially life threatening
Rash	Localized rash	Diffuse rash OR Target lesions	Diffuse rash AND Vesicles or limited number of bullae or superficial ulcerations of mucous membrane limited to one site	Extensive or generalized bullous lesions OR Ulceration of mucous membrane involving two or more distinct mucosal sites OR Stevens-Johnson syndrome
Diarrhoea	Transient or intermittent episodes of unformed stools OR Increase of ≤ 3 stools over baseline per 24-hour period	Persistent episodes of unformed to watery stools OR Increase of 4 to 6 stools over baseline per 24-hour period	Increase of ≥ 7 stools per 24-hour period OR IV fluid replacement indicated	Life-threatening consequences (e.g., hypotensive shock)
Nausea	Transient (< 24 hours) or intermittent AND No or minimal interference with oral intake	Persistent nausea resulting in decreased oral intake for 24 to 48 hours	Persistent nausea resulting in minimal oral intake for > 48 hours OR Rehydration indicated (e.g., IV fluids)	Life-threatening consequences (e.g., hypotensive shock)
Vomiting	Transient or intermittent AND No or minimal interference with oral intake	Frequent episodes with no or mild dehydration	Persistent vomiting resulting in orthostatic hypotension OR need aggressive rehydration (e.g., IV fluids)	Life-threatening consequences (e.g., hypotensive shock)
Fatigue	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	Symptoms causing inability to perform usual social & functional activities	Incapacitating symptoms of fatigue or malaise causing inability to perform basic self-care functions
Fever (non-axillary temp)	38.0 to < 38.6°C	≥ 38.6 to < 39.3°C	≥ 39.3 to < 40.0°C	≥ 40.0°C
Weight Loss	NA	5 to < 9% weight loss from baseline	≥ 9 to < 20% weight loss from baseline	≥ 20% weight loss from baseline
Headache or Abdominal pain	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	Symptoms causing inability to perform usual social & functional activities	Symptoms causing inability to perform basic self-care functions OR Hospitalization indicated (OR significant impairment of alertness or other neurological function-for headaches only)

Table 6.3: DAIDS Grading of side effects (Continued)

Parameter	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 potentially life threatening
Altered Mental Status (confusion)	Changes causing no or minimal interference with usual social & functional activities	Mild lethargy or somnolence causing greater than minimal interference with usual social & functional activities	Confusion, memory impairment, lethargy, or somnolence causing inability to perform usual social & functional activities	Delirium OR Obtundation OR Coma
Insomnia	Mild difficulty falling asleep, staying asleep, or waking up early	Moderate difficulty falling asleep, staying asleep, or waking up early	Severe difficulty falling asleep, staying asleep, or waking up early	NA
Psychiatric Disorders*	Symptoms with intervention not indicated OR Behaviour causing no or minimal interference with usual social & functional activities	Symptoms with intervention indicated OR Behaviour causing greater than minimal interference with usual social & functional activities	Symptoms with hospitalization indicated OR Behaviour causing inability to perform usual social & functional activities	Threatens harm to self or others OR Acute psychosis OR Behaviour causing inability to perform basic self-care functions
Other Clinical adverse event NOT in the grading table	Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated	Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated	Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated	Potentially life-threatening symptoms causing inability to perform basic self-care functions with intervention indicated to prevent permanent impairment, persistent disability, or death
High ALT/AST	1.25 to < 2.5 x ULN	2.5 to < 5.0 x ULN	5.0 to < 10.0 x ULN	≥ 10.0 x ULN
Low Hb (g/dL)				
Males	10.0 to 10.9	9.0 to < 10.0	7.0 to < 9.0	< 7.0
Females	9.5 to 10.4	8.5 to < 9.5	6.5 to < 8.5	< 6.5

*includes anxiety, depression, mania, and psychosis

6.4.3 Common drug toxicities

Toxicities and unavailable medications may result in substitutions, and a single drug substitution (offending medicine may be replaced, preferably with an alternative medicine of the same class) can be made.

Always consult the study physician in the case of toxicity or if a particular drug or regimen is unavailable to discuss alternatives for switching

Any drug may cause rash, but cotrimoxazole and nevirapine followed by efavirenz are the most likely ones to do so. Provide supportive treatment if no involvement of mucous membranes. If any involvement of mucous membranes, switch drug.

Side-effects and their severity (based on the DAIDS grading) should be recorded on the follow-up form (Form CH.02).

Table 6.3: Common ART toxicities

Drug	Specific drug toxicity	Management
EFZ	CNS effects: irritability, vivid dreams, nightmares, depression, insomnia, difficulty concentrating	<ul style="list-style-type: none"> • Advise client to take pills in evening before bedtime • If persist beyond early treatment phase, switch drug
	Hepatitis	<ul style="list-style-type: none"> • If complain of abdominal pain, severe nausea, jaundice (common signs of hepatotoxicity), check ALT. If ALT > 5×ULN, switch drug. • If not, monitor on a weekly basis. If ALT is rising, switch
AZT	Anaemia	<ul style="list-style-type: none"> • Check Hb if suggestive symptoms • If Hb<8g/dl- switch drug
TDF	Renal toxicity	<ul style="list-style-type: none"> • May result in renal toxicity. Unlikely to be a major issue or present with symptoms in youth. If concern in an individual client- discuss with study physician
NVP	Hepatitis	<ul style="list-style-type: none"> • If complain of abdominal pain, severe nausea (common signs of hepatotoxicity), check ALT. If ALT > 5×ULN, switch drug. • If not, monitor on a weekly basis. If ALT is rising, switch drug
ATZ	Yellowing of eyes	<ul style="list-style-type: none"> • Common side-effect and does not need change of treatment (due to rise in bilirubin levels) • Rarely can get hepatitis. IF abdominal pain, nausea, check ALT. IF ALT> 5×ULN, switch drug

6.4.4 ART in co-infection, pregnancy and treatment failure

Document every incident event (co-infection, pregnancy) on follow-up form (Form CH.02).

Manage co-infections as per national guidelines. Amoxicillin 500mg tablets will be available at the CHIEDZA Centre, but if other treatments needed, refer to PHC.

If client presents with red flags, refer (see Section 6.5.1).

If client becomes pregnant, continue ART as prescribed and refer for ANC at nearest PHC, using written Referral Form. Offer the client to have HIV care at the CHIEDZA Centre or to have care at PHC. If client opts for the latter, provide a detailed referral letter.

Treatment failure should be suspected if client

- i. Admits poor adherence
- ii. Misses appointments
- iii. Has an HIV VL > 1000copies/ml on routine testing.

In the event of i or ii, an HIV viral load should be performed (outside scheduled testing).

If VL > 1000copies/ml, client should receive three sessions of enhanced adherence counselling (1 session per month) and VL repeated in 3 months. If VL remains > 1000copies/ml, client should be referred to health facility for switching to second line treatment. Subsequent follow-up can be provided through CHIEDZA.

6.4.5 Frequency of ART refills

Initially, a two-week supply should be given and clients should be asked to return for assessment of side-effects. Clients should be seen by a nurse on the two-week visit.

After the initial two-week supply, ART can be dispensed for a month and thereafter monthly to three monthly.

6.4.6 Location of ART refills

If clients are accessing ART through CHIEDZA, they can collect their drugs in two ways:

- 1) Through CAPS
- 2) Through individual visits to the CHIEDZA centre

Whichever route they use to collect drugs, the follow-up form (FORM CH.01) must be completed at each ART refill visit.

6.5 Investigations

6.5.1 Screening for TB

National guidelines will be followed.

- Administer TB screening questionnaire (Form CH.01)

- If client answers YES to One or more of the following collect sputum sample
 1. Has client had a cough?
 2. Has client had night sweats for ≥ 3 weeks?
 3. Has client lost weight (≥ 3 kg if able to quantify) in the past 3-4months
 4. Has client had fever or “hot body” for ≥ 3 weeks
 5. Does someone in client’s household have known active TB?
- Give client a sputum jar to provide a sputum sample. Ask client to cough and make sure they don’t spit saliva. You should ask the client to provide sputum in a well-ventilated area (outside in the open air or in the toilet). Complete Form CT.03 and send sample with the form to the local laboratory for Gene XPERT testing for TB.
- The sputum sample can be kept in a fridge overnight (2-8°C) and processed the following day, if it is not possible to get the sample to the laboratory the same day.
- If a client cannot expectorate sputum and provide a sputum sample, refer for a chest X-Ray using the Referral Form
- Ask client to return in a week for test results.
- ART should not be commenced until the TB screening results are obtained. If the client is on ART, continue ART until TB screening results are known.
- TB test results should be recorded on the cohort follow-up form (Form CH.02)
- If test results are positive, client should be referred for TB treatment to the national programme using referral form. Arrange to follow-up client and discuss with study physician when to start ART (if client hasn’t initiated ART). **Note TB treatment must be prioritized over ART.** Adjust ART dose if client on ART (see Section 6.3).
- All positive results should be recorded in the cohort follow-up form (Form CH.02).

6.5.2 Performing a CD4 count

PIMA cartridges are to be stored at 2-30°C.

Check the expiry date of the PIMA cartridge and check that the cartridge has not expired.

The CD4 count is performed using a fingerprick sample. The 3rd and 4th fingers are the most suitable and the sample should be obtained from the lateral aspect of the finger pad, just off the centre.

Warm up the fingers if necessary, by rubbing hands together. Have the client hold their hands downwards to increase blood flow.

Wipe the tip of client’s selected finger with an alcohol swab and let the alcohol air dry. (Ensure you are wearing gloves when you do this)

Remove one PIMA test cartridge from its foil pouch and open the orange plastic cap to fully expose the sample collector. Retain the foil in case Analyser cannot read cartridge barcode.

Use a sterile lancet to make a skin puncture just off the centre off the skin pad. To obtain a representative sample a constant blood flow is of utmost importance. Do not squeeze

or apply strong repetitive pressure to site (milking) as this may result in haemolysis or tissue fluid contamination of the specimen. If necessary, gently massage the finger to obtain a steady flow.

Wipe off the first drops of blood with a dry cloth or gauze. Ensure steady blood flow that generates large enough drops of blood.

Allow blood to flow freely from the pricked finger directly into the sample collector by holding the cartridge at a 45-degree angle for sample loading. Wait until the sample collector capillary incompletely filled with blood, remove cartridge from the finger and let the patient apply direct pressure to the wound site with a clean dry swab.

Hold the cartridge upright and observe the control window to ensure sufficient sample loading. Enough blood is applied when the capillary visible in the control window is filled with blood.

Squeeze the clip of the sample collector between the thumb and index finger and remove the sample collector from the cartridge in one continuous upward movement. Dispose in sharps bin.

Completely close orange plastic cap.

Insert PIMA cartridge into the PIMA analyser immediately after loading a blood sample.

Select “run test” on the PIMA Analyser

Insert the PIMA CD4 test cartridge into the PIMA Analyser in the direction indicated by the arrow on the cartridge. Follow on screen instructions or refer to PIMA Analyser user guide for details on how to proceed with the analysis.

Remove the PIMA CD4 test cartridge when prompted by the PIMA Analyser and read results. You can also print a result via an external PIMA printer so that a hard copy is available.

Discard the cartridge in sharps bin.

Record the result on Form CT.01 (and attach the printed result slip)

Quality control:

Expiry Date: The linear barcode on the PIMA CD4 test cartridge contains the expiry date. If cartridge is past its expiry date the analysis will not start and cartridge will be rejected.

Sample Volume: The PIMA Analyser checks whether sufficient sample has been loaded onto the test cartridge, if insufficient, analysis will not start and an error message will be displayed by the Analyser.

6.5.3 Performing a CrAg test

CrAg LFA strips and diluent are to be stored at 20-25°C. The test is performed using a fingerprick specimen.

The 3rd and 4th fingers are the most suitable and the sample should be obtained from the lateral aspect of the finger pad, just off the centre.

Warm up the fingers if necessary, by rubbing hands together. Have the client hold their hands downwards to increase blood flow.

Wipe the tip of client's selected finger with an alcohol swab and let the alcohol air dry. (Ensure you are wearing gloves when you do this)

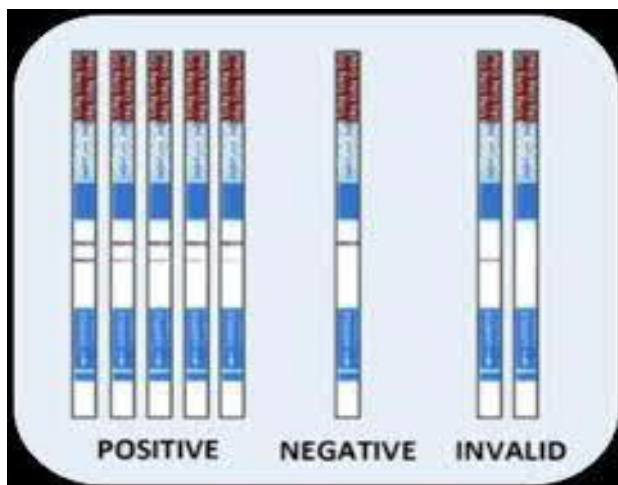
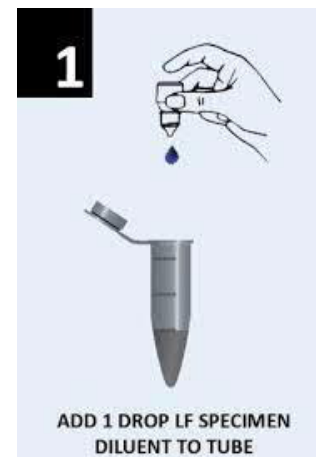
Remove one lateral flow test strip from its container

Use a sterile lancet to make a skin puncture just off the centre of the skin pad. To obtain a representative sample a constant blood flow is of utmost importance. Do not squeeze or apply strong repetitive pressure to site (milking) as this may result in haemolysis or tissue fluid contamination of the specimen. If necessary, gently massage the finger to obtain a 1 drop of whole blood.

The client's finger should be placed directly on the tip of the LFA test strip so that the blood sample (approximately 40 µL) can be absorbed directly onto the LFA strip.

The test strip should then be placed in a 1.5-mL Eppendorf tube containing 1–2 drops of sample diluent, left in an upright position at room temperature for 10 minutes

After 10 minutes read the result on the strip



Record the result on Form CT.01

6.5.4 Performing HIV VL testing

The VL sample should be collected by the nurse.

Use an EDTA tube and collect 6mls. Complete Form CT.02 and send to the laboratory.

The sample should reach the laboratory within 4 hours in a cooler box.

HIV VL testing will be performed using Gene Xpert at the local laboratory. The remainder of sample will be stored at the BRTI (for future drug resistance testing).

6.6 Frequently Asked Questions

7. Adherence support for HIV treatment

Consistent adherence to ART is critical to maintaining viral suppression. CHEDZA will provide an adherence support package to support clients taking ART, which will include:

- Individualised treatment plan
- Flexible drug refills
- Adherence counselling and referrals
- Toll free helpline
- Treatment buddy
- Defaulter tracing
- CAPs groups

7.1 Individualised Treatment Plan

MAKING AN INDIVIDUAL TREATMENT PLAN

Aims to reduce impact of stressors, develop coping strategies and prepare and support clients for taking life-long ART. Tailor the counselling according to clients' regimen and lifestyle

- Counsel on dose frequency, side-effects, nutrition, and other medicines, what to do if feel ill or experience side-effects
- Work out what time suits client best to take medication: tailor to lifestyle
- Work out reminder strategies: cell phone, alarm, calendar, what to do when travelling or going to party
- Discuss client's coping mechanisms and reinforce strengths
- Provide referrals or linkages for psychosocial support
- Ask to come back to the service earlier than the scheduled 2-week appointment if any problems or to contact the service, provide help-line number
- Explain CAPS and encourage client to attend: Give CAPS information sheet
- Help identify Treatment Buddy- encourage Treatment Buddy to attend CAPS
- Discuss whether client wants to receive ART individually or through CAPS

7.2 Flexible drug refills

If clients access care through CHIEDZA, they will be able to pick their medications at the CHIEDZA centre on the allocated day the intervention team will be at a particular cluster OR at CAPS group meetings that will be held once a month in every cluster.

Clients will be able to allocate a treatment buddy or others to collect the medication on their behalf (section 6.2.2). Each client will get a buddy card which the person coming to collect medication on the client's behalf will bring as an identification (this can be the buddy or someone else the client has allocated on a particular day to pick up their

medication). No personal details will be recorded on the buddy card and therefore if lost, there will be no compromise of confidentiality.

7.3 Adherence Counselling

Clients with HIV will need appropriate counselling to encourage them to adhere, help them cope with stressors or to address barriers to taking ART and also to aid them in managing any other illnesses that may stem from living with HIV.

TOP TIPS FOR SUPPORTING AND COUNSELLING CLIENTS WITH HIV

- Greet them and ask about them: Clients with HIV often self-stigmatise- take every opportunity to sub-consciously remind through your interactions that HIV is not what defines them
- Reinforce their strengths
- Praise their adherence and actively point out markers of positive behaviour: CD4 count rising, VL suppressed, U=U etc.
- DO NOT JUDGE WHATEVER IT IS THE CLIENT HAS DONE/DOES
- NEVER tell clients off- taking medication is something they have to buy into, not something providers should impose
- Help clients identify solutions to barriers but do not tell them what to do-work with them to identify what works for a particular client's circumstance
- Check on mental health – they may be depressed or anxious
- Keep it Simple – remember no special diet, no special time for pills is needed
- Take time to explore their context and concerns. An underlying life concern is often the most important reason for not taking medication

7.4 Toll-free helpline

Clients will have access to the helpline to speak to a trained counsellor if they have any concerns (section 12.1.2). If they specifically want to speak to the CHIEDZA provider, they will be put through or receive a call back from the CHIEDZA provider.

7.5 Defaulter Tracing

If there is a >1 week delay in picking up medication, follow-up client with phone call. If not able to get through, try to ring again, do a visit (may be done by the youth worker) or contact the treatment buddy.

7.6 Treatment Buddy

Encourage every client who registers for HIV care with CHIEDZA to identify a treatment buddy. This can be anyone they feel comfortable sharing their HIV status with and whom they feel may support them. The level of involvement the buddy will depend on the client's wishes but some suggested roles of the buddy may be to:

- remind the client to attend for review appointments

- pick up medication on client's behalf
- attend CAPS groups with client (provided the CAPS group client consent)
- encourage client to take their medication
- report to provider any problems client may have (with client's consent)

A buddy card will be given to the client to give to their buddy.

7.6.1 Registration of treatment buddies

If a client who is accessing care at CHIEDZA agrees to have a treatment buddy, a buddy card with the client's cohort HIV cohort ID number (with the prefix D as well as a suffix B (for buddy) for the buddy ID) should be given for the identified individual so they can attend CAPS groups, follow-up appointments with (or instead of) the client. The contact details of the buddy should be recorded on Form CHL.02.

One role of the treatment buddy is to attend CAPS with the HIV-positive individual. Note: Any individual with HIV aged 16-24 and resident in the intervention cluster is eligible to join CAPS even if they do not seek HIV care through CHIEDZA. If they register to access CAPS, complete the CAPS enrolment Form (Form CH.07)- as described below- AND give them the option of bringing a buddy. If they elect to bring a buddy, give them a buddy card. They will then be given a buddy card with the same number as the CAPS ID number of the client (but with prefix P and suffix B (for buddy)).

7.7 CAPS Groups

CAPS groups are support groups that aim to provide:

1. Opportunity for peer engagement
2. ART refills
3. Social support.

7.7.1 Eligibility

- Aged 16-24 years
- HIV-positive
- Resident in the study cluster
- Accessing HIV care at CHIEDZA or PHC

When discussing CAPS with a client: Give client information (including an information sheet) and prepare them to join the CAPS group: this is particularly important for both the individual, as well as the dynamics of the already functioning CAPS groups, since individuals will be joining the CAPS groups on a rolling basis.

Clients can join at any point after diagnosis. However they should:

- Understand the purpose of the CAPS groups
- Agree to terms of confidentiality associated with the CAPS groups
- Have basic understanding of HIV and ART
- Accepting of their HIV status

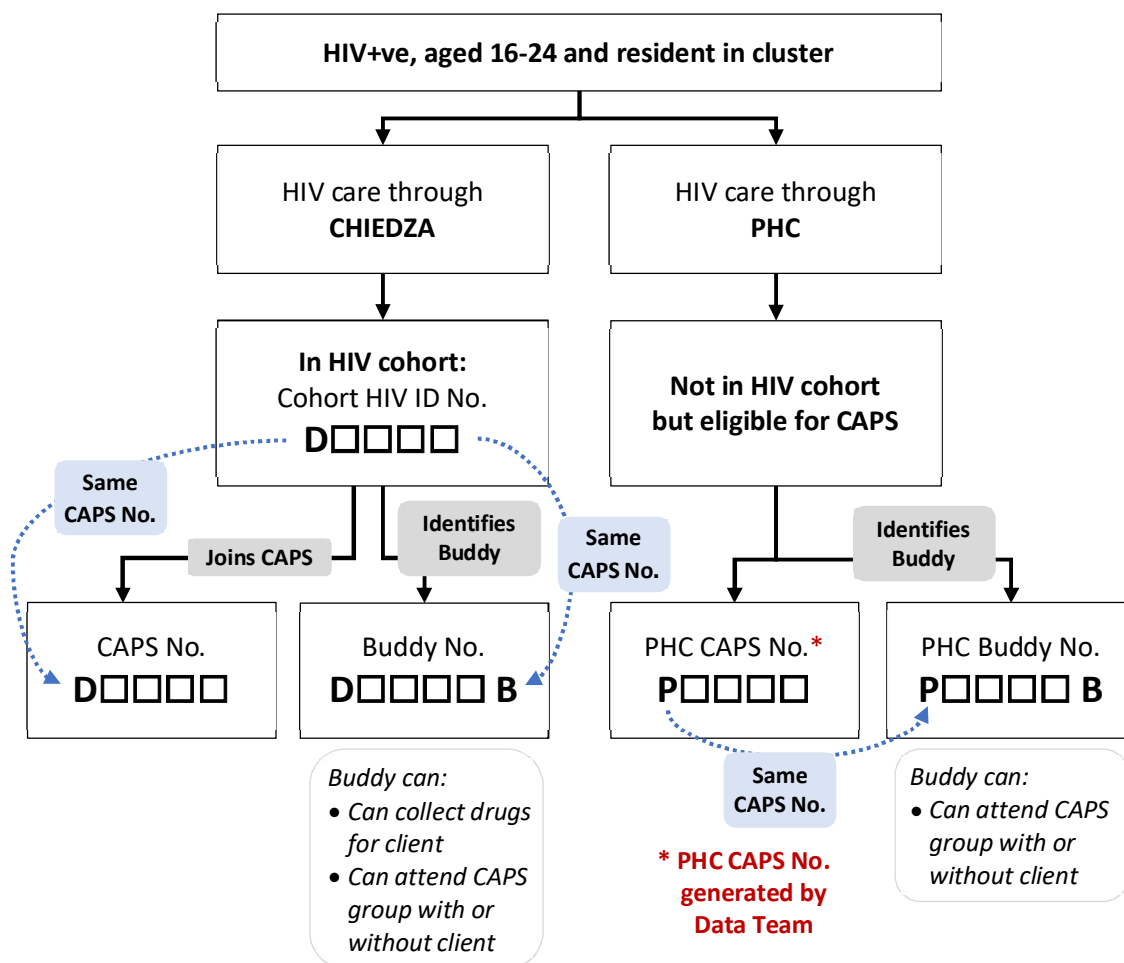
Clients should only be enrolled into CAPS groups when the CHIEDZA provide is satisfied that the client meets the above criteria. Some individuals may require time before they are “ready”.

7.7.2 Registration for CAPS

If a client who is registered for HIV care at CHIEDZA opts to join CAPS, complete a CAPS enrolment Form (Form CH.07) and give the client a CAPS membership card. The membership card number will be the same as the client’s cohort ID number (with a Prefix D).

If a client who is aged 16-24 years and is resident within the cluster but not accessing HIV care through CHIEDZA decides to access CAPS groups, then complete a CAPS enrolment Form and give a CAPS membership card with the CAPS membership number- the membership number will be defined by the data team and will have a prefix P). S/he will also be eligible to have a treatment buddy attend CAPS and if the client has identified a buddy –give a buddy card- the number of the treatment buddy card will be the same as the client’s CAPS number but with a suffix B (for buddy)

Figure 7.1: Registration of HIV+ve clients for CAPS



7.7.3 Logistics

CAPS groups will be held once a month (on a Saturday) in each intervention cluster.

CAPS groups will be held at the CHIEDZA venue.

Light refreshments / snacks will be provided at each session.

A client will need to bring their CAPS membership card to be able to attend a session. A register will be collected at each session (with cohort ID number mentioned on the CAPS card recorded).

Clients will not be given transport money to attend CAPS groups

If participants want a WhatsApp group, they can create one and facilitate it amongst themselves (this is likely to happen organically)

Each CAPS group will be capped at 30 people and It is anticipated that 2 CAPS groups will run in parallel. Each group session will last for a maximum of three hours initially shortening to 2 hours as numbers increase to enable a maximum of 4 groups to be run on the same day. The number of CAPS groups run each Saturday will therefore depend on demand.

Each session will be facilitated by 2 CHWs and 1 youth worker-the facilitators will ideally include males and females.

The CAPS sessions will operate on a rolling basis – there is no requirement for a client to attend every session and clients can attend as many sessions as they want to.

Once every 6 months all CAPS groups will come together for half a day for a joint social activity (i.e. sports competition, braai, talent show etc.).

The CHIEDZA nurse will be available and will work across groups to dispense ART. No reviews will be conducted on the CAPS day- only drug refills will be provided.

The CHIEDZA counsellor will be available to provide one-to-one counselling as requested, by CAPS attendees.

7.7.4 Structure of sessions

There will be no structured curriculum as clients will join CAPS on a rolling basis.

The first session of the CAPS group will set the tone for facilitators and clients for subsequent CAPS groups. The facilitator will be trained to accommodate new young people joining the CAPS group on an ongoing basis, and to be able to navigate a range of discussion topics.

Clients will have flexibility about which group they join when they attend and care will be taken to structure discussions to ensure appropriate group dynamics (e.g. marital status, age gender). Therefore, some sessions may be split by sex/ age/ other depending on the nature of the discussion. This will be decided by the facilitator and / or group.

Each CAPS group will be flexible but to ensure that the CAPS groups do have a support element and to enable discussion, there will be some structure to the session:

- 30 mins: Register, socialise and ice-breaker
- 40 mins: Structured social/physical activity
- 10 mins: Break for refreshments
- 40mins: Structured discussion focused around a specific topic

The group may decide at a CAPS group session the topic that will be discussed during the next CAPS session, which will enable the facilitator to prepare some discussion points / activities for the session. Alternatively, a discussion may be informed by a contemporary event or spontaneously raised by a group.

The sessions will use a variety of approaches depending on the topic and the group including whole group discussions, splitting into groups, drama skits, Aunty Stella cards.

When possible, the youth workers will arrange for short skills workshops to be run on CAPS session days e.g. judo, CV writing. This will depend on availability of providers in a particular community. A workshop may replace the structured discussion.

A CAPS form reporting the session will be completed at the end of each session.

7.7.4.1 Discussion topics for CAPS groups

- Some ideas are listed below but is by no means exhaustive:
- ART and adherence
- Dating and relationships
- Drugs and alcohol
- Mental health
- Fun and healthy sex
- Peer pressure
- Careers and jobs
- Disclosing to others
- Nutrition and exercise
- Confidence, self-esteem and resilience
- Stigma
- Looking and feeling good: general hygiene, MHM

7.7.4.2 Ice-breakers for CAPS Groups

Some websites for ice-breakers include:

- <https://youthgroupgames.com.au/top-ten-icebreaker-games-for-big-groups/>
- <https://funattic.com/41-youth-group-icebreakers/>

7.7.4.3 Resources for CAPS Groups

A library of resources will be made available to facilitators, using available resources. Examples include:

- BRTI CHIEDZA manual
- Auntie Stella cards
- FHI 360 tool kit

7.8 Frequently Asked Questions

8. Management of STIs

CHIEDZA will offer syndromic treatment of STIs. Syndromic STI management refers to the approach of treatment of STIs based on the organisms most commonly responsible for a set of symptoms and/or signs. This is a simplified approach that is taken when it is not possible to do tests for specific organisms that can cause an infection is not possible.

Treatment for STIs will be sourced through the National Programme and all STIs should be reported to the Programme.

In addition, CHIEDZA will also offer GC/CT screening for clients regardless of symptoms.

The CHW or nurse can take the history but the nurse will manage and treat STIs.

8.1 Definition of STI syndromes

8.1.1. Urethral discharge and dysuria in men

Complaint of or visible discharge (colourless, white or purulent) from urethra, or discharge on examination, and/or symptoms of dysuria. The most common causes are *Neisseria gonorrhoea* (gonorrhoea) and *Chlamydia trachomatis* (chlamydia) and the two often co-exist. All males with urethral discharge should be treated for both infections in view of the co-existence and present with similar signs and symptoms.

Trichomonas vaginalis is a less frequent cause of urethral discharge in men, and should be considered as a cause of urethral discharge if symptoms do not improve with first line treatment.

8.1.2. Acute epididymo-orchitis in men

Client presents with acute scrotal swelling and /or scrotal pain or tenderness. Other reasons for acute scrotal swelling are testicular torsion (very painful and a surgical emergency- refer immediately); scrotal trauma (exclude by history taking); irreducible or strangulated inguinal hernia (exclude by history taking and examination).

8.1.3. Balanitis or Balano-posthitis in men

Balanitis refers to inflammation of the glans penis. When both the glans penis and foreskin are involved, then the condition is referred to as balano-posthitis. The condition may not necessarily be related to STIs but rather to hygiene issues or to a drug reaction. Common causes of balanitis are fungi (*Candida*), anaerobic bacteria, protozoa and pyogenic bacteria.

8.1.4. Vaginal discharge in women

Complaint of or visible abnormal (i.e. different from usual) discharge from vagina. All women experience vaginal discharge which will vary with the menstrual cycle . Any woman concerned about a vaginal discharge should be examined and managed appropriately. All women presenting with abnormal vaginal discharge (abnormal volume, colour, odour) should receive treatment for *Neisseria gonorrhoea* (gonorrhoea)

and *Chlamydia trachomatis* (chlamydia), bacterial vaginosis and trichomoniasis (caused by *T. vaginalis*).

Additional treatment for yeast infection (candida) is indicated only if 1 or more of the following are present: i) curd-like discharge, ii) redness of the vulva, iii) vulval itching.

Note that bacterial vaginosis and candida are not STIs.

8.1.5. Pelvic Inflammatory Disease

Refers to the acute syndrome attributed to the ascent of micro-organisms, not related to pregnancy or surgery, from the vagina and cervix to the endometrium, fallopian tubes and adnexal structures. PID can occur as a result of gonorrhoea, chlamydia, mycoplasma, anaerobic bacteria and gram-negative organisms.

8.1.6. Genital ulcers

The most common cause of genital ulcers in both men and females is genital herpes simplex virus type 2 infections. Syphilis and chancroid also cause genital ulcers but they are not as common. If the patient gives a clear history of recurrent attacks of vesicular lesions that are painful and can crust and heal spontaneously, or if the clinical appearance of the lesions is of superficial ulcers then the diagnosis of genital herpes is suspected.

Immunosuppressed persons with HIV infection frequently develop attacks of the genital herpes that produce lesions, which persist and require treatment (with acyclovir).

8.1.7. Bubo

This is a swollen inflamed lymph node in the groin. This usually occurs in persons with lymphogranuloma venereum (LGV) which is caused by the L-types of *Chlamydia trachomatis*. There can be penile and vulval lymphoedema together with the buboes. A small transient genital ulcer, which may heal on its own, may precede the swelling and buboes. The bubo is typically multilocular and may be grooved by the inguinal ligament.

8.2 Procedures

- Take a history from client and conduct an examination
- Give syndromic treatment and review after 7 days to assess for symptom resolution
- Perform partner notification (see Section 8.3.4).
- Give condoms and perform HIV testing (unless tested within the past 3 months)
- Record the type of STI on CHIEDZA eCRF (Form CO.01)
- Complete STI register and complete client-held brown book

8.2.1 Taking a history

Ask about:

- Symptoms (Table 8.1)
- Duration of symptoms

- Use of condoms
- Previous treatment of STIs
- Unprotected sexual intercourse
- Symptoms in partner(s)
- Number of partners in past three months (for partner notification slip)

8.2.2 Performing an examination

Examine in the booth that has an examination couch. The area should be well-lit or use a torch to examine properly if lighting is poor. Have a draw sheet to put over the lower abdomen to provide privacy.

Males:

- Lie supine, expose genital area. Have a draw sheet to cover lower abdomen for privacy. Retract foreskin.
- Visually check for ulcers, warts, skin rash, buboes.
- Examine urethral meatus. If no discharge is seen on inspection of urethra, gently massage penis from the ventral part to the meatus.
- Scrotal palpation for masses, tenderness, swelling.
- Palpate for inguinal lymphadenopathy.
- Examine natal cleft and anal region for ulceration, warts.

Females:

- Lie supine, knees bent, ankles together and let knees fall out and relax client.
- Inspect vulva for cracked, red and painful areas, swelling of vulva, ulcers, warts, buboes (groin lymph nodes), visible discharge from vagina.
- Palpate for inguinal lymphadenopathy.
- Examine natal cleft and anal region for ulceration, warts.
- Using a small amount of KY Jelly on the tip of first gloved finger of right hand, insert finger into vagina until you palpate the cervix. Move the cervix with finger to check for cervical motion tenderness. Examine for adnexal tenderness.
- Conduct bimanual examination. Press on the lower abdomen with your left hand with right hand under the abdomen and palpate for tenderness.

Table 8.1: Symptoms and signs of STI syndromes

When asking question about one syndrome, also ask questions about other syndromes

Symptom	Questions	Signs on examination	Red Flag
MEN			
Discharge	-	• Visible discharge	-
Scrotal symptom	<ul style="list-style-type: none"> • Pain • Swelling • Redness • Scrotal trauma • Discharge 	<ul style="list-style-type: none"> • Tenderness, swelling, mass • Redness 	• Severe tenderness and swelling
WOMEN			
Discharge	<ul style="list-style-type: none"> • Itching • Curd like • Odour: foul/ fishy smell 	<ul style="list-style-type: none"> • Visible discharge • Vulval redness 	-
PID	<ul style="list-style-type: none"> • Purulent discharge • Painful sexual intercourse • Bleeding after sex • Bleeding between periods • Lower abdominal pain • Missed/overdue period* • Recent delivery/abortion miscarriage 	<ul style="list-style-type: none"> • Cervical motion tenderness, • Adnexal tenderness • Lower abdominal tenderness 	<ul style="list-style-type: none"> • Fever >38°C + • Pulse > 100/min • BP <100mmHg • Looks unwell • Severe adnexal or cervical motion tenderness
MEN AND WOMEN			
Urinary symptoms	<ul style="list-style-type: none"> • Dysuria • Frequency 		
Ulcer	<ul style="list-style-type: none"> • Location • Painful • Single/multiple • Recurrent 	• Ulcer or vesicle	-
Bubo	<ul style="list-style-type: none"> • Location • Painful • Red 	• Bubo (groin lymph nodes)	-
Warts	• Warts	• Warts	• Extensive warts

** If missed period and abdominal pain – need to exclude ectopic pregnancy – this is a surgical emergency and should be referred to hospital*

8.2.3 Screening for GC/CT

Offer all attendees GC/CT screening including those who present with STI symptoms (and are managed syndromically)

The only exception is an individual who has been screened and / or treated for GC or in the past 6 months.

If client agrees, give them a urine collection kit and complete Form CO.04 which will accompany the urine sample sent to the laboratory.

ON Form CO.04 record the following:

- 1) A sample number (prefix GC), which should also be entered on the CHIEDZA eCRF (Form CO.01) and on the specimen itself
- 2) Telephone number and pseudonym (not client's real name) that can use to contact the client should the test be positive and the client needs to come to the CHIEDZA centre for treatment. Also record a nickname or pseudonym (not client's real name)
- 3) Whether the client has been given treatment for GC/CT- i.e. if the client has been treated syndromically because they presented with 1) urethral discharge 2) epididymo-orchitis 3) PID 4) vaginal discharge (but only if treated for cervical infection). **Treatments for non-GC-CT STI syndromes should be ticked as NO**

Ask the client to complete a consent form to have their urine stored for future studies. IF they decline consent for urine to be stored, then any urine remaining after the GC/CT test is completed, will be discarded.

Give client a screening slip on which the client's pseudonym and sample number should be recorded.

This is to enable:

1. The client to contact the CHIEDZA team should they want to can enquire about their results. (The screening slip will also have a phone number a client can call to get their result. S/he will have to confirm identity by providing the pseudonym and the sample number)
2. The client's result to be verified when s/he presents for treatment. The client will need to bring the screening slip with them to the CHIEDZA centre if s/he wants to access treatment for their positive test result.

Advise the client that the client will be sent an SMS on the cell phone number s/he has provided on the form CO.04 ONLY if the GC and/or CT test is positive. An SMS will NOT be sent if :

- i) Both tests are negative
- ii) The client has already been treated for GC and CT

Please note, the data team will only send results of GC/CT tests that need auctioning to the field team i.e. if GC and/or CT test is positive **AND** client has not been treated already (as above).

8.2.4 Screening for TV

Only women should be offered screening for TV regardless of whether they have symptoms or not.

TV testing is a point of care test that will be done on site.

If client has already been treated for vaginal discharge or PID and the test is positive, then there is no need to treat twice. A PN slip should be given for a partner to be treated for TV.

8.3 Treatment of STIs

Refer to hospital if red flag signs found

8.3.1 Syndromic treatment

See Table 8.2 for treatment according to National Guidelines

8.3.1.1 Side effects

Counsel client about side-effects of treatment.

All drugs can cause the following side-effects: nausea, vomiting, diarrhoea, skin rash. Metronidazole causes metallic taste in mouth; alcohol should be avoided

Doxycycline causes sensitivity of skin to light

Jarisch-Herxheimer reaction in treatment of syphilis: occurs within few hours of treatment. Symptoms are fever, chills, rigors, headache, hyperventilation, flushing, muscle pain, worsening of skin lesions and anxiety. Treat with anti-inflammatory (aspirin or ibuprofen) and monitor.

When giving intramuscular treatment, ask client to rest in the centre for at least 30 minutes to ensure there is no serious adverse reaction.

8.3.1.2 Allergies

Ask about allergies to drugs. You need to establish what the allergic reaction was i.e. was there a rash, an anaphylactic reaction. Nausea and GI complaints do not count as allergies. Ceftriaxone has some cross-reactivity with penicillin in terms of allergies so if there has been an allergic reaction to penicillin, discuss with study physician whether to give ceftriaxone.

8.3.1.3 Pregnancy

AVOID doxycycline and metronidazole cannot be used in pregnancy. Ceftriaxone can be used in pregnancy. If there is any suspicion of pregnancy i.e. a missed or a late period, do a pregnancy test before starting STI treatment.

Ask client to abstain for 7 days while taking STI treatment. If unable to abstain then they must use a condom.

8.3.1.4 Lack of resolution of symptoms

Can be due to non-adherence or re-infection or rarely resistance.

Unresolved discharge/PID

There are 3 possibilities- either the participant did not take their treatment correctly i.e. the correct dose for the correct amount of time, or was re-infected, or may have a resistant infection that requires second line treatment. In either case, retreat with the original dose and ensure adherence to medicines. If truly compliant and symptoms persist, consult study physician. For clients treated for PID, if there has been no change or symptoms have worsened, there may be an abscess and a referral to hospital may be required. If any concerns, discuss with study physician.

Recurrent ulceration

Most likely reason is HSV-2 infection or herpes.

Counsel clients with GUD that a small proportion will get recurrences if it is herpes. If more than 5 episodes of infection per year, start prophylactic acyclovir- 400mg twice daily for 6-12 months. Stop after this time and if 2 or more recurrences over 3 months occur consider restarting.

8.3.2 Management of positive GC/CT screening result

If the client has already been treated for GC and CT as part of syndromic management (i.e. if they have been treated for PID, vaginal discharge, urethral discharge, epididymo-orchitis) there is no need to re-treat the client even if the test is positive.

If the test is GC-positive OR GC and CT positive: treat for BOTH infections.

If the test is CT-positive ONLY: treat for CT only.

The treatment for CT is azithromycin (1g PO) or doxycycline (100mg BD for 7 days)

The treatment for GC is ceftriaxone (250mg IM) or kanamycin (2g IM)

8.3.3 Management of positive TV screening result

If the client has already been treated for VDS or PID as part of syndromic management, there is no need to re-treat the client even if the test is positive.

The treatment for a positive TV test is metronidazole 400mg PO TDS for 7 days

Table 8.2: First line Management of STI syndromes

Syndrome	Management	Alternative
MEN		
Urethral Discharge	Ceftriaxone 250mg IM single dose PLUS Azithromycin 1gram single dose	Kanamycin 2g IM single dose (Instead of ceftriaxone) Doxycycline 100mg BD x 7 days (instead of azithromycin)
Epididymo-orchitis	Ceftriaxone 250mg single dose PLUS Doxycycline 100mg BD x 10 days	Kanamycin 2g IM (instead of ceftriaxone)
Balanitis	Miconazole Cream twice daily for 7 days Promote hygiene and bathing	If no resolution give metronidazole 2g stat
WOMEN		
Vaginal Discharge	Ceftriaxone IM 250mg one dose PLUS Azithromycin 1gram single dose PLUS Metronidazole 400mg PO three times a day for 7 days AND (if candida suspected) Miconazole 200mg PV every night for 3 days	Kanamycin 2g IM single dose (instead of ceftriaxone) Doxycycline 100mg BD x 7 days (instead of azithromycin) CAUTION IN PREGNANCY: Doxycycline should not be used during pregnancy, or in lactating women. Doxycycline should be replaced by: • Azithromycin 1 gram PO, single dose OR • Erythromycin 500 mg orally, 4 times a day for 7 days Kanamycin 2g IM single dose (Instead of ceftriaxone)
PID	Ceftriaxone IM 250mg one dose PLUS Doxycycline 100mg BD for 14 days PLUS Metronidazole PO 400mg three times a day for 14 days	CAUTION IN PREGNANCY: Doxycycline should not be used during pregnancy, or in lactating women. Doxycycline should be replaced by: • Erythromycin 500 mg orally, 4 times a day for 10 days • For severe PID (red flag), refer to hospital
MEN AND WOMEN		
Genital Ulcers	Advice on washing locally twice a day with salt water (1 teaspoon salt to 1 litre water) PLUS Benzathine penicillin 2.4 mega units IM one dose PLUS Ciprofloxacin 500mg PO twice a day for 3 days PLUS Acyclovir 400mg PO three times a day for 5 days	• If penicillin allergy, use doxycycline 100mg PO twice a day for 20 days • Do not use doxycycline during pregnancy/breastfeeding: treat with erythromycin 500mg PO 4 times a day for 14 days
Bubo	Doxycycline 100mg PO twice a day for 14 days • Podophyllin paint 20% applied externally with instructions to wash off after 4 hours.	• If pregnant/lactating: Erythromycin 500mg PO 4 times a day for 14 days
External genital warts	• Use once then review after one week • For external use only: Do not apply to cervix/ urethra / anus.	• Do not use in pregnancy or if warts extensive. Instead, refer to general surgical team/gynaecology service

8.4 Partner notification

Any sexual partner in the preceding three months should be treated presumptively for the same STIs diagnosed. Exceptions include: warts.

Note that balanoposthitis and candida are not STIs and do not require partner notification.

It is necessary for the participant being treated for an STI (whether syndromically or following a positive GC/CT screen or a positive TV screen) to inform all her/his sexual partners over the past 3 months of the need for them to attend for treatment of a potential STI whether or not they have symptoms.

Give the client a partner notification slip to pass on to their sexual partners. Partners (of clients) can access STI treatment through CHIEDZA regardless of age or geographical location. A code should be entered for the appropriate STI so the provider is aware why the partner has presented (VDS=vaginal discharge; UDS=Urethral discharge syndrome; PID=pelvic inflammatory disease; EPOR=epididymo-orchitis; GUD=genital ulcer disease; HCT=HIV counselling and testing; BUB=bubo; CTS=Chlamydia trachomatis screen; GCS=Gonococcus screen; TV=TV screen.

There is no limit to the number of partner notification slips that can be provided. **If a client has had several partners in past 3 months**, s/he needs to give the contact slip to all partners who s/he has had sex with in the past 3 months. S/he needs to advise them to attend the CHIEDZA centre with their slip so that the team knows which treatment they should get. It is important to use a condom until they have been treated to avoid getting re-infected.

If client says that partner does not want to come, try and get client to bring partner to speak with the counsellor or youth workers to the CHIEDZA service for explanation and counselling.

Partners of clients with STI should not be offered GC/CT screening or TV screening.

8.4.1 Treatment of partners of clients with STIs

Partners will be defined as those who present with a partner notification slip.

Collect the Partner Notification slip- do not lose this- each slip must be returned to the data office.

Give STI treatment to partners if they present with a partner notification slip. Treat for the appropriate STI – the same treatment that the index client was treated for. This should be done regardless of whether the client has symptoms.

Record the treatment given in the STI register.

Offer HIV testing: If the partner tests HIV-negative, provide appropriate post-test counselling. If the partner tests HIV-positive, provide post-test counselling and refer to a

PHC for onward HIV care. The partner will only be eligible for HIV care through CHIEDZA if 1) aged 16-24 years and 2) residing in the cluster.

Figure 8.1: Flow chart for syndromic management of STIs

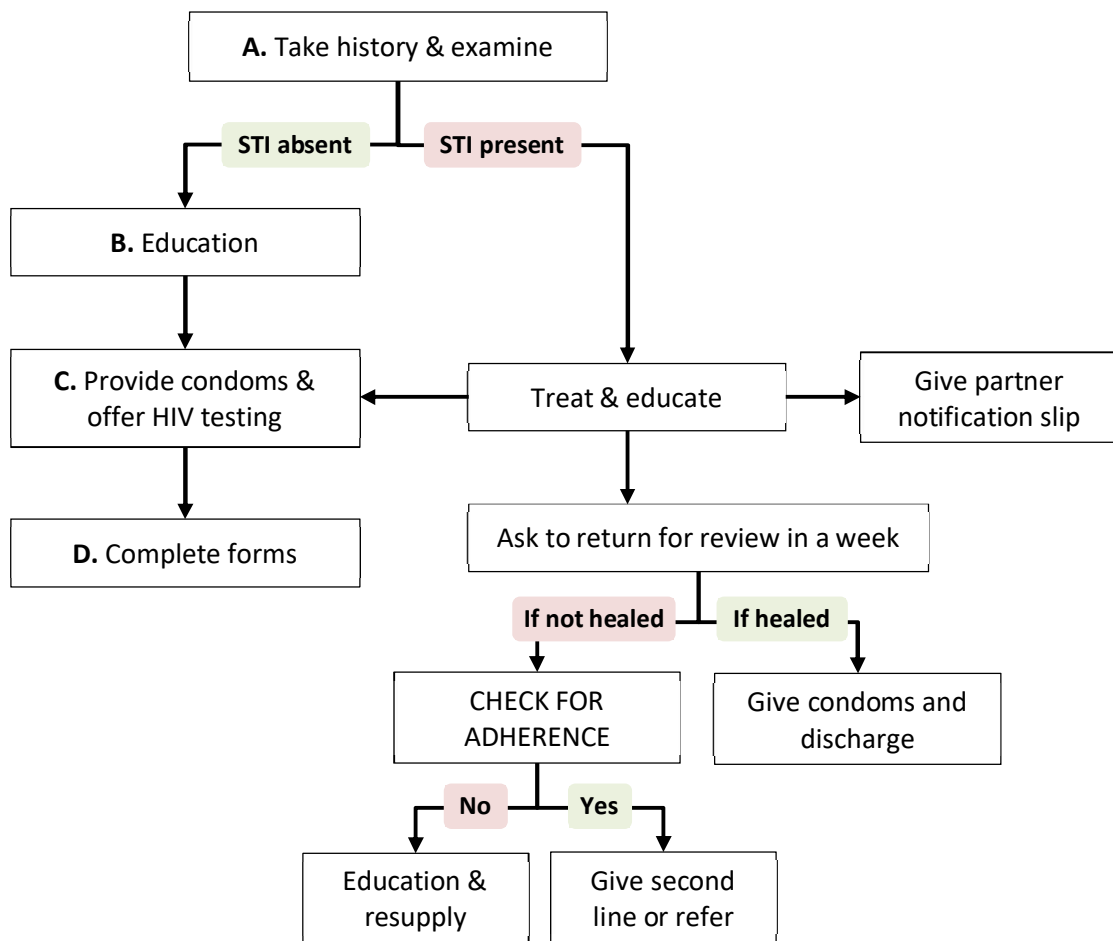


Figure 8.2: Urethral discharge Syndrome Management

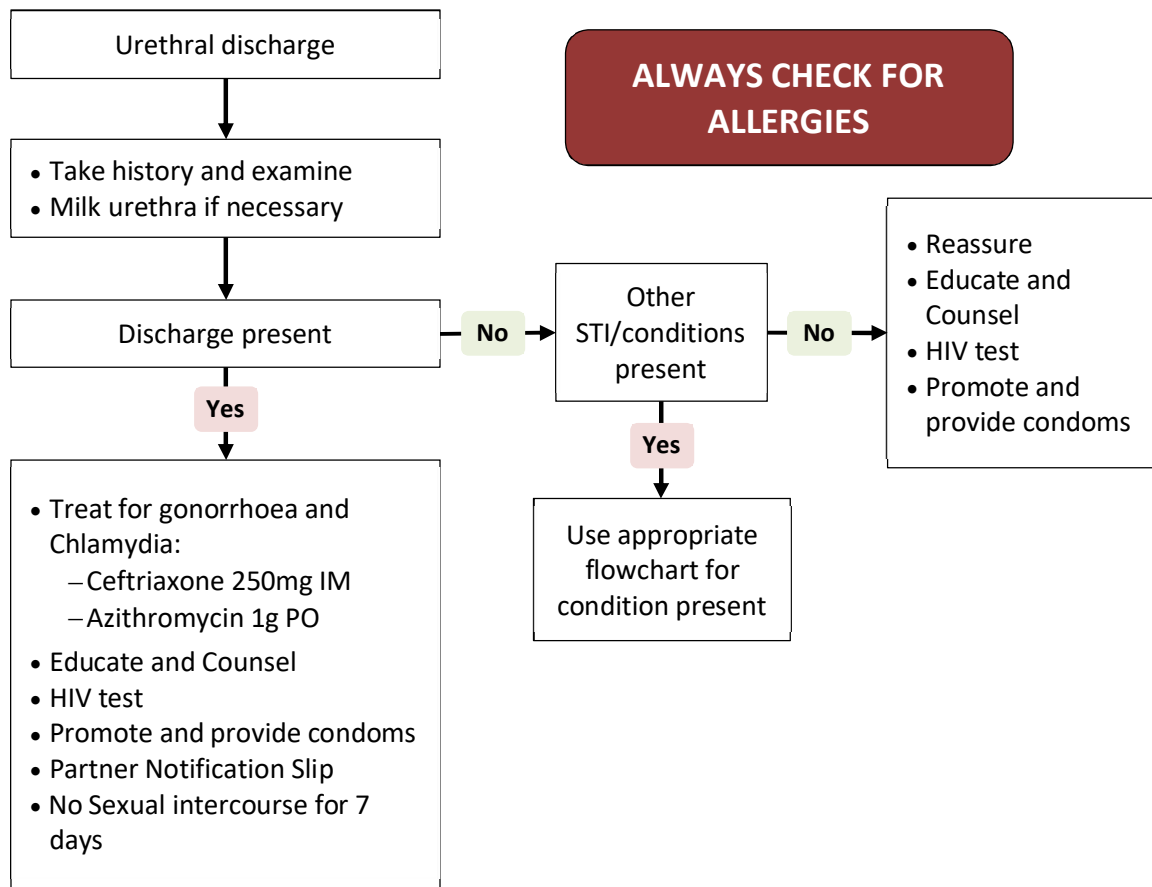


Figure 8.3: Acute Scrotal swelling Syndrome management

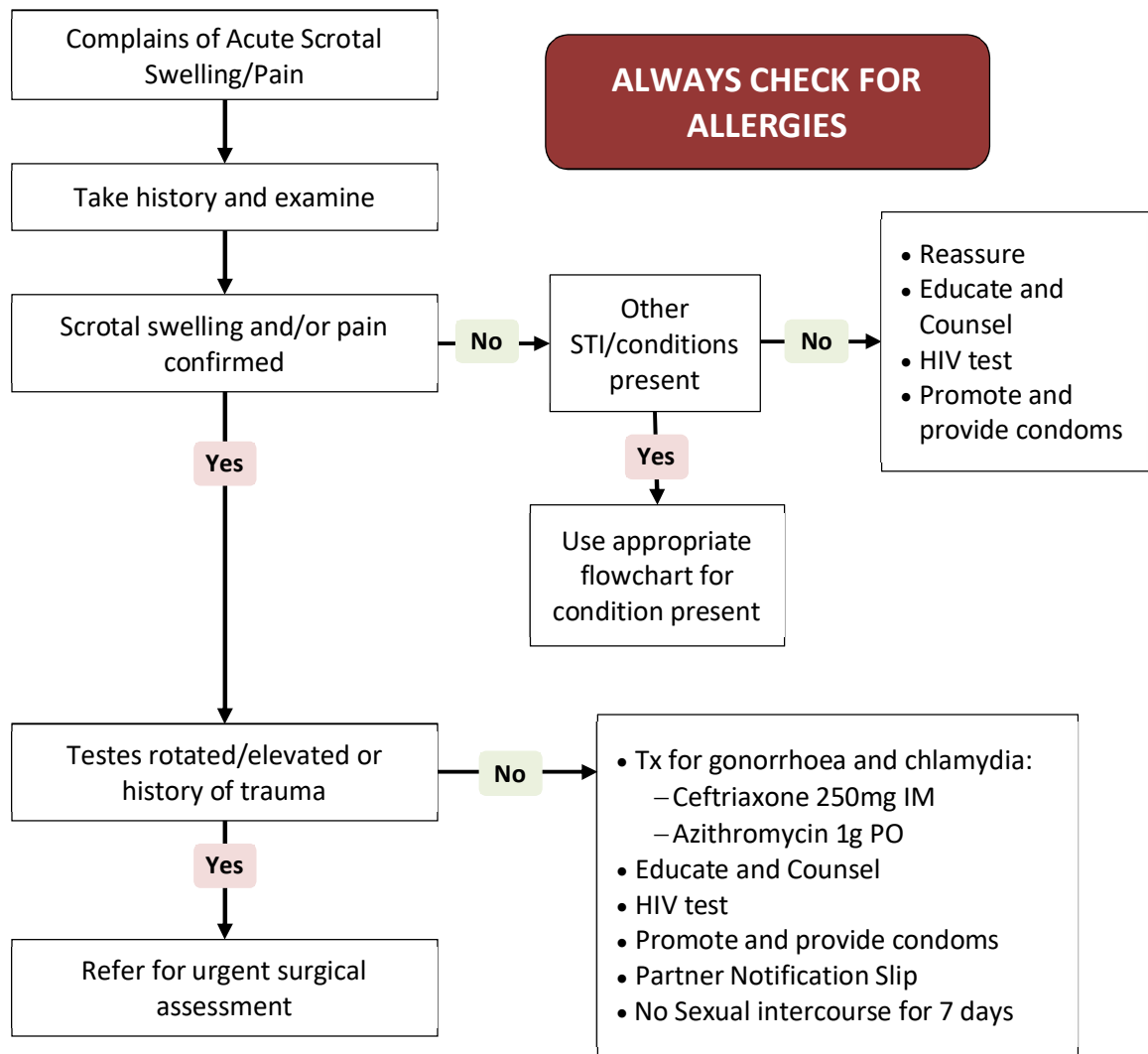


Figure 8.4: Vaginal Discharge Syndromic Management

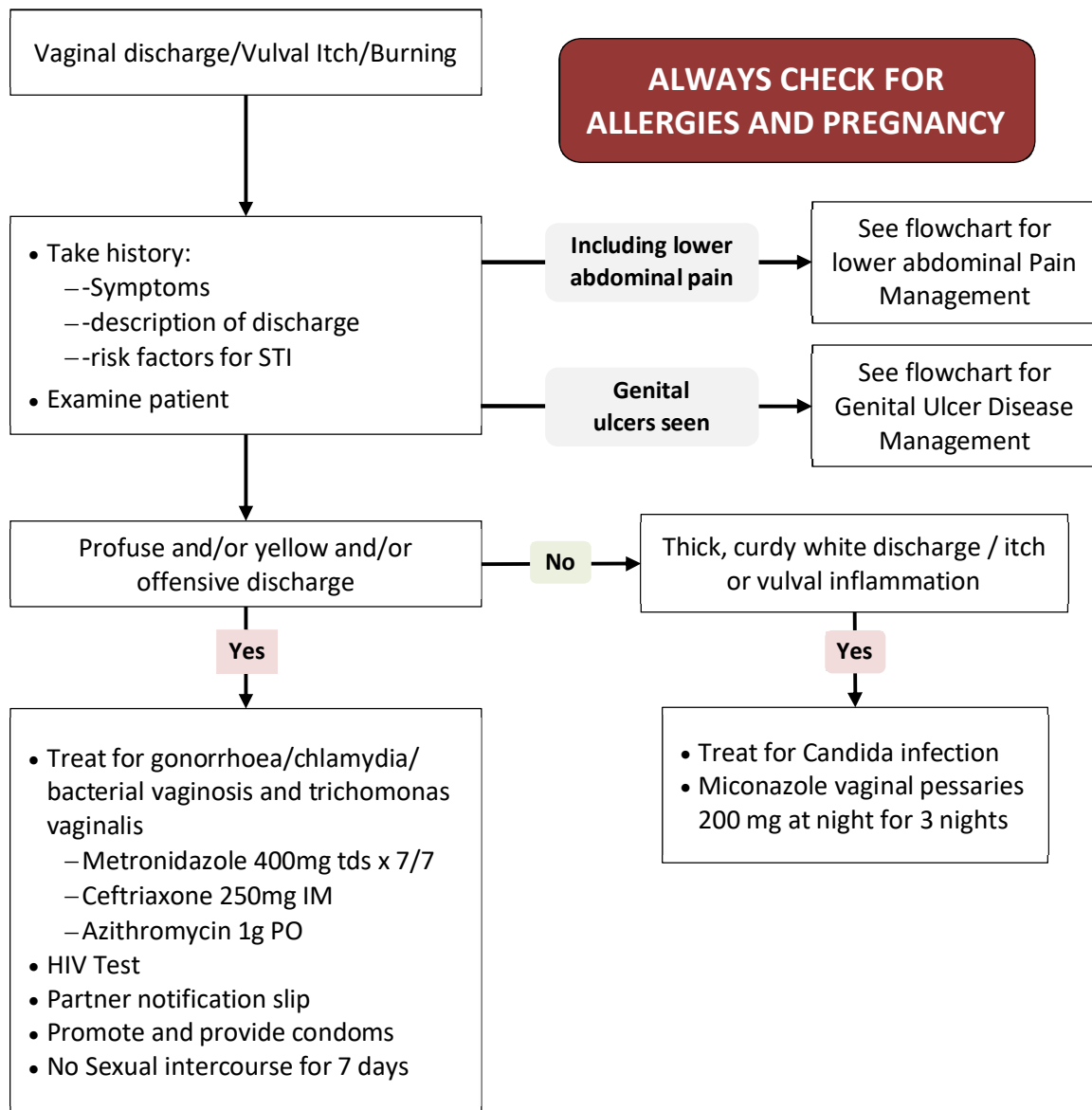


Figure 8.5: PID Management

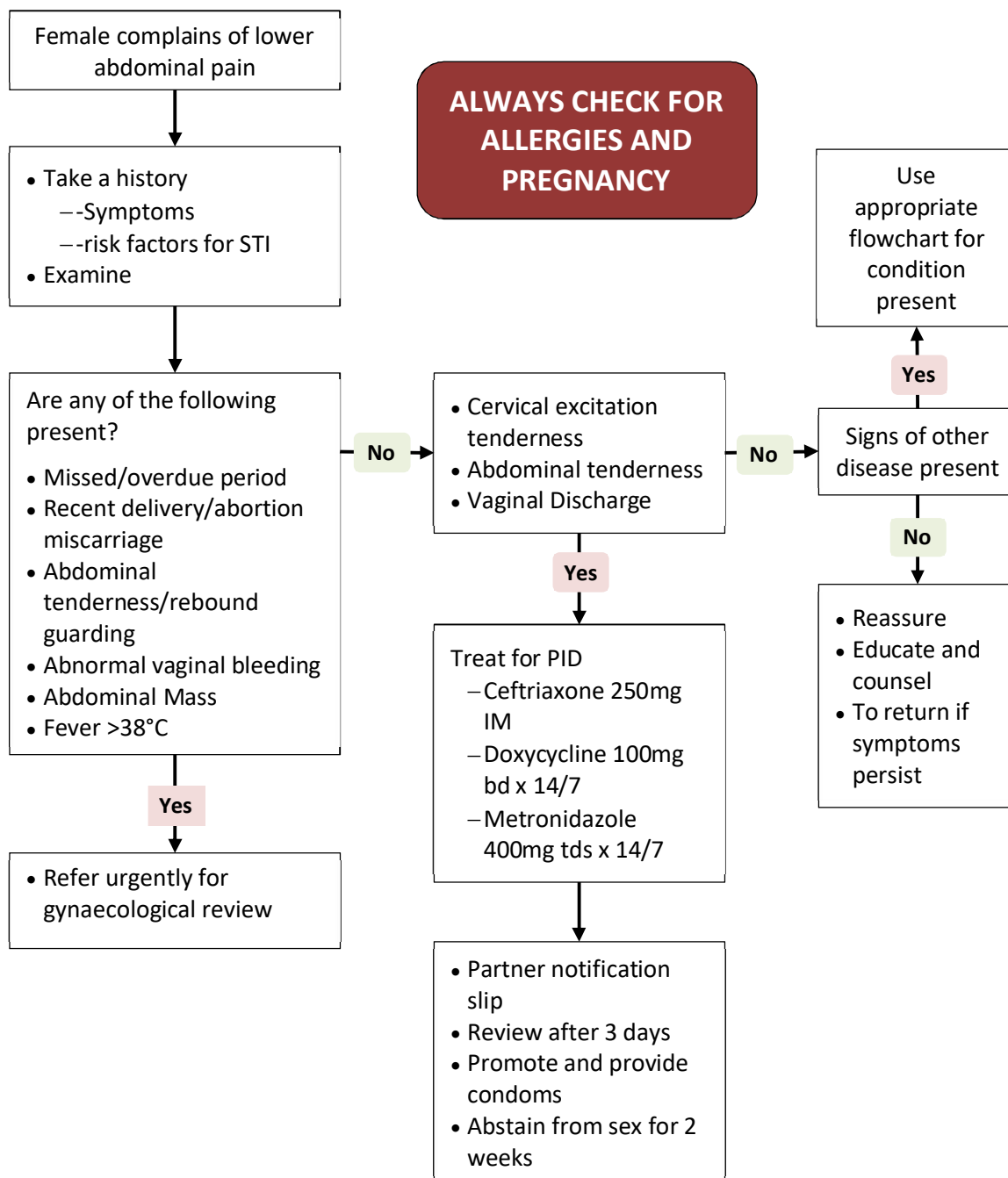


Figure 8.6: Genital Ulcer Syndromic Management

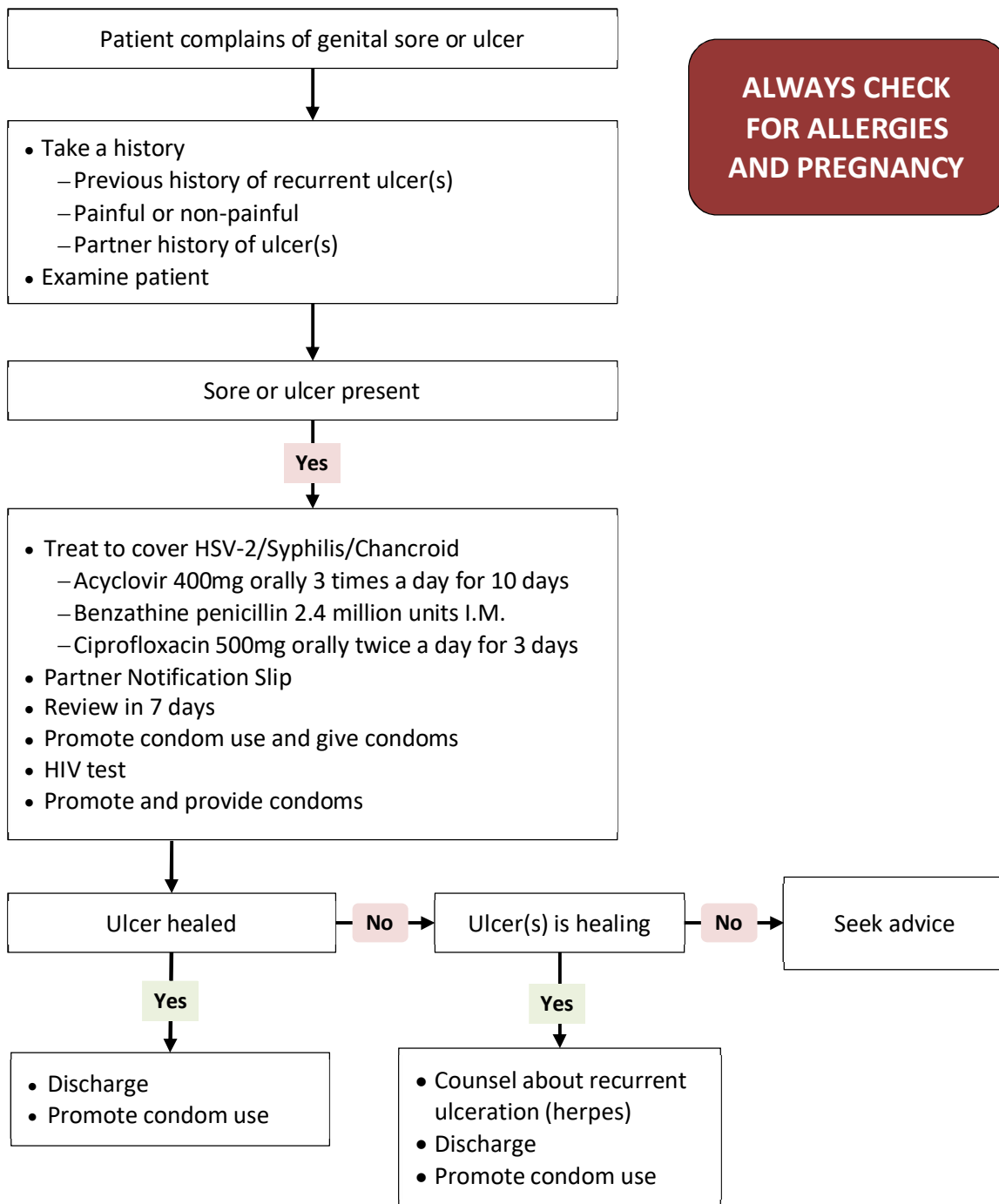
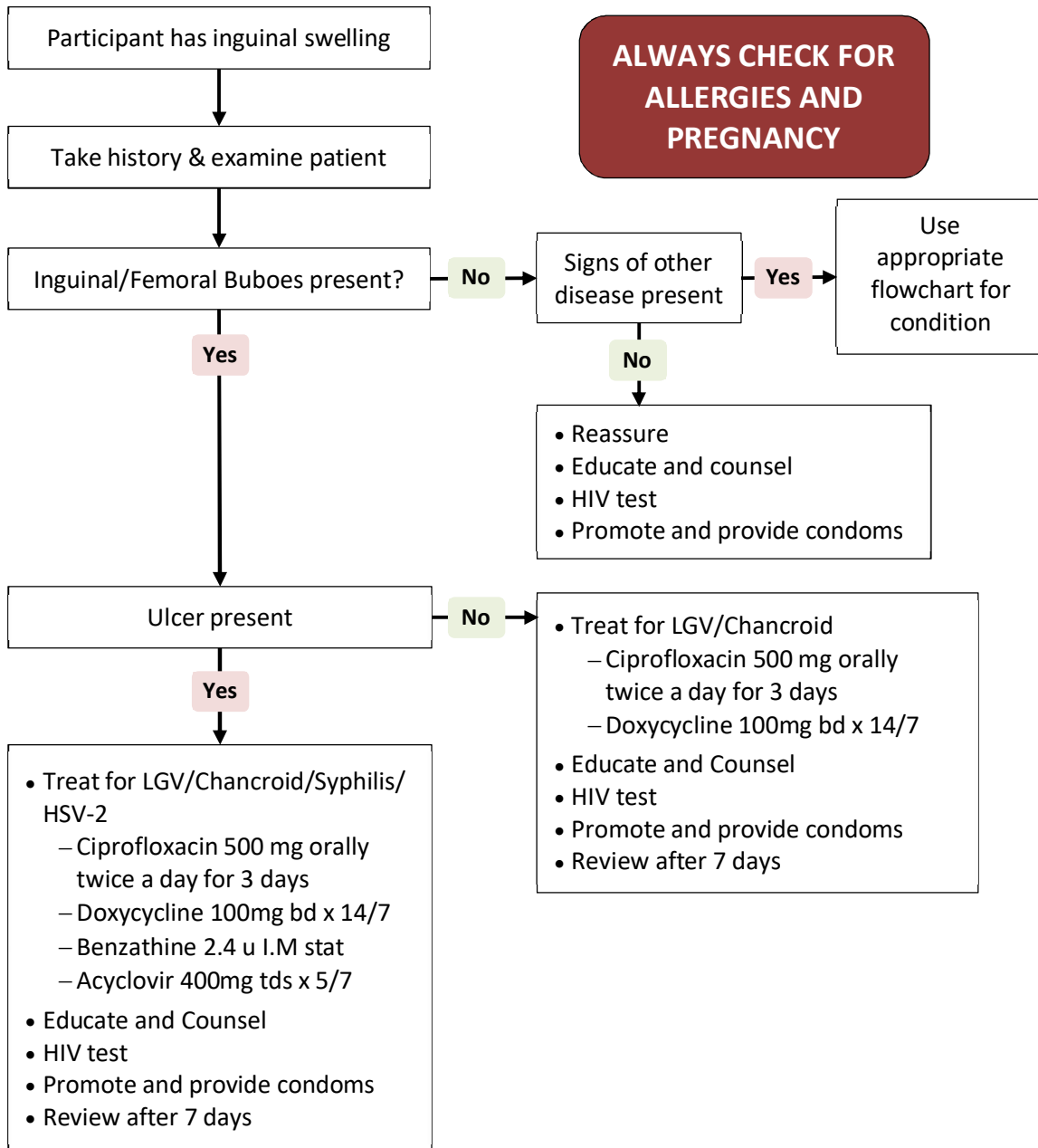


Figure 8.7: Inguinal buboes management



8.5 Frequently Asked Questions

Does a condom protect against all STIs?

No, it does not protect against genital warts or genital herpes as these can be transmitted by skin to skin contact.

Can STIs make someone infertile?

Yes, chlamydia and gonorrhoea can lead to lower fertility if left untreated.

Are STIs curable?

Most STIs are curable if treatment is taken as prescribed and the partner is treated. If there is unprotected sexual intercourse during treatment or the partner is not treated, you may get re-infected.

There are certain STIs that are not curable, notably herpes and HIV. Once infected with herpes, the virus stays in nerve cells and can occasionally “wake up” and cause ulcers. This doesn’t always happen and many people may have one episode and not get another episode again. Warts are curable but they recur easily and sometimes are not easy to get rid of.

9. Condom Provision

A combination of publicly-sourced and purchased male condoms will be provided to all CHIEDZA clients. This chapter outlines the process of condom provision and how to demonstrate the use of a male condom to clients.

Every member of the CHIEDZA team i.e. CHW, nurse, counsellor and youth worker should be able to provide condoms and demonstrate the use of a condom.

9.1 Procedures

Male condoms will be offered to all clients, male and female.

Condoms will be packaged in CHIEDZA bags for distribution. Each package will contain:

- a) 4 purchased/fancy condoms and 8 public-sourced condoms
- b) a leaflet on condom use
- c) CHIEDZA leaflet listing available services.

Publicly-sourced condoms will be available in baskets in the CHIEDZA centre for clients to pick out as they so wish.

Condom packages will also be available in the consultation booths for distribution by CHIEDZA providers.

Providers will also offer condoms packages to all clients who visit a consultation booth. Information about the condoms (see panel below) and demonstration on condom use should be provided to the client with the condom package, depending on the client's level of knowledge and wishes.

No data records need to be filled for condoms provided. The project will record the total number of condoms provided per cluster over the project period.

9.2 Information about condoms

CONDOMS PREVENT UNWANTED PREGNANCY & STIs

- A condom covers the penis during sex and collect semen. By collecting semen, condoms stop sperm from getting into the vagina, so sperm can't meet up with an egg and cause pregnancy
- Condoms cover the penis, which prevents contact with semen and vaginal fluids that may carry infections. Condoms therefore protect against sexually transmitted infections including HIV.

Using a condom is the only method of birth control that also help prevent STIs and HIV

CONDOMS CAN BE SEXY

- Condoms come in lots of different styles, shapes, and textures that increase sensation for both partners. Having your partner put the condom on your penis can be a sexy part of foreplay, especially if you add lubricant. Condoms can even delay ejaculation, so sex lasts longer.
- You can use condoms for oral, anal, and vaginal sex, so they protect you from STIs no matter how you get down. That's really the sexiest part of all: condoms let you focus on pleasure and your partner without worrying about pregnancy or STIs. Sex with condoms is better sex because it stops stress from killing the mood.

Protection is important, but so is pleasure. Luckily, condoms offer both!

CONDOMS HELP OTHER BIRTH CONTROL METHODS WORK EVEN BETTER

- Adding condoms to your birth control line-up can give you extra pregnancy protection. No method is 100% effective, so adding condoms as a backup helps you prevent pregnancy if you make a mistake with your other method or it fails.
- Condoms can add extra protection to all other birth control methods, like the Pill, the Ring, the Injection, the IUD and the Implant.

CONDOMS HAVE NO SIDE EFFECTS

- Most people can use condoms with no problem — there are no side effects. Very rarely, latex (rubber) condoms can cause irritation for people with latex allergies or sensitivities. And sometimes the lube on certain types of condoms may be irritating.
- If you're allergic to latex, try switching brands or using plastic condoms. Condoms made from soft plastics like polyurethane, polyisoprene, and nitrile are latex-free.

9.3 Demonstrating use of a male condom

Requirements: 1) Condom Demonstration model; 2) condom packet

- Before opening, check expiry date on condom packet
- Make sure there are no holes on the condom packet
- Open condom packet with hands, do not use your teeth
- Make sure that the condom is not inside out before putting on. You will know this because the condom will not roll down if inside out. *One way to check is to blow into the condom- if it is the right way round there will be a little air bubble.*
- Pinch the air out of the condom tip with one hand and roll the condom over the penis with the other. Roll the condom all the way down to the base of the penis and smooth out any air bubbles



- After ejaculation, withdraw your penis from the vagina when still erect. While doing this, hold the condom at the base of the penis so that there is no sperm spillage
- Wrap condom and dispose of it in a bin

NOTES

- **Do not** use if condom is past expiry date or any holes in the sachet
- **Do not** use condoms with oil-based lubricants as they can damage the condom
- **Do not** use more than one condom at a time- it does not add any additional protection

9.4 Frequently Asked Questions

10. Menstrual Hygiene Management

The onset of puberty and menstruation is an important experience for girls and young women, and appropriate menstrual health management (MHM) is directly linked with basic human rights and overall wellbeing. With this in mind, CHIEDA will provide all female clients MHM including products, education, pain management.

This chapter describes how to provide MHM. MHM can be provided by a CHW or nurse.

10.1 MHM products

The following products will be available and female clients should be offered and given information about all the products. Note: clients can choose only one product at a time, but they will be able to change their choice after a minimum trial period of three months. If they decide they want to change, they will need to bring in the original product and return it to the CHIEDZA team to get an alternative product.

Table 10.1: MHM products

MHM Product	Hardware
MENSTRUAL CUP	<ul style="list-style-type: none">• 1 menstrual cup/participant• 1 pack of disposable pads*• 2 pairs of underwear• Soap• Pain medication (6 paracetamol or 6 ibuprofen)
REUSABLE PADS	<ul style="list-style-type: none">• 1 pack of AFRIPADS (3 maxi pads and 1 super maxi pad)/participant• 3 pairs of underwear• Soap• Pain medication (6 paracetamol or 6 ibuprofen)
PERIOD PANTS	<ul style="list-style-type: none">• 3 pairs of period pants• Soap• Pain medication (6 paracetamol or 6 ibuprofen)

**This will be provided as clients may want to use disposable pads concurrently with the cup initially as they may be worried by leakage. Once confident that leakage does not occur, they would stop using a disposable pad with the cup*

10.1.1 Information to give clients about products

Advise clients to use products as follows:

10.1.1.1 Period pants

Period pants are washable menstrual underwear that are designed to absorb menstrual blood much like a sanitary pad. Period pants can be worn like regular underwear and, depending on flow, the pants can absorb up to 2 tampons worth of blood before needing to be changed. Every young woman and every period is different and unique, and therefore how often the period pants need to be changed will vary, but on average will need changing 2-3 times over 24 hours. The period pants are made from soft and absorbent materials so should not feel moist or uncomfortable.

Remove the used period pants and rinse with cold water. After rinsing, wash them separately or with the rest of your laundry. If you are not at home when you change your

underwear, fold the used period pants and place in a waterproof bag or plastic bag and wash when you get home. When washing your pants, it is very important that you use cold water and that you do not use bleach or fabric softener. To dry the period pants, simply hang them to dry under the sun and then store away with the rest of your underwear.

Never wear period pants when they are not completely dry.

Period pants can be used for years or until they do not feel that they absorb enough.

10.1.1.2 Reusable Pads (AFRIpads)

- Wash the pad before first use with cold water and soap. Avoid washing with hot water. Dry the pads in the sun. Sunlight is a natural bleach and bacteria killer. On top of that, pads dry fastest in the sun: 2-3 hours. The pads will only reach their most absorbent capacity after washing them with soap. This is because the fabric comes straight from the factory where it was made and has never been in touch with water. It is also hygienic to wash the pads first.
- Fold the used pad following the 'easy fold & carry' instructions. The blood will be 'packed' inside the leak proof fabric and others will not be able to smell the pad. The plastic bag serves as extra protection. Remember that it is very important to change your pad in time.
- Once used, rewash and reuse. Compare it to washing knickers and wearing them again.
- Use pad until it feels that they do not absorb enough anymore, and this depends on how well the pads are taken care of. The pads can be used for at least 12 months, but much longer if well taken care of.

The project will only replace the reusable pads every 12 months, unless damaged or lost. Tell client to bring in the reusable pad to show that it is damaged if they want it replaced sooner.

Figure 10.1: How to use a reusable pad (AFRIpad)



10.1.1.3 Menstrual cup

The cup is a product that is inserted into the vaginal opening when a woman has a period. It holds the menstrual blood and the cup can be removed to throw out the blood, washed and inserted in again. It avoids the need for buying sanitary pads and the cup can be used again and again.

There is NO need to wear a pad if a cup is being used. However, the cup will be given with a “back-up” pack of disposable pads to alleviate initial concerns a client may have about leakage- hence they may wish to use a pad initially together with using the cup until they are confident that the cup does not cause leaks.

(A disposable pad is a thin pad of absorbent material that is used to absorb the blood coming out during periods. A sanitary pad is worn in the underwear such that it exactly covers the opening of the vagina. Once used, wrap in a waste paper and put in a garbage bin. **Tell clients to never flush a disposable pad down a toilet.**

The project will only provide the cup once. It will only be replaced if it is lost or damaged. Tell the client that if they want the cup replaced because it is damaged, they will need to bring the damaged cup with them.

Advise clients to use cup as follows:

- Fold the cup as you insert it into the vagina.
- When removing, remember to squeeze the bottom part of the cup until you feel or hear the suction release. Then, gently rock the cup from side to side while pulling down. Make sure that you do not pull the cup out by the stem alone! It is important to relax.
- The first few times using the cup you may feel that removing your cup is a complicated process. After a few tries you'll realize that it can actually be quick and simple!
- When you have removed your cup, empty it into the toilet, and rinse it with water. If you do not have access to water, you can wipe it with some tissue or simply reinsert it directly after emptying it. But make sure to rinse it at your next available opportunity. While on your period, there is no need to disinfect your cup between uses.
- The menstrual cup should be cleaned between your menstrual cycles by boiling for 5 minutes. If this is not a good option for you, use a disinfecting wipe, or wash with hot water.
- The cup can start to change colour over time. This is normal because blood is quite strong, but with good cleaning you can minimize the change in colour.
- The menstrual cup does not have to be removed when you go to the toilet. You can go to the toilet as you normally would when you're wearing your cup. After a bowel movement, you may want to check that the menstrual cup is still sitting properly. Do not forget to wash your hands.
- You can swim and sleep with the cup and do not have to worry about leakage or hygiene

Some cultures believe that the hymen (the membrane that partially covers the vaginal opening) should be intact for a virgin and the break of the hymen should only occur through sexual intercourse with a husband. A virgin can use a menstrual cup –the cup rarely reaches or alters the hymen, means that it does not affect “virginity”

Figure 10.2: How to insert the menstrual cup

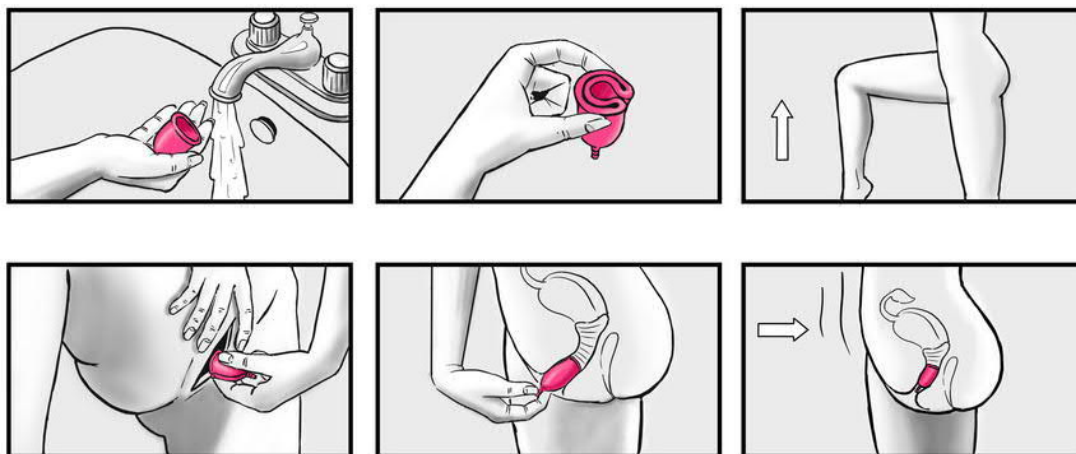


Figure 10.3: How to use a menstrual cup

EASY TO USE IN FOUR SIMPLE STEPS

<p>1. FOLD ME Flatten the cup and fold it in half.</p> 	<p>2. FIT ME Relax and gently push the cup into your vagina and release.</p> 	<p>3. FREE ME Be free with your cup for up to 6 hours. Gently pull the tab to remove.</p> 	<p>4. CLEAN ME Remember to freshen up after 6 hours. Empty cup into toilet, then rinse, boil if possible, and reuse.</p> 
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10.2 Procedures for provision of MHM

Give information about MHM and offer choice of MHM products (Table 10.1)

Encourage the client to watch the educational videos in public area.

Offer products and conduct demonstration of products i.e. the menstrual cup, the period pants, and the reusable pad. Encourage questions about MHM products (Section 10.1.1).

Place the chosen products in the CHIEDZA bag and note her choice of product(s) in CHIEDZA eCRF (Form CO.01).

Offer pain medication (ibuprofen or paracetamol) and note choice in CHIEDZA eCRF (Form CO.01).

On subsequent appointments: ask client what MHM products they have taken up before. The product chosen in the previous visit will flag up when the client’s fingerprint is

entered with SIMPRINTS and Form CO.01 is opened. Record choice of medication and any MHM product change in CHIEDZA eCRF (Form CO.01) and on client-held brown book. Note, a product will only be changed if the client returns the original product.

INFORMATION ABOUT PERIODS

What is a period?

Once a girl reaches puberty in adolescence, her body changes so she is now able to have a baby. One of the changes in the body is that an egg is released into her womb every month and the lining of the womb thickens to prepare to hold a fertilised egg which will grow into a baby. If the egg is not fertilised by sperm from a man during sex, then it will not grow into a baby. The body then gets rid of the extra uterine lining and the unfertilised egg via the monthly bleeding called a period. An egg is released into the womb approximately once a month so a period also occurs once a month.

The lining and unfertilised egg comes out as blood through your vagina. Remember a woman has two openings- one to pass urine and the other the vaginal opening through which she passes the menstrual blood and also has sex.

Once a female starts having periods, that means she is NOW capable of having babies. If the egg does get fertilised when it is released every month, then the womb lining will not be shed and the female will be pregnant. Therefore, if you miss a period, it is important to check for pregnancy.

What age do periods start?

Every girl is different, but most (not all) girls start their periods between the ages of 8 – 18 years.

How long does a period last?

Every girl is different, but most (not all) girls bleed for 2 – 10 days every month. A female will continue to have periods roughly every month until she gets the menopause. This is when the body changes again so that an egg is no longer released every month and she can no longer have a baby. This usually occurs when she is more than 50 years of age although it varies from person to person.

Why do I get pain during my period?

Girls can experience stomach pain and back pain before or during their periods. This is because the muscles of the womb contract to be able to shed the lining.

What should do when I get a period?

You should use products to be able to hold the blood that comes out of your vagina
You should also use painkillers or hot water bottle to help with the pain.
You can otherwise do all the normal things you do during a period.

Can I have sex when I have a period?

It is best to avoid sex during a period because it is less hygienic and increases risk of infection. However, if you do decide to have sex, then use a condom.

Can I get pregnant if I have sex during a period?

This is rare but occasionally having sex during a period can result in a pregnancy.

10.4 Frequently Asked Questions

11. Family Planning

CHIEDZA will partner with PSZ to provide family planning services. Family planning is the practice of controlling the number of children one has and the intervals between their births, particularly by means of contraception or voluntary sterilization.

This chapter outlines the procedures for providing contraception. The initial contraception consultation should be conducted by a nurse. Follow-up family planning consults and counselling and education can be provided by a CHW. All prescriptions must be signed off by a nurse. The team should be familiar with the different types of contraception, how contraception is prescribed, side-effects and contra-indications.

11.1 Types of contraception offered by CHIEDZA

CHIEDZA will offer oral (COC and POP) and injectable (Depo-Provera) contraceptives, as well as emergency contraception and condoms. This section gives detailed information about each method of contraception.

11.1.1 COC Pill (“Control Pill”)

A monthly packet contains 21 white pills (0.3mg norgestrel + 0.03mg ethinyl oestradiol) and 7 brown pills (75mg ferrous fumarate).

The COC works in three ways:

1. It changes the body's hormone balance so that the ovaries do not produce an egg (ovulate).
2. It causes the mucus made by the neck of the womb (cervix) to thicken. This makes it difficult for sperm to get through to the womb (uterus) to fertilise an egg.
3. It makes the lining of the womb thinner. This makes it less likely that a fertilised egg will be able to attach to the womb.

11.1.1.1 Effectiveness of COC Pill

- Correct usage (i.e. not missing any pills and taking extra precautions when necessary - see below): 3 in 1000 become pregnant each year.
- Incorrect usage: 90 per 1000 become pregnant each year
- No usage: 800 per 1000 become pregnant per year

11.1.1.2 Advantages of using the COC:

- It is very effective
- It does not interfere with sex
- Periods are regular and may be less painful and lighter
- It relieves premenstrual tension for some women
- It improves acne in some women
- It reduces the risk of developing cancers of the ovary, colon and womb (uterus).
The protection against cancer of the ovary is quite marked and seems to continue

for many years after stopping the pill. It may also reduce the risk of developing certain types of cyst in the ovary

- It may also reduce the risk of pelvic infection (as the thicker mucus prevents germs (bacteria), as well as sperm, from getting into the womb)
- It may help to protect against some non-cancerous (benign) breast disease

11.1.1.3 Contra-indications to COC:

Absolute: Should NOT use this type of contraception

Relative: Should be offered alternative contraceptives. However, if there are no suitable alternatives, then the COC can be considered. Anyone with a relative contra-indication to COC who has no other alternative should be discussed with the study physician.

Table 11.1: Contra-indications to COC use

Absolute	Relative
<ul style="list-style-type: none"> • Pregnancy, breastfeeding, <6 weeks postpartum • Current breast cancer/ genital cancer • Previous stroke or heart attack • Current or past venous thrombo-embolism • Liver disease (viral hepatitis, cirrhosis, tumours) • Taking ritonavir as part of ART • Taking rifampicin, phenytoin, carbamazepine* 	<ul style="list-style-type: none"> • Hypertension: BP ≥160 mmHg systolic and/ or ≥95 mmHg diastolic • Obesity: BMI ≥40 kg/m² • Diabetes with secondary complications • Chronic renal diseases • Migraine with aura • Epilepsy • Infrequent bleeding /amenorrhoea • Major surgery with prolonged immobilisation

**These drugs reduce the effectiveness of COC and pregnancy becomes more likely*

11.1.1.4 Side effects of COC

Most women do not get side-effects and if they happen, usually settle within 3 months.

COC Does NOT result in weight gain

Table 11.2: Side-effects of COC

Side effect	Response
<ul style="list-style-type: none"> • Nausea • Headaches • Breast tenderness 	<ul style="list-style-type: none"> • Usually go away within days-weeks of starting the pill. • REASSURE • If persist, a different brand may work (although CHIEDZA offers only 1 brand)
<ul style="list-style-type: none"> • Tiredness • Not interested in sex • Skin changes • Light bleeding between periods 	<ul style="list-style-type: none"> • REASSURE. If troubling and significant, change contraception method • Light bleeding usually stops by 3 months. REASSURE
<ul style="list-style-type: none"> • Rise in BP 	<ul style="list-style-type: none"> • Monitor 6 -12 monthly. If high BP, change contraception

11.1.1.5 Conditions warranting stopping of COC:

- Pregnancy or suspected pregnancy
- Severe headaches especially if associated visual disturbance or aura
- Unexplained vaginal bleeding
- Breast cancer
- Unexplained chest pain / shortness of breath

Figure 11.1 Contra-indications to COC

Most Women Can Safely Use OC Pills

You should NOT use the Pill if you:	
<p>May be pregnant</p>	<p>Gave birth in the last 3 weeks</p>
<p>Are breastfeeding a baby less than 6 months old</p>	<p>Have high blood pressure</p>
<p><u>BOTH</u> smoke cigarettes <u>AND</u> are 35 or older</p>	<p>Have severe headaches</p>
<p>Ever had breast cancer</p>	<p>Had blood clots in your legs or lungs</p>
<p>Have liver or gallbladder disease</p>	<p>Had a stroke or heart attack</p>
<p>Have been told by a doctor that you have lupus</p>	<p>Have diabetes</p>
<p>Take medicine for tuberculosis, seizures, or HIV/AIDS</p>	
<h2 style="margin: 0;">Do you think you can use OC Pills?</h2>	

Source: Chin-Quee D¹, Ngadaya E, Kahwa A, Mwinyihari T, Otterness C, Mfinanga S, Nanda K. Women's ability to self-screen for contraindications to combined oral contraceptive pills in Tanzanian drug shops. *Int J Gynaecol Obstet.* 2013;123:37-41.

11.1.1.6 How to take the COC:

When to start

The COC can be started up to and including Day 5 of menstrual cycle (Day 1 being first day of the period) without needing additional protection (i.e. condoms or abstinence from sex).

If starting after day 5: condoms should be used for additional 7 days after starting COC.

The COC should be started with the first white pill and continued along the packet taking the white pills. After the 21 white pills are over, the brown pills should be taken. The pills should be taken in the correct order and taken at around the same time each day. Taking the pills in the wrong order could mean that the woman is not protected from pregnancy.

During the days that the brown pills are being taken, there will be a “withdrawal bleed”. This is a bit like a period although it is not really a menstrual period.

When a pack is finished, another pack should be started the next day whether or not the woman is still bleeding.

The woman will be protected from pregnancy during the seven days when she takes the brown pills, if she has taken her pills correctly **AND** she starts the next pack on time (i.e. as soon as the first pack is finished).

If she has taken her pills correctly, she will be starting each packet on the same day of the week as the month before.

**Ask client to write down the day of the week she starts the first pack.
All subsequent packets should be started on the same day of week**

What happens if there is no period (withdrawal bleed)?

It is normal to have bleeding during the seven-days when taking the brown pills. However, no bleeding between pill packs is also common. Client is not likely to be pregnant if the pills have been taken correctly and she has not vomited or taken any medicines that can interfere with the pill (see below). Advise client to start the next pack after the usual seven-day break and continue to take pills as usual.

A pregnancy test should be done if:

- There is no bleeding after the next pack (two packs in total); **or**
- Pill has not been taken correctly; **or**
- Client has reason to think she may be pregnant

What to advise if there is bleeding whilst on the pill (breakthrough bleeding)?

During the first few months, while the body is adjusting to the pill, there may be some vaginal bleeding in addition to the usual bleeding between packs. This is not serious but more of a nuisance. It may vary from spotting to a heavier loss like a light period. The COC should NOT be stopped. This usually settles after the first 2-3 months. If it continues, consult with study physician. Another brand of COC may be suitable.

How to skip a period (withdrawal bleed)?

There are times when it is useful not to have a period - for example, during exams or holidays. The woman can avoid the 7 days of brown pills- instead she can just go straight to the next packet and start taking the 21 white pills. She can have the usual brown pills after completing the 21 days of white pills.

What should you do if you forget to take a pill or start your pack late?

Missing pills or starting the pack late may make the pill less effective and cause the woman to become pregnant. The chance of pregnancy after missing pills depends on: when pills are missed in the cycle (HIGHER risk if the missed pills are at the end or beginning of the packet) and how many pills are missed:

- Missing one pill anywhere in the pack or starting the new pack one day late isn't a problem. She will still have contraceptive cover.
- Missing two or more pills or starting the pack two or more days late may affect contraceptive cover.

If the woman is 24 hours late or more taking the pill, it counts as a missed pill.

What to do if woman has been vomiting or had diarrhoea?

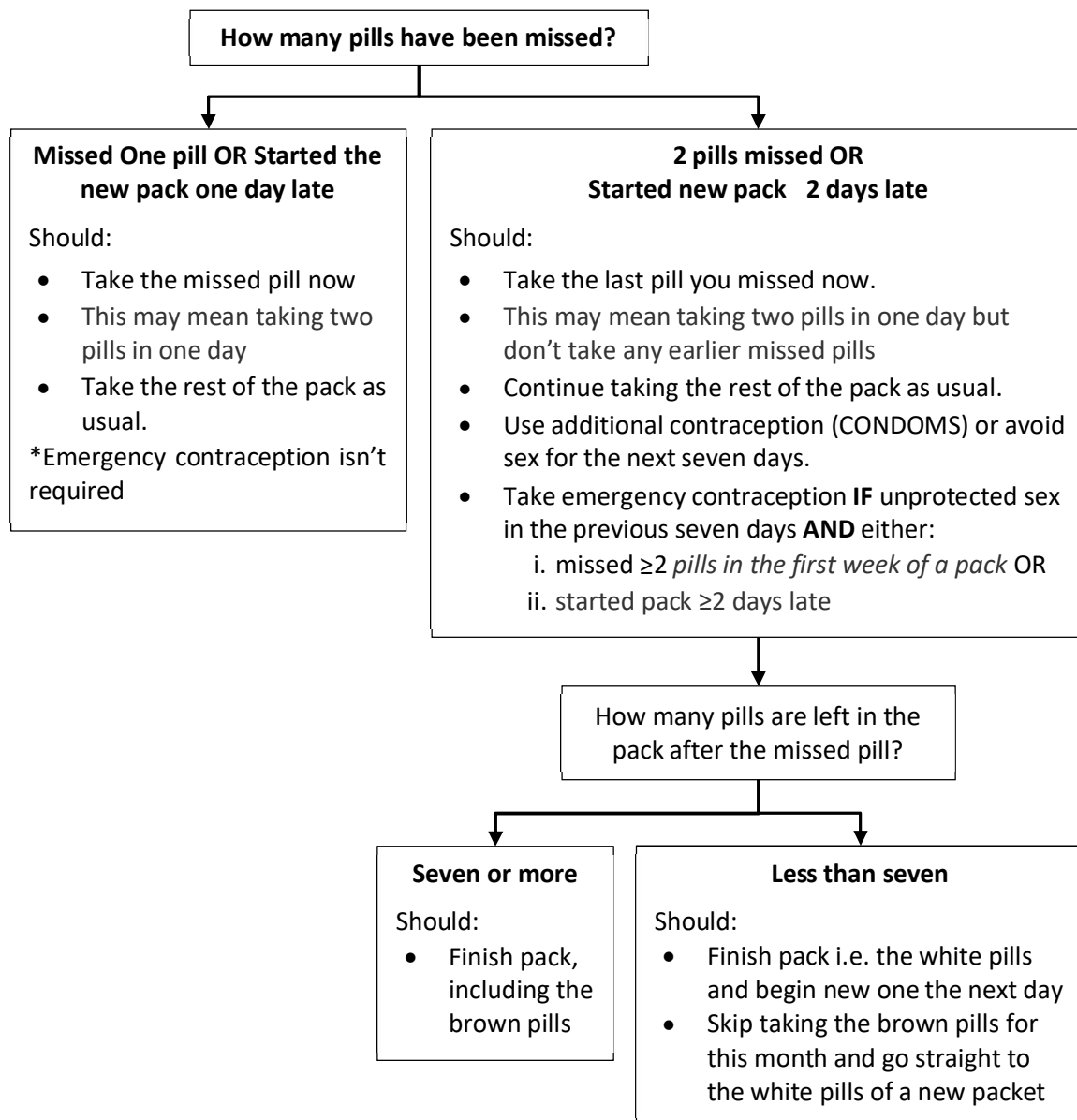
If there is vomiting within 2-3 hours of taking a pill, the pill will not have been absorbed. If woman is well enough, she should take another pill as soon as possible. Provided that she does not vomit this second pill and it is taken on the same day, she will remain protected from pregnancy. If she continues to vomit, the advice is the same as for missing pills (see above).

Mild diarrhoea does not affect the absorption of the pill. Severe diarrhoea may affect it and if there is severe diarrhoea, consider this as the same as missing pills (see above).

What to do if a woman thinks she is pregnant?

If a woman is worried ask a nurse for advice, or do a pregnancy test. Taking the pill doesn't affect a pregnancy test. Always take a pregnancy test if a woman misses more than one bleed. If she does become pregnant, there's no evidence to show that taking the combined pill harms the baby

Figure 11.2: Flow chart for dealing with a missed COC pill



** Consider taking emergency contraception if pills were missed earlier in the pack or in the last week of the previous pack*

What if a woman wants to become pregnant?

If she wants to try for a baby it’s advisable to wait for one natural period before trying to get pregnant. This means the pregnancy can be dated more accurately and you can start pre-pregnancy care such as taking folic acid. Don’t worry if she does get pregnant sooner, it won’t harm the baby.

The woman has taken emergency contraceptive pill and wants to restart her regular COC?

If she has taken emergency contraception pill she should take her next contraceptive pill within 12 hours and use additional contraception such as condoms for 7 days.

11.1.1.7 Medicines that interfere with COC:

Some medicines do but most do not. Therefore, before woman takes any other medicines, including those available to buy without a prescription or herbs, she should get advice from health professional about what to do. CHIEDZA staff should discuss with study physician before advising clients.

**Antibiotics (except rifampicin) do not interfere with the effectiveness of COC.
Woman should continue taking pills as normal if taking antibiotics.
NO additional protection is needed**

If a medicine that interferes with the COC is only going to be used for a short time, advise client to take extra contraceptive precautions for the duration of the therapy, and seven days after treatment, for example, condoms or not having sex. If the medicine is to be used on a long-term basis, then advise a different form of contraception.

11.1.2 POP (“Secure”)

This contains the synthetic progestogen Norgestrel 0.075mg. It is commonly used when the COC is unsuitable. The POP is particularly suitable for breast feeding mothers.

Progestogens protect against pregnancy by thickening the sticky mucus made by the neck of the womb (cervix). The mucus forms a plug in the neck of the womb which stops sperm from getting through to the womb (uterus) to fertilise an egg.

11.1.2.1 Effectiveness of the POP

- Correct usage: 3 in a 1000 per year will become pregnant
- Incorrect usage: 80 in a 1000 per year will become pregnant
- No usage: 800 in a 1000 per year will become pregnant

11.1.2.2 Advantages of using the POP

- It does not interfere with sex.
- Can take it any time after childbirth, including immediately after delivery.
- Can take it when breastfeeding.
- It has a lower dose of hormone than the combined pill.
- It does not have a higher risk of blood clots (unlike the COC). It can therefore be used by some women who cannot take the COC e.g. if smoker, migraines, high BP.

11.1.2.3 Contraindications to taking POP

- Current or past breast cancer
- Severe liver disease
- Taking anti-epileptics, rifampicin for TB, nevirapine and ritonavir. Other antibiotics do not affect the POP.

11.1.2.4 Side-effects of the POP

Side-effects are uncommon. If one or more do occur, they often settle over a couple of months or so.

- mood swings
- increase in acne
- breast discomfort
- Can affect periods: Irregular periods, spotting between periods or no periods may occur. If woman does develop irregular bleeding while taking the POP, she should inform the health provider. Sometimes irregular bleeding can be due to another reason - for example, an infection, which may need to be treated.

There is no evidence that the POP causes women to put on weight

11.1.2.5 How to take POP:

The woman should start taking the pill on the first day of her next period. It is immediately effective from then on. It will also start to work straightaway if she begins taking it up to the fifth day from the start of her period. (i.e. if Day 1 is the first day of the period, the POP can be started on Day 1, 2, 3, 4 or 5 and it will work straightaway.)

If the POP is started on any other day, additional contraceptive methods (such as using condoms or not having sex) should be used for the first 48 hours. This is until the POP has become effective.

If the woman has just had a baby, the POP is immediately effective if she starts taking it before day 21 after birth. If started after Day 21, additional contraception (for example, condoms or not having sex) should be used for 48 hours.

The POP must be taken at the same time of day, every day including when the woman has periods. The most important thing is to get into a routine. She should not stop taking it when she has a period. She should take it **every** day. When one pack is finished, another pack should be started the next day.

What do I do if she misses a pill?

If less than 3 hours late:

The woman should take a pill as soon as she remembers. The next pill should be taken at the usual time. She is protected from pregnancy.

If more than three hours late:

The woman should take a pill as soon as she remembers. If she has missed more than one, she should only take one.

The next pill should be taken at the usual time. This may mean taking two pills in one day. This isn't harmful.

She is **NOT** protected from pregnancy. The pills should be continued as usual but an additional method of contraception, such as condoms or avoiding sex, should be used for the next 48 hours.

If the woman has had unprotected sex during this time, she should take emergency contraception.

What if there is vomiting or diarrhoea?

If there is vomiting within two hours of taking the POP, the pill will not have been absorbed. The woman should take another pill as soon as she feels well enough. As long as she does not vomit again, the contraception is not affected. The next pill should be taken at the usual time.

If there is severe diarrhoea or vomiting that continues for more than 24 hours, this may make the POP less effective. She should keep taking the pill at the normal time, but treat each day that there is severe diarrhoea should be treated as if there is a missed pill. Follow the instructions above.

What should the woman do if she thinks she may be pregnant?

If she took all the pills correctly and there is no upset stomach or she is not taking any other medicines which might affect the POP, then it's unlikely she is pregnant. She should continue to take the pills as normal.

If she takes the POP when she is pregnant it will not harm the baby. If worried, she should get a pregnancy test. Taking the POP doesn't affect a pregnancy test.

If the woman does become pregnant there's a very small risk that the pregnancy develops outside the uterus (womb). The woman should seek medical advice as soon as possible if she has sudden or unusual pain in the lower abdomen.

The woman wants to have a baby. Can she try to get pregnant as soon as she stops taking the POP?

She can try to get pregnant as soon as she stops taking the POP. She can stop taking it at any time. Ideally, she should wait for one natural period before trying to get pregnant because the pregnancy can be dated more accurately and she can start pre-pregnancy care such as taking folic acid. She should not worry if she gets pregnant sooner, it won't harm the baby.

The woman has taken emergency contraceptive pill and wants to restart her regular POP?

If she has taken emergency contraception pill she should take her next contraceptive pill within 12 hours and use additional contraception such as condoms for 2 days.

11.1.3 Injectable contraceptive ("Depo-Provera" or "Depo")

Contains a progestogen (medroxyprogesterone acetate) and is a LARC. It works by suppressing ovulation (release of the egg into the womb) and by making the mucus plug in the neck of the womb (cervix) thicker so the sperm cannot get through. If the sperm cannot meet the egg, then pregnancy cannot happen.

11.1.3.1 Advantages of using Depo

- It does not interfere with sex.
- Do not have to remember to take a daily pill. The injection lasts for 13 weeks. You don't have to think about contraception for as long as the injection lasts.
- Suitable contraceptive for those who are unable to take oestrogen containing contraceptives such as COC.
- It's not affected by other medicines.
- It may reduce heavy painful periods and help with premenstrual symptoms for some people.
- Can use it while breastfeeding.

11.1.3.1 Side-effects of using the Depo

The periods may change in a way that's not acceptable to the woman. Her periods will probably change. Most often, periods will stop completely. Some injection-users will have irregular periods or spotting (bleeding between periods). Some injection-users will have periods that last longer and are heavier. These changes may be a nuisance but they're not harmful.

Some uncommon side-effects:

- Spotty skin
- Mood swings

The injection works for 13 weeks. It can't be removed from the body, so if there are any side effects, they will continue during this time and for some time afterwards.

There can be a delay of up to one year before the return of periods and fertility after stopping the injection.

11.1.3.2 How to use the Depo injection

The injection can be given any time during the menstrual cycle. If given from day 1-5 of the cycle (i.e. the first to the 5th day of the period), there is immediate protection against pregnancy. If given at any other time during the cycle, condoms should be used or sex avoided for 7 days to allow time for the effects of the injection to establish. The injection is given every 12-13 weeks.

Late getting an injection:

If the woman is more than one week late getting the injection, she may need a pregnancy test before getting the next shot (depending on how late she is). If she has had unprotected sex in the past 5 days, she will need emergency contraception.

The woman has just had a baby. Can she use the Depo?

The injection can be started any time after giving birth. If the injection is given within 21 days of giving birth, there is immediate protection against pregnancy. If started later than day 21 after giving birth, she will need to use an additional method of contraception, such as condoms, or avoid sex, for seven days.

When using the injection within six weeks of giving birth, there is a higher chance of heavy and irregular bleeding. The injection can be used safely while breastfeeding.

11.1.4 Emergency Contraception (“Morning after pill”)

Emergency contraception should be used when a woman has had unprotected sex i.e. sex without using contraception or thinks her contraception might have failed. The morning after pill contains a progestogen (levonorgestrel 1.5mg).

It is one pill which should be taken within 5 days (120 hours) of having unprotected sex but try and give it as soon as possible to the woman who has had unprotected sex should she request it. It becomes less effective the longer the period between unprotected sex and taking the pill, especially beyond 3 days.

It should **NOT** be used as a regular form of contraception

Does emergency contraception cause an abortion?

No. Emergency contraception may stop ovulation (releasing an egg), fertilisation of an egg, or a fertilised egg from implanting in the uterus (womb). Medical research and legal judgement are quite clear that emergency contraception prevents pregnancy and is not abortion. Abortion can only take place after a fertilised egg has implanted in the uterus.

Are there any side effects?

There are no serious short or long-term side effects. Some women may feel sick or may get headaches or a painful period. A very small number will vomit. It may alter the next period. Most side effects go away within a few days

Can it fail?

Some women can get pregnant even though they have taken the emergency contraception correctly and within 72 hours. She may also become pregnant if she delays taking it especially beyond 3 days after unprotected sex, if she vomits within 3 hours of taking it or if she has further unprotected sex. If she vomits within three hours of taking the dose, another dose should be taken. If she vomits later than 3 hours, the pill will have been absorbed.

Can she continue to use other contraception?

If she forgot her regular pill, she should take it within 12 hours of taking the morning after pill. The woman should use additional protection, such as condoms for 7 days with the COC and for 2 days with the POP.

11.1.5 Condoms

Remember condoms also prevent pregnancy and are a form of contraception. It is important to stress that they are **ONLY** effective if used regularly i.e. **EVERY** time when client has sex. It may be suitable for those who do not have a regular sexual partner. If there is a condom breakage, emergency contraception can be given. Another advantage of the condom is that it prevents getting STIs.

Refer to Chapter 9 for more information about condoms.

11.2 ART and contraception

If a client is taking ART, they can still be given contraception. However, there may be interactions of contraceptives with certain ART drugs.

Currently, it is recommended that females taking ART should be encouraged to have the Depo-Provera.

There is a possible likelihood that the contraceptive efficacy may be reduced with the COC or the POP, but if the client insists she does not want the Depo-Provera injection, discuss with the study physician and provide a COC or POP, but advise use of condoms, as efficacy of the contraceptives may be reduced.

11.3 Procedures for providing contraception

- Educate client about the different methods of contraception offered and provide benefits and side effects of each method (Section 11.1). Remember to mention:
 - Pills and injections do not protect against STIs
 - Tell client about emergency contraception and that CHIEDZA provides it
 - Condoms are themselves a form of contraception but not reliable unless used **EVERY** time and correctly when the client has sex.
- Take history and examine to understand eligibility for i) type of contraception and ii) to work out lifestyle factors that make a particular contraception more suitable than others:

Table 11.3: Sexual history and examination

History	Examination
Health factors:	
<ul style="list-style-type: none"> - Diabetes and complications - Breast or liver cancer - Previous stroke or heart disease - Previous clots in leg or lungs - Severe headaches or migraines - Recent serious operations - Epilepsy - High BP 	Measure Blood Pressure Measure Weight Ask about LMP and do pregnancy test if applicable
<ul style="list-style-type: none"> • Medication history • Menstrual cycle; irregular or heavy bleeding? • Previous pregnancy & family size 	
Life-style factors:	
<ul style="list-style-type: none"> • Motivation and reliability: Willing to take pill regularly? • Have regular sexual partner? • Frequency of having sex • Previous contraceptive experience • Desire/plan to have child: i.e. need for reversibility 	

- Based on history and examination, counsel about contraceptive options available. Give client time to ask questions and make an informed decision about their preferred choice
- On repeat appointments, ask about adherence and side-effects or problems and if client is happy with choice. Check BP at least annually if client is on COC.
REMEMBER: most side-effects are transient so reassure client that they will go with time. If unsure, consult study physician.
- Dispense contraception and give repeat appointment date
 - In the first appointment, give a 3-month supply of COC or POP; thereafter give 6 monthly.
 - Always give an extra one pack of pills to ensure client does not miss any doses in case she is unable to attend-she should always have an extra pack of pills available.
 - Encourage use of condoms as well to protect against STIs especially HIV and give condoms with pills and injection.
 - Discuss strategies for remembering to take contraception: alarm, calendar
 - Complete Family Planning register and record contraceptive given on CHIEDZA eCRF (Form CO.01) and on the client-held brown book.

11.4 Dealing with abortion or miscarriage

If a client presents asking for abortion or has had an unsafe abortion, she should be referred to PSZ for further management.

Figure 11.3: What type of contraception should I use?



Source: <https://cdn.shopify.com/s/files/1/1375/3665/files/contraception-methods-image.jpg>

11.5 Frequently Asked Questions

12. General counselling

The CHIEDZA intervention will include general counselling for common issues faced by youth including mental health, substance and alcohol abuse, discrimination and stigma, specific issues faced by key populations, violence and so on. Referrals for counselling could be on issues that are not necessarily related to SRH or HIV- they will be on issues that concern the client and where the team judges that a counsellor may be able to help.

12.1 Providing counselling

Every member of the intervention team will be trained in communication with youth and on counselling on specific health issues (as outlined in the Manual of Operations).

However, this section pertains to referrals made by the rest of the CHIEDZA team to the CHIEDZA counsellor. The intervention team will include a counsellor who will receive additional specialist training on counselling, specifically focusing on common issues faced by youth. The intervention team, including nurses, CHWs and youth workers should refer clients to the team counsellor if particular issues arise that they identify as being beyond their remit to handle.

Record that the client has been referred to the counsellor in the CHIEDZA eCRF (form CO_01).

The counsellor will provide assistance as needed and refer accordingly based on the issue presented by the client. Assist the client in contacting/ accessing the referrals, including calling the referral organisation to set up an appointment if the client agrees. S/he may simply opt to take contact details. Where possible and if the client agrees, the youth worker should accompany the client particularly in red flag situations.

The counsellor should complete the referral register if a referral is made and follow-up with the client about the outcome of the referral (Section 13).

All reasons for counselling should be record in the counselling register.

12.1.1 Procedures

Clients who access counselling will have been referred by the CHIEDZA team. This service will be provided by the counsellor only.

- Greet the clients in non-judgemental and supportive tone
- Practise active listening to their concern(s) and issue(s). Ask them to relate an account of an acute event that may have prompted the consult (if appropriate).
- Offer a range of support options appropriate to the issue, including
 - i. brief counselling (this should not exceed 30 minutes*)
 - ii. referral to appropriate specialist services
 - iii. information on services including the helpline
- Create a plan with the client, and **follow up** as appropriate. In particular, **all red flags must be followed up.**

*Please note that CHIEDZA does not provide a comprehensive, specialist counselling service. CHIEDZA will not provide ongoing counselling- if this is required, please refer the client. If any concerns about what to do, discuss with team coordinator or study physician as appropriate.

12.2 Helpline for General Health Counselling

CHIEDZA is partnering with YAZ to provide a toll-free Helpline for all CHIEDZA clients. The YAZ Helpline (which already exists) provides free advice, information and counselling on HIV/AIDS, TB, GBV, VMMC, SRH, relationships and sex, faith and career guidance. Leaflets with information about the helpline and the phone number will be available at the CHIEDZA centres.

While the YAZ helpline counsellors are trained to provide information and advice, they will be trained on the CHIEDZA protocol and how the existing helpline can complement the CHIEDZA intervention, and, specifically, on data collection by the YAZ team that will be relevant to process evaluation.

12.2.1 Procedures

CHIEDZA clients visiting a help booth will be given information about the helpline and the leaflet.

Give clear instructions to the client that they should identify themselves as CHIEDZA clients if/when they call the helpline and that they can request the helpline counsellor to transfer their call to a CHIEDZA provider if required.

When a client calls the YAZ Helpline, a trained counsellor will respond and link the client to a relevant service provider, as per the client's needs.

If the client asks to specifically speak to a CHIEDZA provider, the YAZ counsellor will transfer the call to the CHIEDZA provider .

12.2.2 Procedures on receipt of a client call

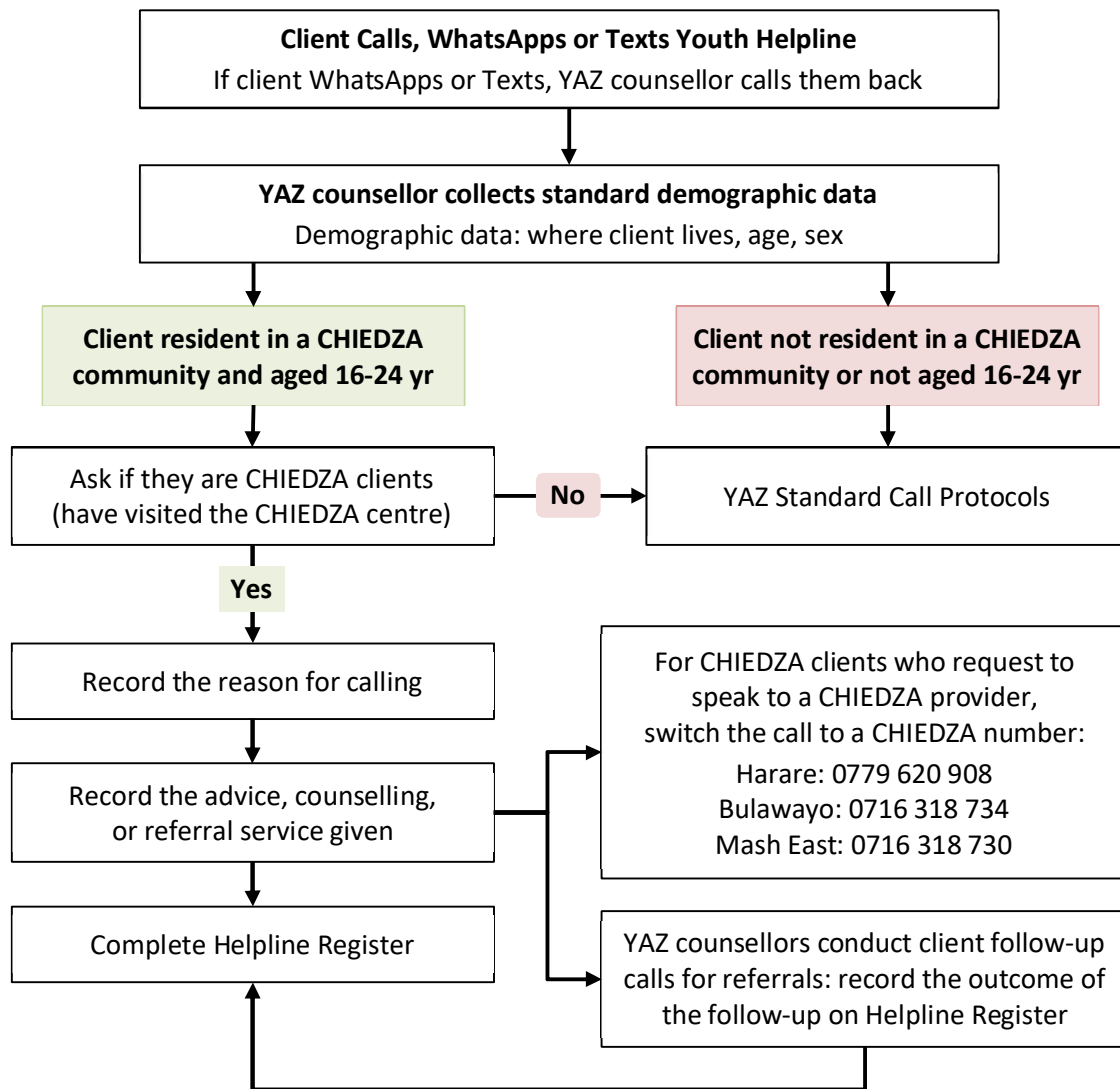
A YAZ helpline data dashboard already exists (to log every call) and this will be customised to collect data on CHIEDZA clients (Figure 12.1).

Note: YAZ Helpline standard procedures include follow-up phone calls for any referral services provided. YAZ counsellors will also record the outcomes of follow up calls for CHIEDZA Clients.

The YAZ counsellors will collate the information about CHIEDZA clients on to the Helpline Register and submit this monthly to the CHIEDZA team.

These data will be used to understand the additional support CHIEDZA clients seek, why they use the Helpline and assess the role of a Helpline in the health-seeking behaviours of young people.

Figure 12.1: YAZ Helpline Flow Chart



12.2 Frequently Asked Questions

Forthcoming

13. Referrals

There will be multiple referral pathways from CHIEDZA:

1. Referral to partner programs for VMMC, cervical cancer screening, PrEP (where available or applicable)
2. Referral to health facilities (this can be a health facility of the client's choice or a cluster health facility)- for linkage to HIV care, FP/contraceptive options not being offered at CHIEDZA, acute clinical events.
3. Referrals for advanced services for issues like mental health, violence, and other red flags as they arise.

13.1 Procedures

The procedures for referrals should will be modified by cluster, based on the relationships established, as well as the types of services, programs and organisations that can be accessed in that community. For each cluster the types of services, programmes and organisation together with contacts (names of responsible person, telephone number, address) will be compiled and summarised in a list available for all staff.

A Referral form will be used to make any type of referral. Every time a referral is made, it should be documented in the Referrals Register, along with the client's phone number and a pseudonym selected by a client (to facilitate follow-up).

13.1.1 Partner Program referrals

- Clients who agree to VMMC and cervical cancer screening (or PrEP) will be given a written referral to identified partner programs in the community. This will be recorded in the CHIEDZA eCRF (Form C0_01).
- The youth workers may escort a client, if the client wishes to.

13.1.2 Health facility referrals

- Clients who test HIV positive through CHIEDZA may opt for subsequent HIV care at a health facility or clients may require referral to a health facility for acute care.
- The client should be given a written referral.
- The youth workers may escort a client, if the client wishes to.

13.1.3 Other referrals

- This is mainly for “red flag” clients i.e. a client who presents with signs and symptoms indicating immediate harm to themselves or others.
- A youth worker or the counsellor must escort the client to a provider capable of providing support or treatment to the client where possible. Ideally this provider should have been contacted by the CHIEDZA team.
- A written referral highlighting the urgency of the referral will be given CHIEDZA providers to the client.

- The external specialised provider should sign on the referral slip to note that they have seen the client.

13.2 Documentation and Follow-up of referrals

Referrals made to partner programmes (i.e. for VMMC or cervical screening) will be noted on the CHIEDZA eCRF (Form Co_01). Any referrals made for VMMC or Cervical screening should also be entered into the Referrals Register.

Referrals made for linkage to HIV care should follow the procedures described in Section 5.

All other referrals should be documented in the Referral Register and should be followed up and the outcome noted in the Referrals Register.

When calling a client to follow-up on referrals, check that it is the client you are speaking to by asking:

- i. If client has attended CHIEDZA and the name of the centre they attended
- ii. Pseudonym they recorded on referral register

13.3 Frequently Asked Questions

SECTION 3

14. Safety considerations

Field staff are responsible for ensuring their safety and for drawing attention to their team coordinator any concerns arising from their work that they believe impacts on their safety, health and well-being.

Below is a guide of some of the common problems that may arise. It is by no means comprehensive. Any frequently anticipated problems not listed in this chapter should be discussed at the weekly team meetings and may be added to this chapter.

Any untoward incident that affects safety of staff or operations (e.g. toilets not working), including issues discussed below, should be reported using the CHIEDZA Incident Form and also raised at the weekly debrief meetings.

14.1 Sharps injuries

These are defined as injuries from sharps include needlestick injuries and injuries from other medical supplies such as syringes, scalpels, lancets and glass from broken equipment. One of the main risks is transmission of blood-borne viruses such as HIV (common in our setting), Hepatitis B and Hepatitis C. The occupational risk of transmission following a significant sharps injury has been shown to be about 1 in 3 when the source is infected with Hepatitis B virus and is HBe antigen positive in an unvaccinated recipient, about 1 in 30 when the source is infected with HCV and about 1 in 300 when the source is HIV-positive. The risk of transmission is higher if the injury is deep, the needle is bigger and the source is untreated.

All staff likely to be exposed to blood should be vaccinated against Hepatitis B

14.1.1 Prevention of sharps injuries

Blood or body fluid from any individual must be regarded as potentially hazardous.

Ensure that any cuts or lesions you may have are covered with a waterproof dressing whilst on duty.

Wear disposable gloves if exposure to blood or body fluids is anticipated, including mopping up spillages.

Always ensure that a sharps bin is available to dispose of any sharp at the point of use. Never start a procedure without having a facility available to dispose of sharps.

Never re-sheath needles. Do not leave a used needle or blade unattended. Always dispose of sharps safely before undertaking another task.

If you find a sharp/needle in an inappropriate place, do not pick up with your hands. Pick up the sharp with forceps, or gently scoop into a dustpan using a brush and place into the nearest Sharps box and report the incident.

Do not allow sharps boxes to become more than two thirds full. It is the responsibility of the study team to ensure that sharps boxes are checked and changed when two thirds full.

Do not shake the sharps box contents down. Sharps can fly out of the box causing injury.

Always place sharps boxes well away from public access areas at a suitable height, e.g. work surface level or waist level.

14.1.2 Dealing with a sharps injury

In the event of a sharps injury, immediately,

1. encourage the **wound** to bleed, ideally by holding it under running water
2. wash the **wound** using running water and plenty of soap; do not use antiseptics or skin washes
3. **do not** scrub the **wound** while you're washing it
4. **do not** suck the **wound**
5. wash exposed mucus membranes (e.g. eyes) with lots of water

Contact your team coordinator immediately and if unavailable seek medical help at your nearest health facility for accessing PEP. Staff members must NEVER act as their own clinician.

It is the responsibility of the team coordinator to ensure that the field team is able to access advice and PEP within two hours of exposure

14.1.3 PEP

The risk of someone being HIV-infected after a needlestick injury from an HIV-infected source person has been estimated at 3 per 1,000, but is lower if the source person is on antiretroviral therapy. The risk after exposure to splashes or contact with other tissues is lower than this. With PEP, this risk can be reduced by 50-95%.

PEP will be offered to staff who are exposed while carrying out duties that are directly related to the work they have been assigned. PEP will NOT be offered to staff for sexual exposures, with the exception of rape while in the field, or exposures while carrying out private duties or duties that have been assigned by another institution.

The team coordinator should ensure that a staff member who experiences a needlestick injury is referred to an appropriate practitioner for PEP, appropriate testing of samples is performed and the staff member is followed up.

14.1.3.1 Indications for PEP

1. **Needlestick injury**
2. **Mucosal contact** (e.g. mouth or eyes): if contact is with blood or constituents of blood (e.g. serum/plasma/semen), or with untreated tissue (e.g. fresh vaginal swab)

material). PEP is not indicated if the contact is with other body fluids (e.g. urine, vomit, saliva, faeces).

3. **Skin contact:** if there is an obvious portal of entry (e.g. a wound or ulcer) on the skin of the exposed person, or if there is extreme contact with the blood or other untreated tissue (e.g. a major splash with blood). PEP is not indicated if there is no obvious portal of entry and the exposure is brief.
4. **Rape:** If a staff member is raped while on field assignment and there has been penetrative vaginal and/or anal intercourse, or if there is oral mucosal contact with semen.

PEP must be started within 72 hours of exposure. **PEP** has little or no effect in preventing HIV infection if it is started **later** than **72 hours after** HIV exposure.

The full course of PEP is 4 weeks and treatment and follow-up will be according to the Zimbabwe National guidelines

14.1.3.2 Testing of samples

Blood from both the source person and the exposed person should be tested for HIV as soon as possible after the incident. The source person should receive full pre-test counselling, and has the right to refuse to be tested. The source person should ideally be tested for HIV using a serological sample sent to a laboratory, not using a rapid blood-based test or with oral mucosal sample. The importance of maintaining confidentiality for the exposed person is paramount.

The team coordinator is responsible for ensuring that the serological testing is done and reported promptly, and that the confidentiality of both the exposed person and the source person is maintained. This should be done by assigning a code to each person.

The decision to continue or stop prophylaxis should be based on the Table 15.1

Table 14.1: Decision to continue or stop prophylaxis

STOP PEP
<ul style="list-style-type: none"> • Exposed person HIV-positive
<ul style="list-style-type: none"> • Exposed person <u>and</u> source person are HIV-negative, where source person is from a low risk group
CONTINUE PEP course
<ul style="list-style-type: none"> • Exposed person <u>and</u> source person are HIV-negative but source person is from high HIV incidence risk group where early HIV infection cannot be excluded
<ul style="list-style-type: none"> • Exposed person is HIV-negative <u>and</u> source person is either HIV-positive or cannot be tested

14.1.3.3 Follow-up

The exposed person should be encouraged to have further counselling and HIV testing at 4 weeks, 3 months and 6 months after the incident to document any sero-conversion.

The exposed person should be assessed clinically at 2 and at 4 weeks if they are receiving PEP to assess their clinical and mental state, with particular assessment of potential drug-related side effects. The exposed person should abstain from being a blood donor and from sex or use a condom consistently during the first six months after exposure. Condoms will be provided by the team coordinator.

14.2 Personal Safety

Personal Safety refers to the freedom from physical harm and threat of physical harm, and freedom from hostility, aggression, harassment, and devaluation at the workplace.

Safety includes worry about being victimized as well as actual incidents.

Each staff member should recognise and avoid possible harmful situations or persons in their work surroundings. Any concern, however small, must be reported to the study team coordinator, so that appropriate action can be taken to maintain the safety of the study team.

Personal Safety

- Reduce or eliminate opportunities that may make you a target
- Increase awareness in places you're most comfortable
- Trust your instincts regardless of feeling embarrassed
- Prepare your schedule daily with safety in mind
- Report anything suspicious or anything that makes you uncomfortable
- Move around in pairs in areas where you have safety concern

The study team should refuse to allow clients on to the premises that are under the influence of alcohol or illicit substances.

There will be zero tolerance of abuse of staff. Clients who are in any way abusive to a staff member should be given a warning and escorted from the premises by a male staff member.

When conducting examinations, always offer a chaperone (of the same gender as the client) to the client. This protects both the staff member and the client.

The study vehicle should be parked in a designated parking area within the centres and locked. During outreach, the vehicle should be parked in designated areas only. No valuables should be left in the study vehicle.

Take a 30-minute lunch or tea-break during your shift.

Dealing with the many issues that clients may have can result in burnout and stress. It is important to share some of the problems clients may have approached that you find difficult to deal with professionally or personally to the weekly debrief sessions. Sharing issues with team members can help relieve some of the stress. You are also encouraged to speak with your team coordinator if you are experiencing difficulties with mental health problems. The team coordinator will facilitate referrals for professional help if required. What you share will be treated with complete confidence.

14.3 Manual handling

Manual handling covers a wide variety of activities including lifting, lowering, pushing, pulling and carrying. If any of these tasks are not carried out appropriately there is a risk of injury. **Whenever possible try to lift or move heavy loads in pairs. Do not lift loads if you are pregnant.**

14.3.1 Good handling technique for lifting

- Remove obstructions from the route.
- For a long lift, plan to rest the load midway on a table or bench to change grip.
- Keep the load close to the waist. The load should be kept close to the body for as long as possible while lifting.
- Keep the heaviest side of the load next to the body.
- Adopt a stable position and make sure your feet are apart, with one leg slightly forward to maintain balance
- Reduce the amount of twisting, stooping and reaching
- Avoid lifting from floor level or above shoulder height, especially heavy loads

Figure 14.1: Good handling technique



1. **Adopt a stable position:** The feet should be apart with one leg slightly forward to maintain balance (alongside the load, if it is on the ground). Be prepared to move your feet during the lift to maintain your stability. Avoid tight clothing or unsuitable footwear, which may make this difficult.
2. **Get a good hold:** Where possible, the load should be hugged as close as possible to the body. This may be better than gripping it tightly with hands only.

3. **Start in a good posture:** At the start of the lift, slight bending of the back, hips and knees is preferable to fully flexing the back (stooping) or fully flexing the hips and knees (squatting).
4. **Don't flex the back any further while lifting:** This can happen if the legs begin to straighten before starting to raise the load.
5. **Keep the load close to the waist:** Keep the load close to the body for as long as possible while lifting. Keep the heaviest side of the load next to the body. If a close approach to the load is not possible, try to slide it towards the body before attempting to lift it.
6. **Avoid twisting the back or leaning sideways, especially while the back is bent:** Shoulders should be kept level and facing in the same direction as the hips. Turning by moving the feet is better than twisting and lifting at the same time.
7. **Keep the head up when handling:** Look ahead, not down at the load, once it has been held securely.
8. **Move smoothly:** The load should not be jerked or snatched as this can make it harder to keep control and can increase the risk of injury.
9. **Don't lift or handle more than can be easily managed:** There is a difference between what people can lift and what they can safely lift. If in doubt, seek advice or get help.
10. **Put down, then adjust:** If precise positioning of the load is necessary, put it down first, then slide it into the desired position.

14.4 Frequently Asked Questions

15. Training

This section describes the types and levels of training to be provided to best equip the intervention team to deliver the intervention package.

15.1 Initial Training

Each intervention team will undergo a 4-week training programme on the intervention package (see Appendix 4 for Training Programme).

Each member of the intervention team will be trained on GCP and will be expected to have up-to-date GCP certification

15.1.1 Induction and Training of new staff

New staff who may join the team to replace a team member who leaves will receive training from the Coordinator of the team they are joining. Timelines permitting (staggered start dates in CHIEDZA), this new staff member should 1) attend the initial training of a new intervention team 2) shadow an already existing intervention team or 3) shadow the staff member they will replace if feasible.

15.2 Weekly Debriefs

During the pilot, the intervention team will provide services in the pilot cluster 3 days a week and the team will meet for debriefs, feedback and discussion of any changes to be made in retraining. During the trial phase, a weekly debrief meeting will be held once a week, facilitated by the CHIEDZA team coordinators.

The aim of the weekly debriefs is to i) identify any issues in content or delivery ii) identify and address knowledge gaps iii) discuss difficult cases/issues encountered by the team and iv) retraining required.

- The training will be informed by the issues raised by the team.
- The debrief will serve as an opportunity to discuss and record i) any changes in procedures (recorded in Appendix 1) and ii) FAQs or myths that come up (to inform learning).

The Manual of Operations will serve as a reference for implementation procedures and will be supplemented with further information and guidance as identified during debriefs.

A CHIEDZA Debrief form recording the debrief meeting will be completed at the end of the each debrief, which will be used to supplement the Manual of Operations.

15.3 Refresher trainings

Refresher trainings will be customised to respond to i) challenges faced by the team ii) any changes/new guidelines by the MOHCC. In addition, refresher training will be held 6 monthly.

Appendices

Appendix 2. List of Clusters and Cluster maps

Cluster	Intervention/ Control	Cluster Clinic	CHIEDZA Centre	
Harare Province				
RANDOMISATION DATE: 01/11/2018				
1	Budiriro	Intervention	Budiriro Polyclinic	Budiriro 1 Community Centre
2	Dzivarasekwa	Control	Rujeko Polyclinic	Dzivarasekwa 2 Community Hall
3	Glenview	Control	Glenview Polyclinic	New Glenview Community Hall
4	Hatcliffe	Intervention	Hatcliffe Polyclinic	Hatcliffe Community Centre
5	Highfields	Control	Highfield Polyclinic	Cyril Jennings Hall
6	Hopley*	Intervention	Hopley Satellite Clinic	Hopley Community Centre
7	Tafara	Intervention	Tafara Clinic/ Mabvuku Polyclinic	Tafara Community Centre Number two
8	Mufakose	Control	Mufakose Polyclinic	Mufakose Area 4 Community Hall
9	Sunningdale*	Control	Sunningdale Satellite Clinic	Sunningdale Community Hall
10	Warren Park	Intervention	Warren Park Polyclinic	Magamba Hall, Warren Park
Mashonaland East				
RANDOMISATION DATE: <i>TBC</i>				
1	Epworth		Epworth Polyclinic	Epworth Local Board Hall
2	Dombotombo, Marondera		Dombotombo Clinic	Mbuya Nehanda Community Hall
3	Ruwa		Ruwa Polyclinic	
4	Zengeza, Chitungwiza		Zengeza Clinic	Chitungwiza Community Hall
5	Seke North, Chitungwiza		Seke North Clinic	DDF Seke Chief's Hall
6	St Marys, Chitungwiza		St Marys Clinic	St Mary's Community Hall
Bulawayo				
RANDOMISATION DATE: <i>TBC</i>				
1	Cowdray Park		Cowdry Park Clinic	Nehemiah Centre
2	Emkhandeni		Emakhandeni Clinic	Emakhandeni Hall
3	Mzilikazi		Mzilikazi Clinic	Mzilikazi Youth Centre
4	Nketa		Nketa Clinic	Nketa Hall
5	Nkulumane		Maqhawe Clinic	MMPZ Youth Centre
6	Tshabalala		Tshabalala Clinic	Indlovu Youth Centre
7	Pelandaba		Pelandaba Clinic	Phumelela Youth Centre
8	Pumula		Old Pumula clinic	Isilwane Youth Cente

*Hopley to be covered by the Mashonaland East Team. Corresponding control cluster is Sunningdale

Appendix 3. Forms, CRFs, Logs and Registers

CRFs and Logs to Be Completed at each visit							Time post-enrolment									
A=All Clients, C=Eligible clients only, D=HIV Cohort Clients Only							Weekly									
		Platform	Screen	Enrol/ Reg			1m	3m	6m	9m	12m	15m	18m	24m		
CHIEDZA General							Monthly	2wks	1m	3m	6m	9m	12m	15m	18m	24m
Logs	CL.01 Screening Log	CTO	A													
	CL.02 Attendance Log		C													
	CL.03 eCRF Dispatch Log		C													
	CL.04_Form Transportation Log	Paper														
Menu	Menu Card	Paper														
	Incident Reporting Form	Paper	C													
	Referral Form	Paper														
Forms	Debrief Form	Paper														
	Partner Notification Slip	Paper														
	GC/CT Screening Slip	Paper		C												
Registers	MOHCC HIV Self Testing Register	Paper														
	MOHCC STI Register	Paper														
	MOHCC Family Planning Register	Paper														
	CHIEDZA Referral Register	Paper														
	CHIEDZA Counselling Register	Paper														
	CHIEDZA YAZ Helpline Register	Paper														
	CO.01_Reg_Follow_Services eCRF	CTO			C											
	CO.02_ITHAKA Tracing Form eCRF	CTO														
	CO.03_ELISA Form CRF/eCRF	Paper/CTO														
	CO.04_GC/CT Form CRF/eCRF	Paper/CTO			C											
Apps	ITHAKA APP	ITHAKA		C												
	CHIEDZA HIV Cohort							Monthly	2wks	1m	3m	6m	9m	12m	15m	18m
Logs	MOCC ART Book (Source document for clinical care)	Book		D												
	CHL.01 Locator Form	Paper		D												
	CHL.02 PIMA Logsheet	Paper														
Registers	CAPS Register															
	CAPS Session Form	Paper														
Forms	CH.01_Initial Form eCRF	CTO		D												
	CH.02_Follow-up Form eCRF	CTO														
	CH.03_Unscheduled visit Form eCRF	CTO														
	CH.04_Cohort Exit Form eCRF	CTO														
	CH.05_Death Form eCRF	CTO														
	CH.06_Tracing Form CRF/eCRF	Paper/CTO														
	CH.07_Caps Enrolment Form eCRF	CTO														
	CT.01_CD4 Count and CRAG Form CRF/eCRF	Paper/CTO			D											
	CT.02_HIV Viral Load Form CRF/eCRF	Paper/CTO														
	CT.03_geneXpert TB Screening Form CRF/eCRF	Paper/CTO														



Referral Form

Where client is being referred to:

Dear colleague,

We would be grateful if you could see our client

Client name: _____

Client Age:

Client's Sex: M F

Date of referral / /

CHIEDZA Centre of referral:

Name of referring person:

Reason for referral:

- | | |
|---|---|
| <input type="checkbox"/> HIV care | <input type="checkbox"/> CXR |
| <input type="checkbox"/> TB treatment | <input type="checkbox"/> VMMC |
| <input type="checkbox"/> Antenatal care | <input type="checkbox"/> Cervical screening |
| <input type="checkbox"/> Other problem, see below for details | |

Clinical history or additional information (such as test results):

if you have any questions please contact the Chiedza team:



Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734

CHIEDZA DEBRIEF FORM

This form should be completed for each debrief meeting

Date of debrief meeting	/ /20
Team	HRE BWO ME
Team members present:	Team members absent:
Meeting facilitated by	
Meeting time (24 hour clock)	. to .

Issues in content or delivery of service that arose in last week

Cluster	Issue	Action to be taken

Challenging cases in the past week

Cluster	Challenging case	Action to be taken

FAQs or myths reported in past week

Cluster	What was FAQ/Myth	Response

Common issues that came up on phone calls in the past week

Cluster	What was FAQ/Myth	Response

Training at this meeting

Subject	Name of trainer and any details on mode of training

Any additional training / support that the team members think they need?

CHIEDZA INCIDENT REPORTING FORM

Reported incidents may include needle stick injuries, assaults, fire, flat tyres and any field procedure that requires action

Date of incident	/ /20		
Date of reporting	/ /20		
Team	HRE	BWO	ME
Cluster (and specify area where incident occurred e.g. en route, which area in centre)			
Name of the person reporting incident			
Name/type of persons affected by incident A: CHIEDZA team member(s) only B: CHIEDZA participant(s) only C: CHIEDZA team member(s) AND participant(s) D. Other (i.e. community members)			
Name of the person informed			
Briefly describe incident/problem (write at back of form if not enough space)			
Immediate action taken			
Follow-up action			
Possible preventive actions (write at back of form if not enough space)			
Name of reviewer of incident (Coordinator/PI)			
Date of review	/ /20		
Incident resolved	Y	N	Ongoing
Date incident resolved	/ /20		
Reported to MRCZ	Y	N	N/A
Comment			

CHIEDZA CAPS SESSION FORM

This form should be completed for each debrief meeting

Date of Session	/ /20			
Cluster				
Session time (24 hour clock)	. to .			
Delivered by: (initials & role eg CHW, YW, nurse)				

Description of the social time / type of social activity done:
--

Subjects discussed in Discussion session

Were there any challenges or difficulties in content / delivery /other in CAPS session?

Issue	Action taken

--	--

Was there anything that worked well or was particularly positive in content/ delivery/ other in CAPS Session?

FAQs or myths that came up during the CAPS session

What was FAQ/Myth	Response

Any suggested improvements for future sessions

Any additional training / support that team members delivering CAPS think that they need?

--

CO.01 CHIEDZA

REGISTRATION and SERVICES FORM

B01	USER	User Name of CHIEDZA team (Select your Name)	
B02	FING	Did Client agree to Fingerprint check	Yes No
B05	CLUS	Cluster Number	-
IDENTIFICATION (Explain about SIMPRINTS)			
B03a	FMATCH	If Yes in B02 Search for Finger print	Not Entered Manually
B03a	STDIDFP	If Yes in B02 and Matched in B03aFMATCH Finger print GUID	Not Entered Manually
B03b	MMATCH	If No in B02 Search for Manual ID	Match 1 None
B03	STDIDM	If No in B02 and Matched in B03b MMATCH (Manual ID)	CH
B03c	IDENT	If B03a or B03b is not NONE Client Identified	Yes No
B03	STDIDF	If Yes in B02 and NONE in B03a Register on SIMPRINTS (Finger print GUID)	Not Entered Manually
B03	STDIDM	If No in B02 and NONE in B03b Register Manually (Manual ID)	CH
B02	VISIT	Type of Visit	First Follow-up
OTHER REGISTRATION INFO (Preloaded if Follow-up visit)			
B06	INIT	Client Initials	
B07	AGE	Date of Birth	/ /20
B08	Sex	Sex	Male Female
B09	DATER	Date of Registration (dd/MMM/yyyy)	/ /20
B10	TEST	Current HIV status (Updatable)	Confirmed Positive (on ART) Positive (Not on ART) Unknown Known Negative > 6 months Known Negative < 6 months

CO.01 CHIEDZA

REGISTRATION and SERVICES FORM

SERVICES ACCESSED					
B11	DATE	Date of Visit (dd/MMM/yyyy)	/ /20		
HIV TESTING and TREATMENT SERVICES					
B15	HSERV	HIV Services accessed at this visit	HIV Test (ITHAKA) HIV Test (Blood Based) Joining CAPS Joining HIV Cohort HIV Cohort Visit None		
B14	ARES	ITHAKA test Result (Preloaded linked to ITHAKA csv)	Reactive Non Reactive Indeterminate Unknown/Pending NA		
B16	MOD	Preferred HIV Screening Mode	Provider testing Self Testing at Site (ITHAKA) Self Testing at Home (ITHAKA) NA		
B17	KIT	Barcode of Test –kit (Preloaded if Follow-up Visit)	CH NA		
B18	FRES	HIV Test Outcome (Blood Based)	Positive Negative Indeterminate NA		
B18a	ELISA	If HIV Test Indeterminate Client referred for ELISA	Yes	No	NA
B18b	PATH	If HIV Diagnosed at this visit Partner Slip(s) Given	Yes	No	NA
B18c	PATHN	If Yes in B18b Number of Partner Slips given	NA		
B13	STUDYNOH	If joined HIV cohort Study ID Number	D		

CO.01 CHIEDZA

REGISTRATION and SERVICES FORM

SRH SERVICES				
B19	COND	Condoms given	Yes No No, Out of stock	
B19	SRH	SRH Services accessed at this Visit (Tick all that apply)	Family Planning MHM Cohort Visit MHM Products STI Consultation	STI Treatment STI Review GC/CT Test TV Test None
B20	Preg	Pregnancy Test Result	Positive Negative Indeterminate Not Done	
B21	Meth	Family Planning Method	COC POP Depo EC	Implant Information only IUCD Out of Stock NA
B21	MethO	If Method out of stock specify method and why not available		
B22	Diag	STI Treatment (Tick all that apply)	GUD(MF) UD(M) VD(F) Candida (F) PID(F) Warts(MF)	Epid-orchitis (M) Bubo (MF) Balanitis (M) CT Pos (MF) GC Pos (MF) TV Pos (F) NA
B22a	GCCTP	Client Previously screened for GC/CT	Never	≤6mths ago >6mths ago
B22b	GCCT	GC/CT Testing number	GC	
B22c	PATS	If STI Diagnosed at this visit Partner Slip(s) Given	Yes	No NA

CO.01 CHIEDZA

REGISTRATION and SERVICES FORM

B22d	PATSN	If Yes in B22c Number of Partner Slips given	NA		
B23a	MHMP	MHM Products given (Client can only take one Item – but if not happy with it can return it after 3 months)	Reusable Pads Kit Period Pant Menstrual Cup Information Only Out of Stock Less than 3 months since last product None		
B24a	PARCT	Paracetamol tablets (Max 12)	Yes	No	NA
B24b	BRUF	Brufen Pain tablets (Max 12)	Yes	No	NA
B25	MHM	Joined MHM Cohort	Yes	No	NA
B25a	STUDYN OM	If in MHM cohort Study ID Number (Preloaded)	M		
OTHER SERVICES					
B26	VMMCP	Client previously circumcised	Yes	No	NA
B26b	VMMC	If not circumcised Referred for VMMC	Yes	No	NA
B27	CERV	Referred for cervical cancer screening	Yes	No	NA
B28	COUNS	Referred for Counselling to Chiedza Counsellor	Yes, first time Yes, follow-up No		
B29	REDFLAG	Red Flag (Preloaded)	Sexual assault/rape Severe mental health problem/suicide Severe STI Severe illness (referred to hospital) Miscarriage/Abortion Physical/Emotional Abuse None		

CO.01 CHIEDZA

REGISTRATION and SERVICES FORM

REGISTRATION (First visit only)			
B02	CONS	Client Consent to Fingerprint For Registration	Yes No
B03	STDIDF	If consent for fingerprint (Yes in B02) Register on SIMPRINTS (Finger print GUID)	(Not entered manually)
B03	STDIDM	If fingerprint consent refused (No in B02) Register Manually	CH (Enter barcode manually)

CO.02 CHIEDZA

ITHAKA HIV SELF-TESTING TRACING OUTCOME FORM

L01	STUDN	Barcode kit number	CH
L02	CLUSTER	Cluster Number	-
L03	DATE	Date of completion form	/ /20
L04	INTID	Interviewer ID	
TRACING			
L05	CALL	Phone call outcome	<p>Client attended before a tracing call</p> <p>Client found and given appointment for follow-up visit</p> <p>Client found and has decided not to complete ITHAKA journey</p> <p>Client deceased</p> <p>No response to phone call (number not available/ not answered)</p> <p>Client did not turn up even after the 2nd appointment</p>
L06	APPT	Date of appointment if Client found and has not withdrawn from ITHAKA journey	/ /20
L07	CONFL	Where confirmatory HIV test done	<p>At CHIEDZA</p> <p>Elsewhere</p> <p>No confirmatory testing done (LTFU)</p>
L08	CONFR	Confirmatory HIV Test results	<p>HIV positive</p> <p>HIV-negative</p> <p>Don't know/confirmatory test not done</p>
L09	OUTC	Client linked to care	<p>Yes, to CHIEDZA</p> <p>Elsewhere</p> <p>Not linked to care (LTFU)</p>
L10	COHOT	If linked to CHIEDZA, HIV cohort number	D

ELISA TEST REQUEST FORM

E01	STUDYNO	STUDY NUMBER	CH		
E02	CLUS	Cluster	-		
E03	INITIALS	Client initials			
E04	DATE	Date specimen was collected	/ /20		
E05	COLID	Specimen collected by			
Lab to fill the Section Below					
E06	PROCID	Specimen processed by			
E07	ELISA	ELISA Test Result	Positive	Negative	Indeterminate
E08	COMM	Comments			
E09	COMP	Completed by			

Tear off and insert in client notes

STUDY NUMBER	
CLUSTER	
INITIALS	
DATE OF TEST	
ELISA Test Result	Positive Negative Not Done

CO.04 CHIEDZA

GC/CT SCREENING FORM

TO BE FILLED BY THE FILLED TEAM

G01	SAMPNO	Sample Number	GC		
G02	CLUSTER	Cluster	-		
G03	TREAT	Already treated for GC/CT	Yes	No	
G04	Date	Date specimen was collected (dd/MMM/yy)	/	/	
G05	CONS	Consent for storing urine given	Yes	No	NA(Not Harare)
G06	HCW	Health care worker filling the form (Initials)			

TO BE FILLED BY THE LABORATORY

G07	Date	Date specimen received in the laboratory (dd/MMM/yy)	/ /		
G08	CT	CT Test Result	Positive	Negative	Indeterminate
G09	GC	GC Test Result	Positive	Negative	Indeterminate
G10	ALIQ	Number of aliquots			
G11	Stor1	Storage Aliquot 1	BOX No	Pos No	
G12	Stor2	Storage Aliquot 2	BOX No	Pos No	
G13	COMP	Completed by			

-----Tear Off Here and Send to Site-----

(Only for those not treated)

Cluster	-				
Sample Number	GC				
Pseudonym					
Telephone-Nr					
CT Test Result	Positive	Negative	Indeterminate		
GC Test Result	Positive	Negative	Indeterminate		

CH.01 CHIEDZA_HIV COHORT

INITIAL VISIT Form
(At Registration into HIV COHORT)

C01	STUDYNO	Study ID Number	D
C02	DATE	Date of interview dd/MMM/yyyy	/ /20
C02b	INTVW	Interviewer ID	
C03	HIVNO	OI clinic number	
C04	INIT	Client initials	
C05	DOB	Date of Birth	/ /
C06	SEX	Sex of client	Male Female
C07	MAT	Current Marital status	Married (married or living as married) Single
C08	EDUC	Highest level of education completed	None Primary Secondary Tertiary
C09	EMPLOY	Current occupation (tick all that apply)	Student Formally-employed Self- Employed Unemployed
C10	DATEHIV	Date of HIV diagnosis (confirmed HIV positive result)	/ /
C11	DIAGH	Diagnosed through CHIEDZA	Yes No
C12	PDIAG	If not diagnosed through CHIEDZA (C11 is No) Already on ART	Yes No NA
C13	PDIAGD	If not diagnosed through CHIEDZA and Already of ART (C11 is No and C12 is Yes) Date Started ART	/ /
C14	DRUGS	If not diagnosed by Chiedza and already on ART (C11 is No and C12 is Yes) Please	

CH.01 CHIEDZA_HIV COHORT

INITIAL VISIT Form (At Registration into HIV COHORT)

		tick ART drugs the client is on: (tick all that apply)		
		Not Applicable	Yes	No
		AZT (Zidovudine)	Yes	No
		TNF (Tenofovir)	Yes	No
		ABC(Abacavir)	Yes	No
		3TC (Lamuvudine)	Yes	No
		DDI (Didanosine)	Yes	No
		NVP (Nevirapine)	Yes	No
		EFV (Efavirenz)	Yes	No
		ATV (atazanavir)/ R (ritonavir)	Yes	No
		Other	Yes	No
		Specify Other ART Drugs		
C15	LVLDT	If not diagnosed through CHIEDZA (C11 is No) Did client have a Viral Load	Yes	No NA
C16	LVLV	If not diagnosed through CHIEDZA (C11 is No) What was the last Viral Load		
C17	LVLDT	If not diagnosed through CHIEDZA (C11 is No) What was the date of last Viral Load	/	/
C18	LCD4D	If not diagnosed through CHIEDZA (C11 is No) Did client have a CD4 Count	Yes	No NA
C19	LCD4V	If not diagnosed through CHIEDZA (C11 is No) What was the last CD4 count		NA
C20	LCD4DT	If not diagnosed through CHIEDZA (C11 is No) What was the date of last CD4 Count	/	/ NA
C21	CD4	If diagnosed through CHIEDZA (C11 is Yes) CD4 Count Done	Yes	No NA
C22	CGH	Has client had a cough?	Yes	No NA
C23	NSWT	Has client had night sweats for ≥ 3 weeks	Yes	No NA
C25	WGHTL	Has client lost weight (≥ 3 kg if able to quantify) in the past 3-4 months	Yes	No Don't know NA

CH.01 CHIEDZA_HIV COHORT

INITIAL VISIT Form (At Registration into HIV COHORT)

C26	FVR	Has client had a fever or "hot body " for ≥3wks	Yes No Don't know NA
C27	CNCTT	Does someone in the client's household have known active TB?	Yes No Don't know NA
C28	TB	WHO symptom screen TB suspect	Yes No On TB Treatment NA
C29	SPUT	If TB Suspect (C28 if Yes) Sputum sample collected	Yes No NA
C30	CXR	If no sputum collected (C29 is No), referred for Chest -Xray	Yes No NA
C31	COTRI	Client commenced on cotrimoxazole (If CD4 <350)	Yes No NA
C32	WGT	Current Weight	. kg
C33	BP	Current Blood Pressure	/
C34	DATEART	If diagnosed through CHIEDZA (C11 is Yes) ART initiation today	Yes No NA
C35	ARTNO	If ART not initiated (C21 is No) please indicate why ART was not initiated (Tick all that apply)	CrAg positive Suspected TB Not Ready Acutely unwell Started Cotrimoxazole today NA

CH.01 CHIEDZA_HIV COHORT

INITIAL VISIT Form (At Registration into HIV COHORT)

C36	DRUGS	If started on ART (C21 is Yes) Please tick ART drugs supplied to the client Current is "TC/EFV/TNF): (tick all that apply)		
		NA	Yes	No
		AZT (Zidovudine)	Yes	No
		TNF (Tenofovir)	Yes	No
		ABC(Abacavir)	Yes	No
		3TC (Lamuvudine)	Yes	No
		DDI (Didanosine)	Yes	No
		NVP (Nevirapine)	Yes	No
		EFV (Efavirenz)	Yes	No
		ATV (atazanavir)/ R (ritonavir)	Yes	No
		Other	Yes	No
		Specify Other ART Drugs		
C37	DRUGSQ	How many weeks supply given	NA	
C38	CERV	Referred for cervical screening	Yes No NA	
C39	CERV	Referred for VMMC	Yes No NA	
C40	NVISIT	Follow up appointment date	/ /20	

CH.02 CHIEDZA_HIV COHORT

FOLLOW-UP FORM (all visits after the initial visit)

R01	IDNO	ID Number	D		
R02	CLUS	Cluster Number	-		
R03	DATE	Date of visit (dd/mm/yyyy)	/ /20		
R04	CLI	Who is attending this visit (complete CH08 if missed)	Client Buddy/other Missed		
R05	BUD	If buddy or other, nurse happy with identity of proxy attendee (complete CH08 if No) If Yes Go to R30	Yes	No	NA
Complete Question R05 to R29 if Client Only attended Visit					
R06	VISTP	Is this client's first visit after cohort registration visit	Yes No		
R07	IBUD	Has client identified a buddy	Yes	No	Already Identified
R07b	CBUD	Given Buddy card and recorded contact details	Yes	No	NA
R08	RELB	Relationship of buddy to client	Parent Sibling Other relative Friend No one identified NA		
R09	CAP	Is client joining CAPS	Yes	No	Already Joined
R09b	FCAP	Completed Caps enrolment form	Yes	No	NA
R10	ART	On ART	Yes No		
R11	ARTS	If not on ART being Started at this visit	Yes	No	NA
R12	ARTNO	If ART not initiated at this visit please indicate why ART was not initiated (Tick all that apply)	Investigation/Treatment for Crypto Investigation/Treatment TB Not Ready Acutely unwell NA		
R13		What type of visit is this? <ul style="list-style-type: none"> • Clinical review on ART: Week 2, week 4, month 6, month 12, month 18 post ART • ART Refill visit: On ART and NOT "clinical review on ART" visit 	Clinical review on ART ART Refill visit Review not on ART		

CH.02 CHIEDZA_HIV COHORT

FOLLOW-UP FORM (all visits after the initial visit)

		<ul style="list-style-type: none"> Review not on ART: Client attending but not yet on ART 		
R14	DISC	Disclosure (tick all that apply)	Partner Parent Sibling Family other	Friend(s) Church member Teacher No disclosure Already disclosed
R15	HOSP	Hospitalised since last visit	Yes No	
R16	DHOSP	Number of hospitalisations since last visit (Enter 0 if none)		
R17	RHOSP	Reason for hospitalisation(s) Check all the reasons that apply (Where possible confirm using hospital and patient held cards)	NA TB Infection Specify _____ Trauma/Burns Heart problems Poisoning /overdose Surgery (including elective surgery) Kidney problem Cancer Diabetes Asthma Epilepsy Skin Rash (including SJS) Jaundice Vomiting and Diarrhoea Psychiatric side effects Other Specify _____	
R18	WGHT	Weight (kgs)	.	
R19	BP	Blood Pressure	/	
R20	VL	Has the client had a viral load test done?	Yes No NA	

CH.02 CHIEDZA_HIV COHORT

FOLLOW-UP FORM (all visits after the initial visit)

R21	CD4	Has the client had a CD4 count done? (done at 12 month post cohort registration and/or post starting ART. If these 2 dates are <3 months apart don't repeat)	Yes	No	NA
R22	CERV	Referred for Cervical screen	Yes	No	NA
R23	VMMC	Referred for VMMC	Yes	No	NA
Side-effects/toxicity and DAIDS Grade (if on ART):					
R24a	NAUS	Nausea	Yes	No	Grade NA
R24b	VOM	Vomiting	Yes	No	Grade NA
R24c	DIAR	Diarrhoea or loose bowel movements	Yes	No	Grade NA
R24d	FATG	Fatigue or loss of energy	Yes	No	Grade NA
R24e	RASH	Skin rash	Yes	No	Grade NA
R24f	FVR	Fever	Yes	No	Grade NA
R24g	JAUN	Yellow eyes (jaundice)	Yes	No	Grade NA
R24h	ABDN	Abdominal pain	Yes	No	Grade NA
R24i	HEAD	Headache	Yes	No	Grade NA
R24j	DRM	Vivid /Bad dreams	Yes	No	Grade NA
R24k	CONF	Confusion	Yes	No	Grade NA
R24l	INSOM	Insomnia	Yes	No	Grade NA
R24m	PSYCH	Psychiatric disorder	Yes	No	Grade NA
R25	ISSUE	Does client have any significant issues	Yes	No	
R26	DISSU	If yes, briefly state what			
R27	ACT	Action taken	Referred to counsellor Referred to PHC Referred to Hospital Referred to Other services Problem resolved by discussion No significant issue NA		

CH.02 CHIEDZA_HIV COHORT

FOLLOW-UP FORM (all visits after the initial visit)

R28	ARTEL	If female what was the pregnancy test result for the client at this visit (Put Not applicable for Females who have not been tested or Males)	Positive Negative NA
R29	ARTCH	Is the client changing ART regimen since last visit?	Yes No NA
R30	RESCH	If the client is changing ART regimen what was is the reason for change	Drug reaction Treatment failure Drug not available Other Specify Other _____ NA
R31	DRUGS	Please tick ART drugs the client is taking: (tick all that apply)	
		NA	Yes No
		AZT (Zidovudine)	Yes No
		TNF (Tenofovir)	Yes No
		ABC(Abacavir)	Yes No
		3TC (Lamivudine)	Yes No
		DDI (Didanosine)	Yes No
		NVP (Nevirapine)	Yes No
		EFV (Efavirenz)	Yes No
		ATV (atazanavir)/ R (Ritonavir)	Yes No
R32	DRUGQ	How many weeks' supply given	weeks NA
R33	COTR	Is cotrimoxazole being prescribed	Yes No
R34	COTRQ	How many weeks supply of cotrimoxazole is being given?	Weeks NA
R35	VLOC	Where is this visit taking place?	At CHIEDZA Centre At CAPS
R36	NAPPT	Client's next appointment date	/ /

CH.03 CHIEDZA_HIV COHORT

UNSCHEDULED VISIT FORM

U01	STUDYNO	STUDY NUMBER	D
U02	CLUSTER	Cluster number	-
U03	DATEA	Date of assessment (dd/mm/yyyy)	/ /
U04	INTID	Interviewer ID	
U05	PURP	Purpose of visit (Tick All that apply)	<div style="text-align: right;"> Counselling Lost/ran out of medicines Side-effects of medicine Feel ill Specify illness _____ Other Specify _____ </div>
U06	HOSP	Did this visit result in hospitalisation?	Yes No

Symptoms

Management

For Study Nurse or Study Physician ONLY.			
U07	DIAG	Diagnosis	_____

CH.04 CHIEDZA_HIV COHORT

COHORT EXIT FORM

SE01	STUDN	Study number	D	
SE02	CLUS	Cluster number	-	
SE03	DATE	Date this form is completed	/	/20
SE04	ADATET	Date of termination (the last time participant had a scheduled study visit)	/	/20
SE05	INTID	Interviewer ID		
REASON FOR STUDY EXIT				
SE06	REAEX	Reason for study exit	Death Withdrawal	Lost to follow up Study ended
SE07	WDRW	If participant withdrew, date of withdrawal	/	/20 N/A (Participant has not withdrawn)
SE08	REASONW	Reason for withdrawal	Did not withdraw Participant refused to continue in the cohort Participant moved out of the study area Seeking care elsewhere (but staying in area) Other Specify _____	
SE09	REF	Where did client decide to seek care if decided to seek care elsewhere	PHC Hospital-based clinic Private doctor Faith healer Other Specify _____ Not seeking care elsewhere	
Note: <ul style="list-style-type: none"> If participant not found or moves away from study area without informing study team, that is considered Loss to follow-up (not withdrawal) If participant moves out of a study area and informs the study team, and the move results in them unable to continue following-up, this is considered withdrawal and the "participant moved out of the study area" option should be ticked 				

CH.05 CHIEDZA_HIV COHORT

DEATH FORM

X01	STUDN	Study number	D
X02	CLUS	Cluster	-
X03	DATE	Date this form is completed	/ /20
X04	INTID	Interviewer ID	
X05	DATED	Date of death	/ /20
X06	PLACED	Place of death	At Home Hospital Facility In Community
X07	CAUSED	Cause of death	_____ _____
X08	EXIT	STUDY EXIT FORM (CH.06) completed?	Yes No

CH.06 CHIEDZA_HIV COHORT

TRACING FORM

L01	STUDN	Study number	D			
L02	DATE	Date of initial completion form (today's date)	/ /20			
L03	INTID	Interviewer ID				
TRACING						
L04	CALL	Phone call outcome	<p style="text-align: center;">Participant attended appointment before a tracing call</p> <p style="text-align: center;">Participant found and given appointment for follow-up visit</p> <p style="text-align: center;">Participant found and has decided to withdraw from cohort</p> <p style="text-align: center;">Participant deceased</p> <p style="text-align: center;">No response to phone call (number not available/ not answered)</p> <p style="text-align: center;">Participant did not turn up on the 2nd appointment made</p>			
L05	TVISIT1	Date of first tracing home visit	/ /20	Contact	No Contact	Not Done
L06	TVISIT2	Date of second tracing home visit	/ /20	Contact	No Contact	Not Done
L07	TVISIT3	Date of third tracing home visit	/ /20	Contact	No Contact	Not Done
L08	OUTC	Final outcome of tracing home visit	<p style="text-align: center;">Participant attended appointment before a tracing visit</p> <p style="text-align: center;">Household not found, untraceable</p> <p style="text-align: center;">Household found but participant not found after 3 follow-up visits</p> <p style="text-align: center;">Participant decided to withdraw from cohort</p> <p style="text-align: center;">Participant deceased</p> <p style="text-align: center;">Participant found and given appointment for follow-up visit</p> <p style="text-align: center;">Home Visit not done</p>			
L09	APPT	Date of appointment if participant found and has not withdrawn from cohort Inform study nurse of the new follow-up date	/ /20			
L10	PLIVE	Is the participant alive? If participant died, complete CH.05	Alive	Dead	Unknown	
L11	DOD	If response to L10 is DEAD, Is DEATH FORM (CH.05) Completed	Yes	No	NA (Participant alive)	
L12	COMM	Comment				
L13	EXIT	If participant withdrawn or not found or dead	Study Exit Form Completed (CH.04)			

CH.07 CHIEDZA_HIV COHORT

CAPS ENROLMENT FORM

CA01	CLUS	Cluster number	-
CA02	DATE	Date of Assessment	/ /20
ELIGIBILITY CHECK FOR CAPS ENROLMENT			
CA03	UND	Client Understands purpose of CAPS group	Yes No
CA04	CONF	Client agrees to confidentiality terms of CAPS groups	Yes No
CA05	PRINC	Client understands basic principles of HIV and HIV treatment	Yes No
CA06	HIV	Client accepts HIV status	Yes No
If answer to all Yes, to CA03 to CA06 then proceed and enrol client:			
CA07	ACC	Client accessing HIV care at CHIEDZA	Yes No
CA08	STUDN	If YES, Enter CAPS ID number with prefix D (same as COHORT ID NO). Also enter same number on CAPS card	D
CA09	PHC	If NO, not accessing HIV care at CHIEDZA Enter CAPS ID with prefix P. Also enter same number on CAPS card (Use list of numbers provided by data team)	P

CT.01 CHIEDZA_HIV COHORT

CD4 and CRAG FORM

CD01	STUDYNO	STUDY NUMBER	D			
CD02	CLUS	Cluster Number	-			
CD03	INITIALS	Client initials				
CD04	DATE	Date specimen was collected	/ /20			
CD05	COLID	Specimen collected by				
CD06	PROCID	Specimen processed by				
CD07	CD4C	CD4 Count	cells/uL			
CD08	TESTC	Is CD4 Count <100 cells/uL	Yes		No	
CD09	CRAG	CRAG Test Result	Positive	Negative	Not Done	NA
CD10	COMM	Comments				
CD11	COMP	Completed by				

.....
Tear off and insert in patient notes

CHIEDZA STUDY NUMBER	
CLUSTER	
INITIALS	
DATE OF TEST	
CD4 COUNT RESULT	Cells/uL
CRAG TEST RESULT	Positive Negative Not Done

CT.02 CHIEDZA_HIV COHORT

HIV VIRAL LOAD REQUEST FORM

VL01	STUDYNO	STUDY NUMBER	D	
VL02	CLUS	Cluster Number	-	
VL03	INITIALS	Client initials		
VL04	DATE	Date specimen was collected (dd/MMM/yyyy)	/	/20
VL05	COLID	Specimen collected by		
Lab to fill the Section Below Attach Viral Load result notification to this form				
VL06	DATER	Date specimen was received (dd/MMM/yyyy)	/	/20
VL07	DATE2	Date specimen was processed (dd/MMM/yyyy)	/	/20
VL08	LABNO	Lab Number	Insert Lab Number	
VL09	VLOAD	Viral Load result	copies/ml	
VL10	COMM	Comments		
VL11	RESID	Residual specimen	Box No	Position (-80°C) NA
VL12	RBNO	Lab Number for RBC pellet	Insert barcode for RBC eg. CRB0001 NA	
VL13	COMP	Completed by		

TEAR OFF AND INSERT IN PATIENT NOTES

CHIEDZA STUDY NUMBER	
CLUSTER	
INITIALS	
DATE OF TEST	
HIV VIRAL LOAD RESULT	copies/ml

CT.03 CHIEDZA_HIV COHORT

GENEXPERT TB SCREENING FORM

GX02	STUDYNO	Study Number	D
GX02	CLUS	Cluster	-
GX03	INITIALS	Client initials	
GX04	COLID	Specimen collected by	
GX05	DATE	Date specimen collected (dd/MMM/yyyy)	/ /20
GX06	TIME1	Time of sputum collection (24hr clock)	: HRS

(FOR LAB USE ONLY below this line)

GX07	DATER	Date specimen was received (dd/MMM/yyyy)	/ /20
GX08	LCODE	Lab number	Insert barcode
GX09	VOL	Volume	mls
GX10	QUAL	Quality Tick all that apply	Salivary Mucoid Mucopurulent Blood Stained
GX11	DATEP	Date processed (dd/MMM/yyyy)	/ /20
GX12	PROCID	Specimen processed by	
GX13	MTB1	MTB Detected	Yes No Indeterminate Error
GX14	RIFR1	Rifampicin sensitivity result	No MTB detected Sensitive Provisionally Resistant (must repeat to confirm) Rif result indeterminate

If "Error" in GX13, or "Resistant" in GX14, repeat Xpert test by rerunning the same sample to confirm

CT.03 CHIEDZA_HIV COHORT

GENEXPERT TB SCREENING FORM

GX15	MTB2	MTB detected on repeat test?	Yes	No	Indeterminate	Error	
					Insufficient sputum to repeat test	Not Done	
GX16	RIFR2	Rifampicin result from repeat test?				Sensitive	
						Resistant	
					Rif sensitivity result indeterminate		
					Insufficient sputum to repeat test		
						Not Done	
GX17	MTBFIN	Final MTB detected?	Yes	No	Indeterminate	Error	
GX18	FINALR	Final reported Rifampicin resistance	Sensitive (Sensitive on <u>EITHER</u> GX14 or GX17)				
			Confirmed resistance (resistant on <u>BOTH</u> GX14 AND GX17)				
			Provisional resistance (resistant on GX14, indeterminate/insufficient sputum on GX17)				
			Not reported (No MTB detected / Rif result indeterminate on GX14)				

Tear off and insert in patient notes

.....
TB GENEXPERT RESULT: CHIEDZA STUDY

Screening ID: **D**

Client initials

Date of collection: _____

Date Processed _____

Laboratory Number _____

GeneXpert RESULT (to be completed in laboratory)

Visual appearance	Result (tick what applies)		
	Negative	MTB detected	Rifampicin resistance

Comments

SCREENING LOGSHEET

(Eligible clients are only those aged between 16-24years and reside in Cluster Area or Partner or Buddy)

Date	No.	Age	First Visit (Y/N)	Reside within Cluster (Y/N)	Comment Type Client (C), partner (P) or Buddy (B)	Eligible (Y/N)
	S1001					
	S1002					
	S1003					
	S1004					
	S1005					
	S1006					
	S1007					
	S1008					
	S1009					
	S1010					

eCRF DISPATCH LOG

Source :							
Date Dispatched (Sign)							
DD / MM / YYYY Checked by (at site) _____ Signature							
eCRFs	Tab-2020	Tab-0593	Tab-7216	Tab-0188	Tab-	Total	Correct/Comment (Received by Signature)
ID							
CL.01							
CO.01							
CO.02							
CO.03							
CO.04							
CH.01							
CH.02							
CH.03							
CH.04							
CH.05							
CH.06							
CH.07							
CT.01							
CT.02							
CT.03							

CL.03 CHIEDZA

FORM TRANSPORTATION LOG (Complete in Duplicate)

Cluster Name _____

Date Sent (Sign/Write ID)	Name of Form	Study Number(s)	Date Received (Sign/Write First Name)
<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Sender Signature and ID</p> <p>Signature _____ Driver Signature</p>	<p>CH.</p>	<p>D</p> <p>D</p> <p>D</p> <p>D</p>	<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Receiver Signature and First Name</p>
<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Sender Signature and ID</p> <p>Signature _____ Driver Signature</p>	<p>CH.</p>	<p>D</p> <p>D</p> <p>D</p> <p>D</p>	<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Receiver Signature and First Name</p>
<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Sender Signature and ID</p> <p>Signature _____ Driver Signature</p>	<p>CO.</p>	<p>CH</p> <p>CH</p> <p>CH</p> <p>CH</p>	<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Receiver Signature and First Name</p>
<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Sender Signature and ID</p> <p>Signature _____ Driver Signature</p>	<p>CO.</p>	<p>CH</p> <p>CH</p> <p>CH</p> <p>CH</p>	<p>D D / M M / Y Y Y Y</p> <p>Signature _____ Receiver Signature and First Name</p>

CHL.01 CHIEDZA_HIV COHORT

LOCATOR FORM

Complete for clients enrolled in CHIEDZA HIV Cohort

STUDY NUMBER	D
Date of Birth (dd/mm/yyyy)	/ /
Client's Full Name	
Gender	Female Male
Guardian Full Name (For Clients aged 16-17 years)	
Guardian mobile No.	0
Participant mobile No.	0
Can we/our partners contact you for follow up tests	By phone call Yes No By phone message Yes No
Please tell us any other names that you are known by?	
Please tell us any other names that your guardian is known by?	

Main Address

Alternative Address

1. Nearest landmark to your home (e.g. next to church): _____

2. Is it OK to leave a message if someone else answers your phone? Yes No
If yes, who shall we say is calling? _____

3. May we come to your home? Yes No

4. If yes, with whom do you live with?

<p><u>Alternative contact 1:</u></p> <p>Mobile Number: 0</p> <p>Name: _____</p> <p>Relationship: _____</p> <p>Can we leave a message Yes No</p> <p>Do you live at the same house Yes No</p>	<p><u>Alternative contact 2:</u></p> <p>Mobile Number: 0</p> <p>Name: _____</p> <p>Relationship: _____</p> <p>Can we leave a message Yes No</p> <p>Do you live at the same house Yes No</p>
--	--

Note: When we leave phone messages, we will never reveal information without your prior approval.

CHIEDZA COUNSELLING REGISTER

Cluster Name _____

	Date	Visit Type 1) Initial 2) Follow-up Review	Staff			Age	Sex	Reason for referral	Referred onwards Y/N?- if yes, specify where	Comments
			Initials	Type 1) CHW 2) YW 3) Nurse	Where? 1) CAPS 2) Centre		M/F			
1										
2										
3										
4										
5										

CHIEDZA REFERRAL REGISTER

1. Responsibility of person referring to follow-up with client on outcome
2. Each entry should have an outcome

Cluster Name _____

REFERRAL TO:

- 1) PHC for HIV care; 2) PHC for TB; 3) PHC for pregnancy; 4) PHC for other problem (specify); 5) Hospital (specify); 6) CXR; 7) VMMC; 8) Cervical screen; 9) Other (specify)

	Date of referral	Staff initials and type		Name & phone number of client	Referral to	Date outcome entered	Outcome: 1) Client attended 2) Client did not attend 3) LTFU	Comments
		Initials	Type 1) CHW 2) YW 3) Nurse 4) Couns					
1								
2								
3								
4								
5								

CHIEDZA CAPS REGISTER

(Note: Buddy can attend without client; client refers to HIV+ve individual- therefore enter Buddy and Client ID numbers individually)

Cluster Name _____

Date	Session time XX.XX- YY.YY (24 hour clock)	Client CAPS ID number (check with CAPS membership card)*	Buddy ID number (Check with buddy card)*	Sex of buddy 1)Male 2)Female	Age of buddy

CHIEDZA YOUTH HELPLINE REGISTER

Date	Time of Call	CHIEDZA Cluster	Age	Sex (M/F)	Reason for Calling Helpline	Action taken (If Referred onwards, specify where) mark all that apply	Follow-Up Outcome		Comments
							Attended referral service (if referred) 1)YES 2)NO 3)N/A	1) Unreachable 2) Problem resolved 3) Problem ongoing	
						1. Transferred to CHIEDZA provider 2. Referred onwards (specify where) 3. Advice given by YAZ provider (specify on what) 4. Other (specify)	Attended referral service (if referred) 1)YES 2)NO 3)N/A	1) Unreachable 2) Problem resolved 3) Problem ongoing	



REPUBLIC OF ZIMBABWE

MINISTRY OF HEALTH AND CHILD CARE

HIV SELF-TESTING REGISTER

PROVINCE:..... PROVINCE CODE:.....

DISTRICT:..... DISTRICT CODE:.....

FACILITY NAME:..... FACILITY CODE:

PERIOD: FROM TO



HIV SELF TESTING REGISTER

Column	Remarks:	
	General Instruction:	Begin on a new page every month, make sure you fill in every field of the counseling register, remember each reporting month begins on 1st of every month and closes on the last day of the month. A copy of this register must be kept in all departments where HIV self testing and counseling is being conducted. Draw a line across at the end of every reporting period. Summarise the indicators at the bottom of each page.
1	Month	Record the month on every page
2	Year	Record the year on every page
3	Date	Record the date of visit for every patient/client
4	Sequential number	Write the numbers sequential as clients come on a daily basis for a particular month, starting with 1 for the first client registered. Continue numbering up to the last day of that calendar month. Restart numbering every new calendar month
5	Patient/Client Name and Surname	Indicate Surname Upper space - then First name followed by Initials e.g. Dura Chakauya D for those with more than one name. indicate the physical address and contact number of the client on the bottom line as close as possible to where the patient's address
6	I.D. Number or Identification Code	Record Client I.D. Number or Unique Identification Number (Generate the code by using the last two letters of the clients mothers name followed by the last two letters two letters of the clients surname, last two letters of District of birth, Date of birth and sex of client .EG Norah Moyo's mothers name is Edith and her District of birth of birth is Bulilima and born on the 23rd September 1980. Her UIC therefore is THYOMA230980f
7	Physical address and Phone Number	Write the physical address/village/nearest school where client stays and record the contact details on the client or of their next of kin
8	Sex	Circle M for male and F for female
9	Date of Birth	Write the client's date of birth (dd/mm/yyyy). This should be as close as possible to the client's birth.
10	Age	Write the age in completed years for adults i.e 16 years and above
11	Presenting as couple	Record Yes or No
12	HTS model	Indicate the setting under which the services are offered using codes as follows; a-Facility based (Stand alone /New start Centre), b-Community based (Mobile/Outreach/Campaign/Home based)
13	Pretest information given	Circle "Y" if pretest information was given and "N" if not given
14	Test	Circle "F", Record if the client never tested or "R", if retest
15	Reasons for HIV testing	This column indicates the reasons why the client has come for HIVST: 1. Partner 2. STI 3. VMMC 4. Diagnosis 5. Family Planning 6. Occupational 7. Sexual abuse 8. index case testing [Family member HIV positive, Death of child/spouse] 9. Know HIV status 10. Re-testing for on-going risk 11. PrEP 12. Key population 13. Others-specify
16	Name of kit - Batch Expiry Date & Lot Number	Record Name of kit, Batch Expiry and Lot Number
17	HIV Self Testing	Indicate whether the client tested self and the test result and if client disclosed test result to provider
18	Referred for provider test (Y/N)	a. Indicate whether the client has been referred for provider test. b. Record client test result. c. Record Provider test result This column applies to clients who have a reactive result. The clients are referred for provider testing
19	Linkage to Post-Test Services	Indicate using codes: 1. PMTCT 2. Medical Services 3. VMMC 4. STI 5. PEP 6. PrEP 7. Cervical Cancer Screening 8. TB Services 9. Nutrition 10. Psycho-Social Support 11. Family Planning 12. Admission/In-Patient 13. OPD 14. Adolescent and Sexual Reproductive Health 15. Gender Based Violence 16. Mental Health 17. Peer-led counselling and support 18. Other specify
20	Secondary Distribution	Applies to ANC clients with a reactive or non-reactive result whose partners require HIV testing. The women can be given self test kits to take home for their spouses and index positive
21	Comment	Write any comments where possible
22	Name of Distributor (Surname/First name)	Indicate Surname and First Name of person distributing HIVST kits services (PRINT NAMES IN FULL).
23	Signature	The distributor to sign in this column
24	Total Test	Record total tests, Total reactive, Total non-reactive, Inactive and Provider test positive



REPUBLIC OF ZIMBABWE

MINISTRY OF HEALTH AND CHILD CARE

STI REGISTER

PROVINCE: PROVINCE CODE:

DISTRICT: DISTRICT CODE:

FACILITY NAME: FACILITY CODE:

PERIOD: FROM TO



Version 1: October 2016

Job aid for completing STI register

Instructions for completing STI register

	Column	Instruction
0	General instructions	The register should be kept and filled at all consultation points.
		The ANC department must always have a separate STI register
1	Date	Write the date the client presents with STI
2	Sequential number	Write the numbers sequential as clients comes on a monthly basis, starting with 1 for the first patient seen on the 1st of each month ending on the last patient seen at the end of month
3	STI number	Write the STI number. The number starts at the beginning of the calendar year i.e 1st January to 31 December of the same year
4	Name and physical address	Write the physical address and contact number of the client (Get alternative address and contact number).
5	Age	Write the age in completed months for children and completed years for adults
6	Age category	Encircle A for < 2 months, B for 2 - 12 months, C for 13 - 24 months, D for 5 - 9 years, D for 10 - 14 years, E for 15 - 19 years, F for 20 - 24 years, G for 25 - 49 years, H for 50+ years
7	Sex	Encircle M for male and F for female
8	Presenting complaints /History	Write in full the presenting complaint or history of the client
9	New STI/Repeat STI	New STI/Repeat STI episode, encircle N for someone who is presenting with an STI for the first time, encircle R for someone who has been previously treated for an STI
10	STI Syndrome	Write codes for STI Syndrome as shown (Urethral discharge = 1, Genital ulcer = 2, Vaginal discharge = 3, Lower abdominal pain = 4, Inguinal Bubo = 5, Acute scrotal swelling = 6, Ophthalmia neonatorum = 7, Balanitis and Balanopostitis = 8, Genital warts = 9, Congenital syphilis = 10, Others (Specify) = 11
11	Tested for Syphilis	Encircle Yes if syphilis test was done and No if syphilis test was not done
12	Purpose of Syphilis testing	Encircle the purpose of Syphilis testing as ;a- ANC, b-Sexual Violence, c-Contact, d-Syphyllis exposed infant, e-STI client.
13	Syphillis Test Result	Encircle 1 if syphilis test result was positive and 0 if negative
14	Treatment	Encircle all medicines prescribed in full including dose frequency and duration
15	Tested for HIV	Encircle Yes (Y) if tested for HIV and No (N) if not tested and AP - Already HIV Positive (note that all STI clients must be offered HIV test)
16	HIV Test Result	Encircle 1 if HIV test result was positive, 0 if negative and N/A if not tested
17	STI Contact Slips Issued	Encircle Yes (Y) contact slip was issued and No (N) if not issued
18	STI Contact Slips Received	Encircle Yes (Y) if contact presents contact slip for treatment and No (N) if no contact slip not received (meaning contact did not come for treatment)
19	Condom Information given	Encircle Yes (Y) if client was given condom information or No (N) if this is not done.
20	Condoms issued	Encircle Yes (Y) if client was given condoms or No (N) if not given
21	Comments	Write any comments for management of STI (including referrals done)



REPUBLIC OF ZIMBABWE

MINISTRY OF HEALTH AND CHILD CARE

HIV TESTING SERVICES REGISTER

PROVINCE:..... PROVINCE CODE:.....

DISTRICT: DISTRICT CODE:

FACILITY NAME:..... FACILITY CODE:

PERIOD: FROM TO



Version 5: June 2017

HIV TESTING SERVICES REGISTER

Column	Remarks:	
	General Instruction:	Begin on a new page every month, make sure you fill in every field of the counseling register, remember each reporting month begins on 1st of every month and closes on the last day of the month. A copy of this register must be kept in all departments where testing and counseling is being conducted. Draw a line across at the end of every reporting period. Summarise the indicators at the bottom of each page.
1	Month	Record the month on every page
2	Year	Record the year on every page
3	Date	Record the date of visit for every patient/client
4	Sequential number	Write the numbers sequential as clients come on a daily basis for a particular month, starting with 1 for the first client registered. Continue numbering up to the last day of that calendar month. Restart numbering every new calendar month
5	HTS Number	Record the Province, District, Site codes, year, V the check digit and sequential number with 5 digits i.e. PPDDSS - YYYY - V - #####, e.g. 03 08 OE - 2016 - V - 00001. Continue sequentially through to 31st December. Restart the numbers the following year 1st January
6	Surname & first Name / Address of Client	Indicate Surname Upper space - then First name followed by Initials e.g. Dura Chakauya D for those with more than one name. indicate the physical address and contact number of the client on the bottom line as close as possible to where the patient stays e.g name of school, village e.t.c
7	Sex	Circle M for male and F for female
8	Date of birth	Write the client's date of birth (dd/mm/yyyy).(This should be as close as possible to the client's birth).
9	Age	Write the age in completed months for children and completed years for adults
10	Pretest information given	Circle "Y" if pretest information was given and "N" if not given
11	Presenting as couple / partner/s	Indicate whether the couple has received HTS together by (Y/N). Use parenthesis() symbol to indicate couples who are counselled together. (See National HTS Guidelines for definition of Couple)
12	HTS Model	Indicate the setting under which the services are offered using codes as follows; a-Facility based(Stand alone /New start Centre/ Health Facility), b-Community based (Mobile/Outreach/Campaign/Home based)
13	Reason for HIV Testing	A. This column indicates the reasons why the client has come for HTS: a-TB, b-PMTCT: b1-ANC, b2-L/D, b3-Post delivery (PD), b4-Partner. c-STI, d-VMMC, e-Diagnosis, f-Family Planning, g-EPI, h-Nutrition, i. Exposed infant, j-Occupational, k-Sexual abuse, L-INDEX case testing, L1-[Family member HIV positive, L2-Death of child/spouse], m-Know HIV status, n- From self test; O- Re - testing; p-for on - going risk; q. - PrEP ; r. - Others-specify B. Re-testing before ART initiation. (See definitions from HTS Guidelines)
14	Test F- First ever test R - Retest	Indicate whether the HIV test is-F(First test),R (Retest test).The first test is the first time ever that the client tested for HIV.Retest indicates whether client has been tested for HIV before(not time specific).
15	Pregnant and Lactating women (Only)	This column applies to women that are pregnant, in labour and delivery, including lactating mothers that are tested for the first time or subsequently test for the current pregnancy or lactating period. F-First test (specific to the present pregnancy, delivery and lactation). R-Retest (subsequent test for the present pregnancy, delivery and lactation)
16	Test 1	Record the name, expiry date, lot number and the result of each kit used following the national algorithm. Enter the HIV test result as either P - Positive; N - Negative
17	Test 2	Record the name, expiry date, lot number and the result of each kit used following the national algorithm. Enter the HIV test result as either P - Positive; N - Negative
18	Parallel Test	Parallel test1 and test 2.Record the name of the test kit and results.
19	Test 3	Record the name, expiry date, lot number and the result of each kit used following the national algorithm. Enter the HIV test result as either P - Positive; N - Negative
20	Final Result	Record the final HIV test result by circling the appropriate symbol - P - Positive; N - Negative; I - Inconclusive
21	Received Results and Post Test Counselling	Indicate if the client received results and post test counselling or not by circling the appropriate, (Y=yes ,N=no)
22	Name of tester	Indicate Surname and First Name of person offering HTS services (PRINT NAMES IN FULL).
23	Post test linkages	Indicate using codes :1. PMTCT;2. Medical Services,3. VMMC; 4. STI; 5. PEP; 6. Cervical Cancer Screening; 7. OI/ART services; 8. TB services; 9. Nutrition; 10. Psychosocial support; 11. EPI/Growth monitoring / Under 5 12. Family planning 13. Admission/In patient 14. OPD 15. Adolescent reproductive health 16. Gender based violence 17. Others (specify)
24	Consent/Assent to Patient Tracing (multiple response)	Inconclusive Indicate whether the patient has given consent to be followed up as individual (1) or family members for index case tracing (2) or both
25	Comments	Write any comments where possible
26	Rapid HIV testing quality controls	Run internal and external quality control as per national policy. Document the results on table 26-Document all controls run in red ink in the respective rows.

Appendix 4. CHIEDZA Training Programme

Purpose

This guide is part of the CHIEDZA Training Curriculum for the intervention team, who will be implementing the program, to be trained to provide quality, comprehensive and youth-friendly health services to youth. The training is directed at all cadres of the intervention team but certain sessions will be cadre-specific. The training will assume a level of cadre-specific knowledge and experience

Training Objectives

- To increase awareness of barriers and facilitators to youth friendly health services.
- To build team capacity and skills to address health issues and provide age-responsive counselling and health services specific to the needs of youth in study communities.
- To develop skills and approaches to enhance access to and coverage of HIV, SRH and general health services care and ensure appropriate referrals are made
- Introduce standards for quality health care services for youth

Expected Training outcomes

- Understand the objectives of the CHIEDZA project
- Able to provide high-quality services responsive to the needs of youth
- Able to operationalize and implement the CHIEDZA intervention according to the standard operating procedures

Structure of Training programme

The training will be conducted over a 4 week period. The following will be covered:

- WEEK 1 The principle of engagement, communication and provision of youth-friendly services.
The flow of clients across the intervention and the structure of a consult.
How to record and manage data.
- WEEK 2 Providing services across the HIV care cascade, including HIV testing and counselling, initiating HIV treatment, providing HIV care and adherence support. Youth workers will have a parallel session on days 2-4 this week to train on outreach and community sensitisation.
- WEEK 3 Providing SRH and general health services. This will include family planning, STI syndromic management, menstrual hygiene management and provision of general health counselling.
- WEEK 4 Managing digital platforms to be used in the study, specifically the ITHAKA HIV self-testing platforms and using biometrics.
This week will also include setting up and a trial run of the procedures at the pilot site.

Participatory teaching methods

Training will use participatory learning approaches where the facilitators will provide practical sessions underpinned by discussions of potential situations. Participatory approaches include: group discussions, case studies, practical exercises, presentations/videos, role-playing, question-and-answer sessions, brain storming, and learning games.

Guide for Facilitators

Trained and experienced facilitators will provide the training. These will include the research coordinators, social workers, psychologists, doctors, nurses and youth, as appropriate.

- Do maintain good eye contact
- Do prepare in advance
- Do involve participants
- Do use visual aids
- Do speak clearly
- Do speak loud enough
- Do encourage questions and participation
- Do recap at the end of each session
- Do bridge one topic to the next
- Do write clearly and boldly
- Do summarize
- Do use logical sequencing of topics
- Do use good time management
- Do K.I.S. (Keep It Simple)
- Do give feedback
- Do position visuals so everyone can see them
- Do avoid distracting mannerisms and distractions in the room
- Do be aware of the participants' body language
- Do keep the group focused on the task
- Do provide clear instructions
- Do check to see if your instructions are understood
- Do evaluate as you go
- Do be patient

Checklist for training

Facilitators should ensure that they have all the material needed for the particular training session. This may include:

- Flip chart paper and stand
- Computer / Projector
- Sticky notes, markers, pens, pencils,
- Condoms, pills, HIV testing kits- for demonstration
- Name tags for everyone
- Logistical items: transportation vouchers, attendance sheets, meals / snacks etc

CHIEDZA Training Programme

Venue(s): Biomedical Research and Training Institute (BRTI)
 Introductory meeting to be held at the CHIEDZA Office: 59, Pendennis Road, Mount Pleasant, Harare
 Training to be held at the main BRTI Offices: Training Room, 10 Seagrave Road, Avondale, Harare

Dates: Friday January 4th to Friday February 1st 2019

Training Timetable: This is the initial training programme that will be conducted over a 4 week period. There will be a 30min tea-break in the morning (1030-1100Hrs) and a one hour lunch break (1315-1415Hrs). This may be modified based on the activities on the day.

An introductory session will be held before the training programme starts to introduce the intervention team to each other and to the research team, and to introduce the project, the goals and structure of the training programme, what is expected from the team and the specific roles of each team member.

Time	Activity	Learning Objectives	Facilitators
INTRODUCTORY MEETING			
Friday January 4 th 2019			
1300-1330hrs	Introductions & Ice breakers, Housekeeping rules Meet management team		
1330-1415hrs	Overview of the CHIEDZA Trial	Understand CHIEDZA project- background, aims and structure	Rashida Ferrand & Connie Mavodza
1415-1500hrs	Overview of the Intervention What is expected of the team	Understand the intervention: what, how, where and who Understand role, skills and competencies required to deliver intervention	
	Role of members Overview of training programme Introducing the Manual of Operations	Identify knowledge/skills gaps and identify training opportunities Understand how the training will be structured	

Time	Activity	Learning Objectives	Facilitators
WEEK 1: YOUTH ENGAGEMENT SKILLS AND INTERVENTION FLOW			
DAY 1 (Monday January 7th 2019)			
0800-1700hrs	Read the Manual and Protocol	Familiarise yourself with: 1) Purpose and structure of project 2) Intervention procedures	Private Study
DAY 2 (Tuesday January 8th 2019)			
0800-0830hrs	Register and Meet the Project Team		
0830-1030hrs	Engaging and Communicating with youth	Get skilled in provision of Youth Friendly services, particularly:	
1100-1315hrs	Engaging and Communicating with Youth	1) Attitudes and approach	MMPZ
1415-1615hrs	Engaging and Communicating with Youth	2) Communication skills	
1615-1630hrs	Wrap Up		
DAY 3 (Wednesday January 9th 2019)			
0800-0830hrs	Recap of Day 2 Activities + clarifications		
0830-1030hrs	Flow through the intervention	Understand flow of the client through the CHIEDZA service; Structure of a general consultation with a client	CHIEDZA Team
1100-1315hrs	Flow through the intervention		
1415-1615hrs	CHIEDZA consultation		
1615-1630hrs	Wrap Up		
DAY 4 (Thursday January 10th 2019)			
0800-0830hrs	Recap of Day 3 Activities + clarifications		
0830-1030hrs	Data collection and management	Different types of data records and their purpose; Understand how to collect and record data;	Data team
1100-1315hrs	Data collection and management	Introduction to forms, logs, slips, registers to be used;	
1415-1615hrs	Data collection and management	Flow of data from intervention site to office; Troubleshooting	
1615-1630hrs	Wrap Up		

Time	Activity	Learning Objectives	Facilitators
DAY 5 (Friday January 11th 2019)			
0800-0830hrs	Recap of Day 4 Activities + clarifications		
0830-1030hrs	Data collection and management	Different types of data records and their purpose; Understand how to collect and record data;	Data team
1100-1315hrs	Data collection and management	Introduction to forms, logs, slips, registers to be used;	
1415-1615hrs	Data collection and management	Flow of data from intervention site to office; Troubleshooting	
1615-1630hrs	Wrap Up		
WEEK 2: HIV Care Continuum			
DAY 1 (Monday January 14th 2019)			
0800-0830hrs	Recap of WEEK 1 + clarifications		
0830-1030hrs	HIV Testing & Counselling (HTC)	HIV test flow; How to pre and post-test counsel clients; How to do	CHIEDZA Team
1100-1315hrs	HIV Testing & Counselling (HTC)	OMTs and BBTs and interpret results; Reporting back to MOHCC	
1415-1615hrs	HIV Testing & Counselling (HTC)	and to OMT providers; Partner/index-linked testing;	
1615-1630hrs	Wrap Up		
DAY 2 (Tuesday January 15th 2019)			
0800-0830hrs	Recap of Day 1 + clarifications		
0830-1030hrs	Linkage to and provision of HIV Care	How to link clients from a positive test to care; The first	CHIEDZA Team
1100-1315hrs	Linkage to and provision of HIV Care	appointment & pre-ART assessment; How to perform CD4 count,	
1415-1615hrs	Linkage to and provision of HIV Care	CrAg and LAM testing; How to initiate ART;	
1615-1630hrs	Wrap Up		
DAY 3 (Wednesday January 16th 2019)			
0800-0830hrs	Recap of Day 2 + clarifications		
0830-1030hrs	Provision of HIV Care	Routine follow-up visits; Refills and linkage with facilities maintaining records;	CHIEDZA Team
1100-1315hrs	Provision of HIV Care	Unscheduled visits and dealing with acutely unwell clients;	
1415-1615hrs	Provision of HIV Care	Viral load testing; Maintaining records and reporting to MOHCC;	
1615-1630hrs	Wrap Up		

Time	Activity	Learning Objectives	Facilitators
DAY 4 (Thursday January 17 th 2019)			
0800-0830hrs	Recap of Day 3 + clarifications		
0830-1030hrs	Adherence support	Understand how to support ART adherence within CHIEDZA; Adherence counselling; Dealing with missed visits; Running a CAPS group;	CHIEDZA Team
1100-1315hrs	Adherence support		
1415-1615hrs	Adherence support		
1615-1630hrs	Wrap Up		
DAY 5 (Friday January 18 th 2019)			
0800-0830hrs	Recap of Day 4 + clarifications		
0830-1030hrs	Revision: HIV testing and counselling	Consolidate the learning on managing the HIV care cascade	CHIEDZA Team
1100-1315hrs	Revision: HIV treatment and care		
1415-1615hrs	Revision: Adherence support		
1615-1630hrs	Wrap Up		
WEEK 3: SRH & General Health services			
DAY 1 (Monday January 21 th)			
0800-0830hrs	Recap of WEEK 2 + clarifications		
0830-1030hrs	Family Planning	Types of family planning- how they work, how to use; Individualising Family planning; family planning consult; Repeat consults; Dealing with side-effects; keeping records and reporting to MOHCC	PSZ
1100-1315hrs	Family Planning		
1415-1615hrs	Family Planning		
1615-1630hrs	Wrap Up		
DAY 2 (Tuesday January 22 nd 2019)			
0800-0830hrs	Recap of Day 1 + clarifications		
0830-1030hrs	Family Planning	Consolidate the learning on Family Planning; How to provide condoms and do condom demonstrations	PSZ
1100-1315hrs	Family Planning		
1415-1615hrs	CONDOM provision and demonstration		
1615-1630hrs	Wrap Up		

Time	Activity	Learning Objectives	Facilitators
DAY 3 (Wednesday January 23 rd 2019)			
0800-0830hrs	Recap of Day 2 + clarifications		
0830-1030hrs	Syndromic management of STIs	Types of STI syndromes; an STI consult; How to treat; How to follow-up; repeat consults; Partner notification; Dealing with side-effects; keeping records and reporting to MOHCC	CHIEDZA Team
1100-1315hrs	Syndromic management of STIs		
1415-1615hrs	Syndromic management of STIs		
1615-1630hrs	Wrap Up		
DAY 4 (Thursday January 24 th 2019)			
0800-0830hrs	Recap of Day 3 + clarifications		
0830-1030hrs	Menstrual Hygiene Management	Understanding MHM; MHM consult and flow; MHM products and individualising choices; Counselling and provision of MHM package; Dealing with side-effects and reporting to MOHCC/donors	CHIEDZA Team with AFRipads and Butterfly Cup
1100-1315hrs	Menstrual Hygiene Management		
1415-1615hrs	Menstrual Hygiene Management		
1615-1630hrs	Wrap Up		
DAY 5 (Friday January 25 th 2019)			
0800-0815hrs	Recap of Day 4 + clarifications		
0815-1030hrs	Counselling and red flag management	Principles of counselling; Dealing with common issues: VMMC, CX screening, substance and alcohol use, violence, mental health General counselling consult and recording; Referral pathways	Tarisai Bere
1100-1315hrs	Counselling and red flag management		
1415-1615hrs	Counselling and red flag management		
1615-1630hrs	Wrap up		
WEEK 4: WORKING WITH DIGITAL PLATFORMS			
DAY 1 (Monday January 28 th)			
0800-0815hrs	Introducing Digital platforms		
0815-1030hrs	Using ITHAKA	How to operate and manage ITHAKA	ITHAKA TEAM
1100-1315hrs	Using ITHAKA		
1415-1615hrs	Using ITHAKA		
1615-1630hrs	Wrap up		

Time	Activity	Learning Objectives	Facilitators
DAY2 (Tuesday January 29 th 2019)			
0800-0815hrs	Recap of Day 1 + clarifications		
0815-1030hrs	Using ITHAKA		
1100-1315hrs	Using ITHAKA	How to operate and manage ITHAKA	AVIRO TEAM
1415-1615hrs	Using ITHAKA		
1615-1630hrs	Wrap up		
DAY 3 (Wednesday January 30 th 2019)			
0800-0815hrs	Recap of Day 2 + clarifications		
0815-1030hrs	Using Simprints		
1100-1315hrs	Using Simprints	How to operate and manage SIMPRINTS	SIMPRINTS TEAM
1415-1615hrs	Using Simprints		
1615-1630hrs	Wrap Up of Day 16		
DAY 4 (Thursday January 31 th 2019)			
0800-0815hrs	Recap of Day 2 + clarifications		
0815-1030hrs	Using Simprints		
1100-1315hrs	Using Simprints	How to operate and manage SIMPRINTS	SIMPRINTS TEAM
1415-1615hrs	Using Simprints		
1615-1630hrs	Wrap Up of Day 16		
DAY 5 (Friday February 1 st 2019)			
Pilot Logistics			
Site visits and set ups			
Role plays at sites			
END OF TRAINING			

Appendix 5. Branding Materials

CHIEDZA BRANDING
PHASE 1 & 2
Updated 27.03.19

1. Buddy card
2. CAPS card
3. GC/CT Screening slip
4. Partner Notification slip
5. HIV Results slip
6. Referral form
7. ITHAKA flyer
8. Minibus
9. T-shirts
10. Menu of services - female
11. Menu of services - male
12. External leaflet
13. Telescopic Welcome Banners
14. YAZ Card
15. Activities Calendar
16. Suggestion Box
17. MHM Brochure

Wangu/Skeem Sami

Number: D B
(Cohort)

Number: P B
(non-cohort)

Cluster:



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Mashonaland East 0716 318 730
Bulawayo 0716 318 734

CAPS MEMBERSHIP CARD

CAPS MEMBERSHIP CARD

Number: D
(Cohort)

Number: P
(non-cohort)

Cluster:



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Mashonaland East 0716 318 730
Bulawayo 0716 318 734



Chiedza
Ukukhanya
Health For Our Future



GC/CT
Screening Slip

I am called: _____

Centre:

Sample Number:

If you have a question about your result, call or whatsapp:



Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734



I am called: _____

Centre:

Sample Number:

If you have a question about your result, call or whatsapp:



Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734



I am called: _____

Centre:

Sample Number:

If you have a question about your result, call or whatsapp:



Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734



I am called: _____

Centre:

Sample Number:

If you have a question about your result, call or whatsapp:



Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734



Partner
Not. Slip

Visit the Chiedza Centre for Advice



Centre:

Issue Date: // Date attended: //

Centre is open on _____

VDS UDS PID EPOR GUD HCT BUB CTS GCS TV

Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734

Visit the Chiedza Centre for Advice



Centre:

Issue Date: // Date attended: //

Centre is open on _____

VDS UDS PID EPOR GUD HCT BUB CTS GCS TV

Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734

Visit the Chiedza Centre for Advice



Centre:

Issue Date: // Date attended: //

Centre is open on _____

VDS UDS PID EPOR GUD HCT BUB CTS GCS TV

Harare 0779 620 908, Mashonaland East 0716 318 730, Bulawayo 0716 318 734

HIV Results Slip

DATE: / /

NAME OF CLIENT

CENTRE:

TYPE OF TEST

RESULTS: POSITIVE NEGATIVE



  Harare: 0779 620 908 Mashonaland East: 0716 318 730 Bulawayo: 0716 318 734

DATE: / /

NAME OF CLIENT

CENTRE:

TYPE OF TEST

RESULTS: POSITIVE NEGATIVE



  Harare: 0779 620 908 Mashonaland East: 0716 318 730 Bulawayo: 0716 318 734

DATE: / /

NAME OF CLIENT

CENTRE:

TYPE OF TEST

RESULTS: POSITIVE NEGATIVE



  Harare: 0779 620 908 Mashonaland East: 0716 318 730 Bulawayo: 0716 318 734

DATE: / /

NAME OF CLIENT

CENTRE:

TYPE OF TEST

RESULTS: POSITIVE NEGATIVE



  Harare: 0779 620 908 Mashonaland East: 0716 318 730 Bulawayo: 0716 318 734

Referral Form



Where client is being referred to:

Dear colleague,
We would be grateful if you could see our client

Client name: _____

Client Age:

Client's Sex: M F

Date of referral / /

CHIEDZA Centre of referral:

Name of referring person:

- Reason for referral:
- | | |
|---|---|
| <input type="checkbox"/> HIV care | <input type="checkbox"/> CXR |
| <input type="checkbox"/> TB treatment | <input type="checkbox"/> VMMC |
| <input type="checkbox"/> Antenatal care | <input type="checkbox"/> Cervical screening |
| <input type="checkbox"/> Other problem, see below for details | |

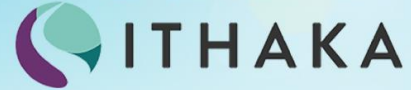
Clinical history or additional information (such as test results):

if you have any questions please contact the Chiedza team:

ITHAKA
flyer



HIV Self-testing support by:



Available at the CHIEDZA Centre or in the comfort of your own home



Step 1: Register

Securely register with your Self Test Barcode & cellphone.



Step 2: Test

Follow in-app guidance to test.



Step 3: Report

Report your results for more information and guidance.



Step 4: Stay Connected

For more expert advice and assistance.

Simple. Secure. **Free.**

Visit the Chiedza team for more information & free access to ithaka



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Bulawayo 0716 318 734

www.ithaka.co.zw

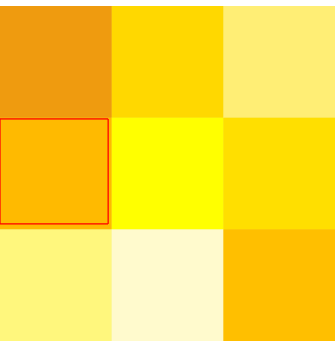
Minibus



T-shirt
Blue



T-shirt
Yellow



M.O.S
Female &
Male

MENU OF SERVICES

Hey Guys!
Here are our services,
especially for you!

Get your mind, body and health
on the bright path with our...

- HEALTH INFORMATION
- COUNSELLING
- HIV TESTING

Available at the CHIEDZA Centre or in the
comfort of your own home.

- FAMILY PLANNING
- RELATIONSHIP ADVICE
- HIV TREATMENT
- CONDOMS
- REFERRAL SERVICES
- HIV TREATMENT SUPPORT

- Ask us about our Wangu/ Skeem Sami programme

LIVING BRIGHT
BEGINS HERE




Chiedza
Health For Our Future



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Bulawayo 0716 318 734


Chiedza
Ukukhanya
Health For Our Future

MENU OF SERVICES

Hey Girl!
Here are our services,
especially for you!

Get your mind, body and health on
the bright path with our...

- HEALTH INFORMATION
- COUNSELLING
- PERIODS - PRODUCTS & EDUCATION
- HIV TESTING

Available at the CHIEDZA Centre or in the
comfort of your own home.

- FAMILY PLANNING ADVICE &
CONTRACEPTIVE PRODUCTS
- PREGNANCY TESTING
- HIV TREATMENT
- RELATIONSHIP ADVICE
- CONDOMS
- REFERRAL SERVICES
- HIV TREATMENT SUPPORT

- Ask us about our Wangu/ Skeem Sami programme




Chiedza
Ukukhanya
Health For Our Future



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Bulawayo 0716 318 734

Hey there!

Are You 16 -24 Years Old?

Love Having Fun?

Want To Meet Other Young People?
+ make New Friends?

Want Free Health Services
And Free Health Products?

Visit CHIEDZA !
Open 11:00 - 18:00



**LIVING
BRIGHT
BEGINS
HERE!**



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Bulawayo 0716 318 734



Telescopic
Welcome
Banner





Welcome to

Chiedza
Ukukhanya
Health For Our Future

COMMUNITY
NUM

Internal poster

MENU OF SERVICES

Hey Guys!
Here are our services,
especially for you!

Get your mind, body and health
on the bright path with our...

- HEALTH INFORMATION
- COUNSELLING
- HIV TESTING

Available at the CHIEDZA Centre or in the
comfort of your own home.

- FAMILY PLANNING
- RELATIONSHIP ADVICE
- HIV TREATMENT
- CONDOMS
- REFERRAL SERVICES
- HIV TREATMENT SUPPORT

- Ask us about our Wangwi/ Skeem Sani programme!

**LIVING BRIGHT
BEGINS HERE**



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Bulawayo 0716 318 734





MENU OF SERVICES

Hey Girl!
Here are our services,
especially for you!

Get your mind, body and health on
the bright path with our...

- HEALTH INFORMATION
- COUNSELLING
- PERIODS - PRODUCTS & EDUCATION
- HIV TESTING

Available at the CHIEDZA Centre or in the
comfort of your own home.

- FAMILY PLANNING ADVICE &
CONTRACEPTIVE PRODUCTS
- PREGNANCY TESTING
- HIV TREATMENT
- RELATIONSHIP ADVICE
- CONDOMS
- REFERRAL SERVICES
- HIV TREATMENT SUPPORT

- Ask us about our Wangwi/ Skeem Sani programme!

**LIVING BRIGHT
BEGINS HERE**



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Bulawayo 0716 318 734




MENU OF SERVICES

Hey Guys!
Here are our services, especially for you!

Get your mind, body and health on the bright path with us...

- HEALTH INFORMATION
- COUNSELLING
- HIV TESTING

Available at the CHECTO Centre or in the comfort of your own home.

- FAMILY PLANNING
- RELATIONSHIP ADVICE
- HIV TREATMENT
- CONDOMS
- REFERRAL SERVICES
- HIV TREATMENT SUPPORT

...and we offer our Men's' Abuse-Inn-Program!

LIVING BRIGHT BEGINS HERE

Checto
Centre for Health, Education & Community Transformation

Head Office: 0776 661 076
Head Office of East: 0716 218 730
Branches: 0716 218 724



Youth Helpline

For Free (telone, Econet, netone):
SMS "YAZ" to 33500

or text / whatsapp **"call me back"** to **0777469107**
Econet subscribers only **can call toll free line "393"**

- ◆ Helpline hours are Monday-Friday **08:00 am-06:00pm.**
- ◆ If you have visited CHIEDZA, let the Helpline know when you call!

Access free advice information, counselling, and referrals on:

- ◆ HIV/AIDS
- ◆ Sexual and Reproductive Health and Rights (Family Planning Services, condoms)
- ◆ TB
- ◆ GBV
- ◆ Reproductive cancers
- ◆ Pre- exposure prophylaxis (PreP)
- ◆ Post-exposure prophylaxis
- ◆ HIV self-testing Kits
- ◆ VMMC
- ◆ Relationships & Sex
- ◆ Career Guidance
- ◆ Healthy living
- ◆ Faith
- ◆ Safe Shelter
- ◆ Legal Assistance

Download YAZIPO application on google play store

CAPS/ Buddy
Leaflet
(front & back)



LIVE BRIGHT... WITH A TREATMENT BUDDY!

What is a treatment buddy?

Anyone you feel comfortable sharing your status with and who you feel will support you.

A treatment buddy's role:

- Support
- Picking up your medication
- Attending CHIEDZA Peer Support groups (CAPS) with you

Grab a **WANGU/SKEEM SAMI** card and give it to your **TREATMENT BUDDY!**

WE'RE Living Bright!

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Bulawayo 0716 318 734



Wangu/Skeem Sami

Number: D **B**
(Cohort)

Number: P **B**
(non-cohort)

Cluster:

Chiedza Ukukhanya Health For Our Future

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CHIEDZA Adolescent Peer Support (CAPS)
Together, we shine!

What will you get from CAPS groups?

- Meet fellow young people
- Social support
- Prescription refills

Come, let's talk about confidence, self-esteem, dating & relationships, peer pressure, careers, nutrition & exercise, general health and much much more....

Living Bright begins HERE!

Saturdays at the CHIEDZA Centre.
Light refreshments / snacks will be provided.

CAPS MEMBERSHIP CARD

Number: D
(Cohort)

Number: P
(non-cohort)

Cluster:

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Bulawayo 0716 318 734

Harare 0779 620 908
Mashonaland East 0716 318 730
Bulawayo 0716 318 734



Activities Calendar

ACTIVITIES CALENDAR

20__



Month



SUN	MON	TUE	WED	THU	FRI	SAT

Learn more at
www.chiedza.co.zw

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Bulawayo: 0716 318 734

Suggestion
Box



Here are some easy steps to follow so you can track your period using a simple calendar, diary, or piece of paper:

To measure the length of your period

Step 1: Mark down the first day that you bleed.

Step 2: Mark down the last day that you bleed.

Step 3: Repeat steps 1 and 2 for 3 months.

Step 4: Add the number of days you bleed for month 1, 2, and 3 and divide by 3 to calculate the average length of your period.

To measure your period cycle

Step 1: Write down the first day that you bleed.

Step 2: Write down the first day of your NEXT period.

Step 3: Count the number of days in-between the first days of your period for the two months.

Step 4: Estimate the first day of your next period (3rd month) by counting the same number of days between the first day of the 1st month and the first day of the 2nd month



•Pain Management

If you have menstrual cramps, take some pain medication such as ibuprofen or paracetamol. For the best results, try to take these medications the day before your period is due to start or just as soon as bleeding or cramping starts.

If you do not want to or cannot use medication, heat can also help. Place a hot towel or hot water bottle on your lower back or tummy. You can also do some light stretches or other forms of exercise to relieve the pain.

Everything you need to know about...
YOUR PERIOD!



www.chiedza.co.zw
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Bulawayo: 0716 318 734

UNDERSTANDING YOUR PERIOD

•What is a period?

Menstruation, or a period, is a very natural process that physically mature females go through every month. During menstruation, a female will typically bleed through her vagina for about 3 to 7 days.

•How do periods happen?

Every month, a sexually mature female's ovary releases an egg cell that travels towards the uterus through the fallopian tube. The uterus prepares for a possible pregnancy by developing a uterine lining made of tissue and blood vessels. This lining is called the endometrium.

If the egg is not fertilized and pregnancy does not occur, the uterine lining is shed and it exits the body through the vagina as a mixture of blood and tissue over a course of 3 to 7 days. This cycle is called a menstrual cycle and is generally 25 to 35 days long. The cycle starts over again with an egg that begins to mature in one of the ovaries.

PRODUCTS & SERVICES

Period Products

You can choose one of the following reusable products:

- The Menstrual Cup
- Reusable Pads
- Period Pants

Period Services

- Menstrual Health education
- Pain management education
- Pain management medication (Paracetamol and/or Ibuprofen)

PERIOD PANTS

•How to use them

You should aim to change your period pants 2-3 times a day. When you feel the need to change your period pants, remove them and rinse with cold water.

After rinsing, wash them separately or with the rest of your laundry. If you are not at home when you change your underwear, fold the used period pants and place in a waterproof bag or plastic bag and wash when you get home. When washing your pants, it is very important that you use cold water and that you do not use bleach or fabric softener.

To dry the period pants, simply hang them to dry under the sun and then store away with the rest of your underwear.

Never wear your period pants when they are not completely dry.

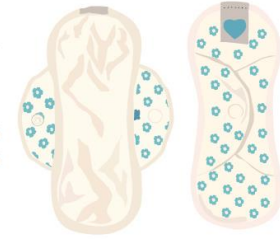


You can use your period pants for up to 2 years or until you feel they do not absorb enough anymore.

REUSABLE SANITARY PAD

•How to use one

Wash the pad before first use with cold water and soap. Dry the pads in the sun. You should aim to change your pad 2-3 times a day. Once used, fold the used pad following the 'easy fold & carry' instructions. The blood will be 'packed' inside the leakproof fabric and others will not be able to smell the pad. The plastic bag serves as extra protection.



Once used, rewash and reuse. Compare it to washing knickers and wearing them again.

The project will only replace the reusable pads every 12 months, unless damaged or lost. You need to bring in the reusable pads to show that they are damaged.

MENSTRUAL CUP

•How to use one

Fold the cup as you insert it into your vagina. When removing, remember to squeeze the bottom part of the cup until you feel or hear the suction release. Then, gently rock the cup from side to side while pulling down. Make sure that you do not pull the cup out by the stem alone! It is important to relax.

When you have removed your cup, empty it into the toilet, and rinse it with water. If you do not have access to water, you can wipe it with some tissue or simply reinsert it directly after emptying it. Every month, make sure you boil your cup for 3-5min at the end of your period.



The project will only provide the cup once. It will only be replaced if it is lost or damaged.

MANAGING YOUR MENSTRUAL HEALTH

•Taking care of your body

•Tracking your period

This is an easy way to predict how long you will bleed for during your period and when you will next start your period.

This can help you prepare for your upcoming period every month and also alert you if you have missed your period (which may be a sign that you may be pregnant).