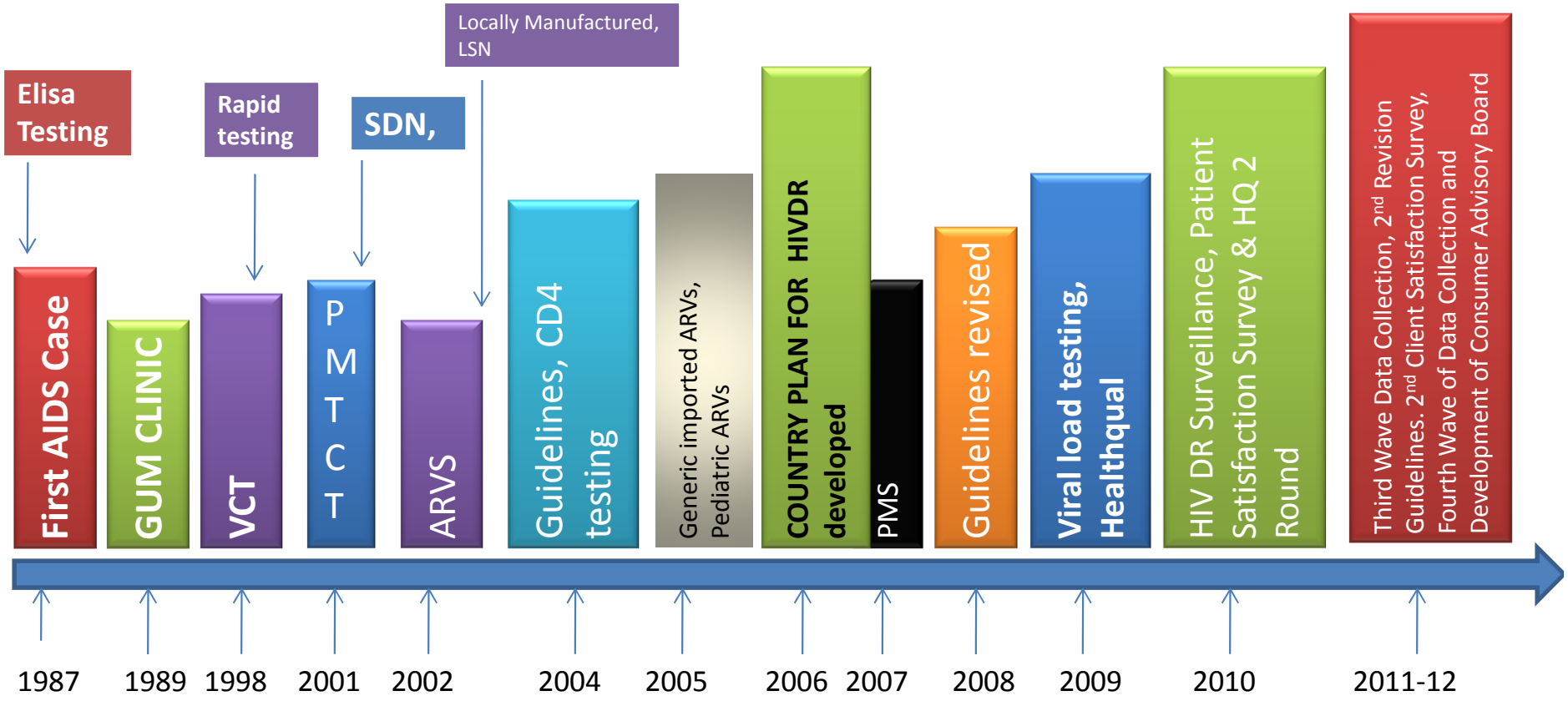
Guyana's HIVDR Strategy

Dr. Shanti Singh,
Programme Manager,
National AIDS Programme.
Ministry of Health

Historical Progress of the National HIV Responses



Why HIVDR monitoring for Guyana

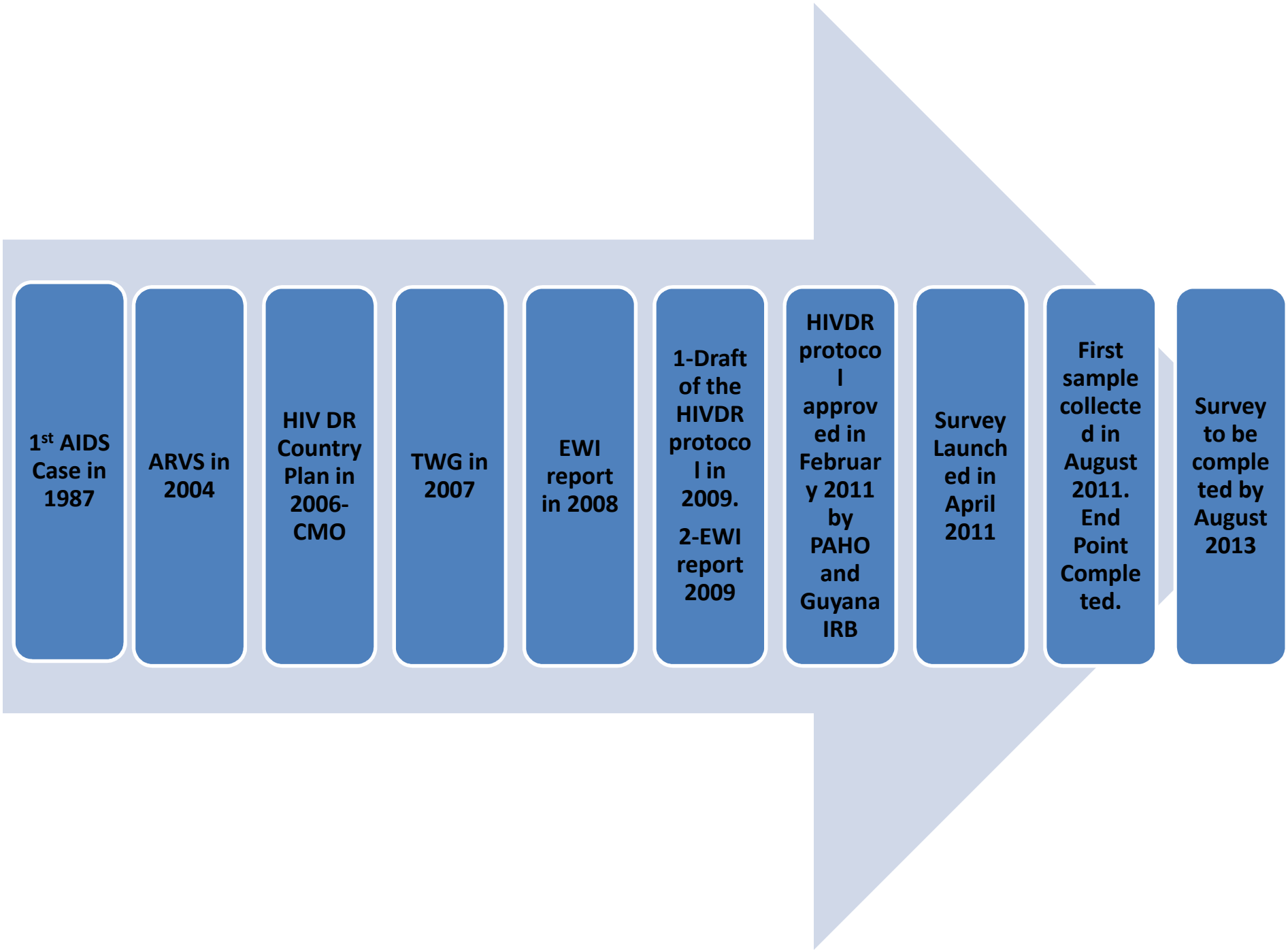
- Programme relatively established
- Expansion of treatment- 1 site in 2002 to 19 sites in 2009.
- Movement from 1st Line to 2nd line therapy
- Consideration for SDN in PMTCT.
- Adherence is an issue.

Snap Shot of the Treatment programme

	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of persons on ARVs	123	497	1,002	1,611	1,965	2,473	2,832	3,059	3,432
Total increase over previous year	NA	374	505	609	354	508	359	227	373
Percentage (%) increase	NA	304	101	60.7	21.9	25.8	14.5	8.0	12.2

Increase in the number of patients on second line -58 in 2006 to
296 in 2010 and
305 in 2011.

Indicators	*2010*	*2011*
Adult Male	*77.3%*	*76.9%*
Adult Female	*83.4%*	*83.8%*
Children- Male	*90.0%*	*80.0%*
Children- Female	*78.6%*	*85.7%*


1st AIDS Case in 1987
ARVS in 2004
HIV DR Country Plan in 2006- CMO
TWG in 2007
EWI report in 2008
1-Draft of the HIVDR protocol in 2009.
2-EWI report 2009
HIVDR protocol approved in February 2011 by PAHO and Guyana IRB
Survey Launched in April 2011
First sample collected in August 2011. End Point Completed.
Survey to be completed by August 2013

HIVDR monitoring

Two main components:

- EWIs
- HIVDR Survey

Indirectly- Quality of care, patient involvement and satisfaction

HIV DR Team

National Level

-Programme Manager

-HIV Treatment Coordinator

- HIVDR survey coordinator

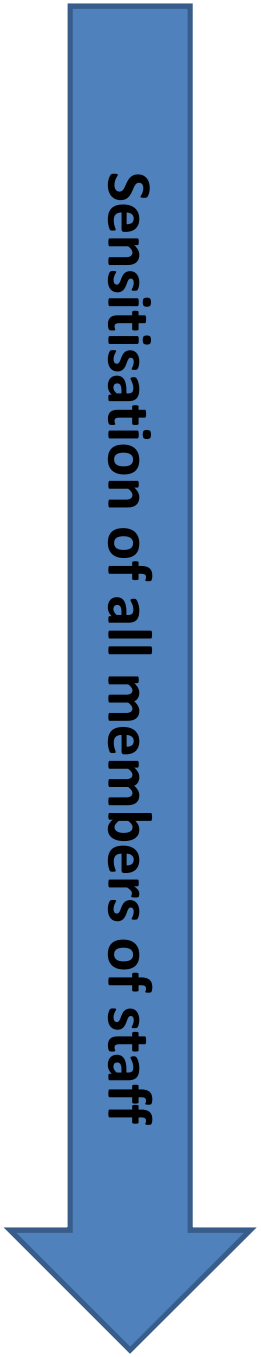
NTCT (Site) Team

- Clinic Coordinator
- Clinic Liaison

Laboratory Team

-Laboratory Coordinator

- Laboratory Liaison



Early Warning Indicators

- EWI 1: To determine the percentage of adult patients initiating ART who are prescribed an **appropriate first-line** ART regimen.

- EWI 2: To determine the percentage of patients initiating ART who ***are lost to follow-up 12 months after ART initiation.***

- EWI 3: To determine the percentage of adult patients who are taking an ***appropriate first-line ART regimen 12 months after ART initiation.***

- EWI 4: To determine the percentage of patients who **picked up** all prescribed ARV drugs on time during their first year.

Early Warning Indicators

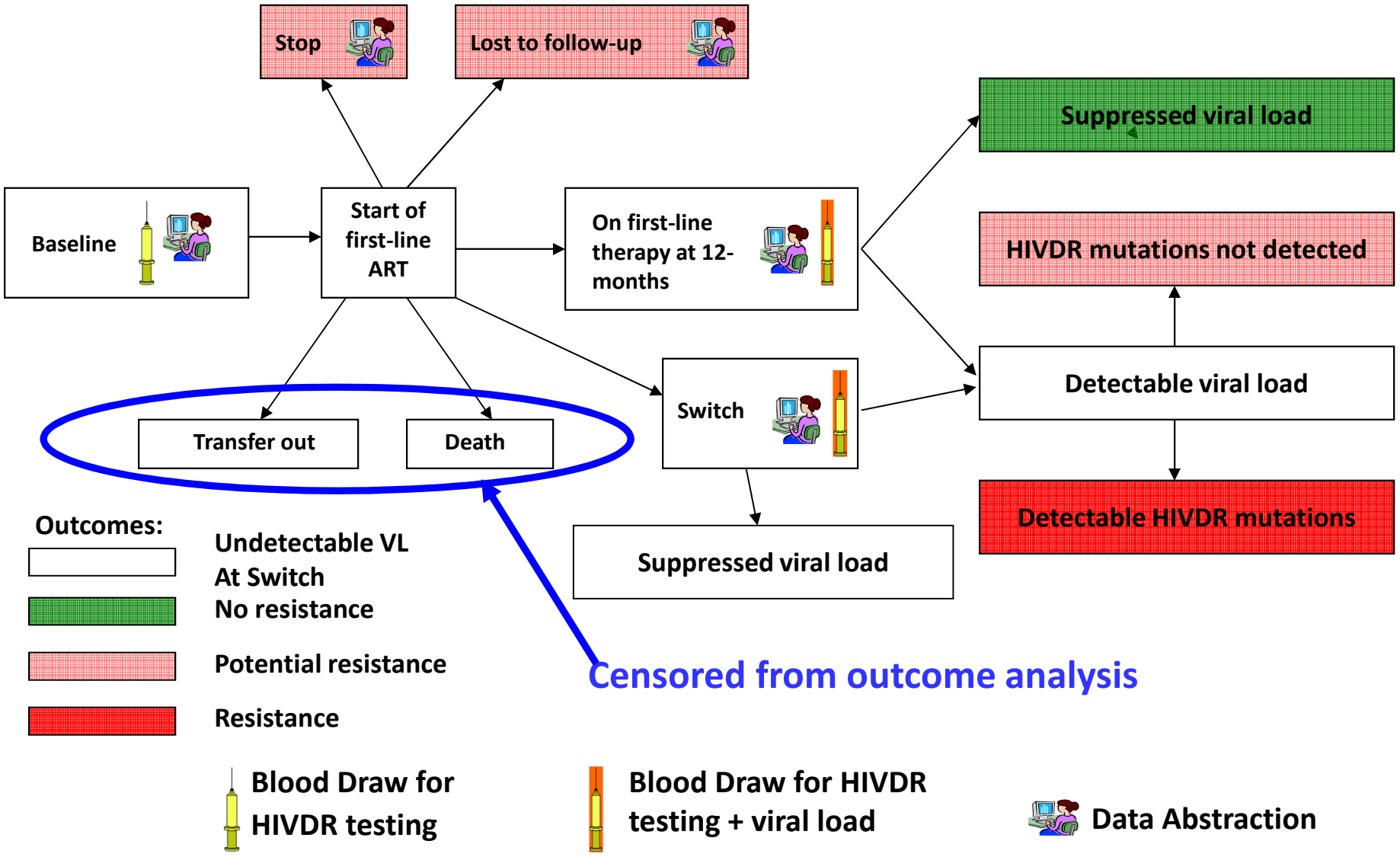
- EWI 5: To determine the percentage of patients ***who attended all clinical consultations*** on time during their first year of ART.

- EWI 6: To determine the percentage of months in a designated year in which there were no ***ARV drug stock-outs.***

HIVDR Survey Monitoring Objectives

- Proportion of site attendees that achieve HIVDR prevention
- Identify factors potentially associated with HIVDR resistance
- Identify the mutations and pattern of mutation

Evaluations, Endpoints, and Outcome Classifications



Eligibility- Inclusion Criteria

- Eligible for ART, as defined by country's national guidelines.
- Patients who initiate an adult ART regimen (dosage), on or after the survey start date, at age 16 and above.
  - This includes individuals who have previous ARV drug experience (e.g., PMTCT, other ARV exposure) if they are eligible to initiate and do initiate first-line ART at the sentinel site.
- Patients who are able to give consent for participation in the survey following the informed consent process according to the country's protocol.

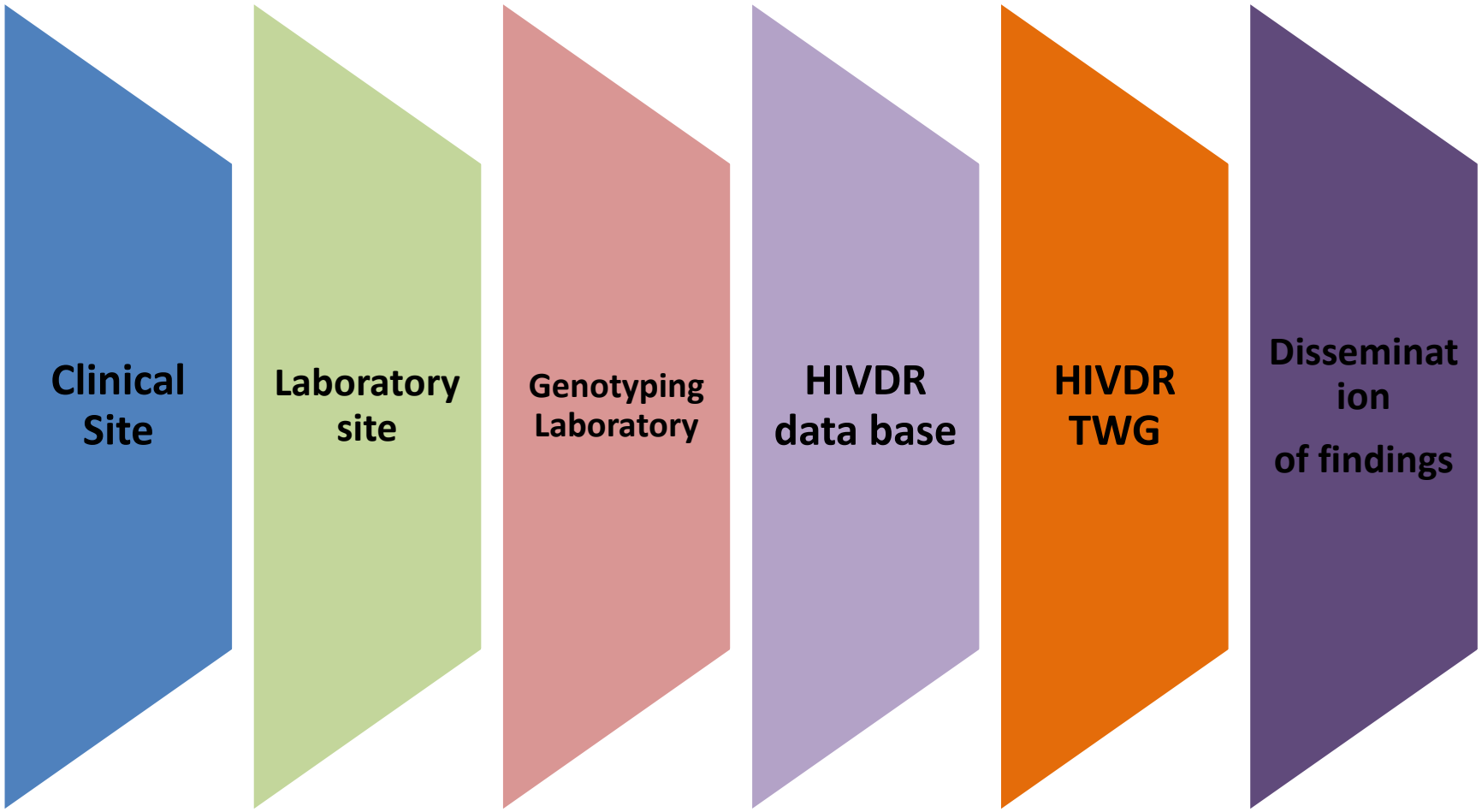
Eligibility Criteria- Exclusion Criteria

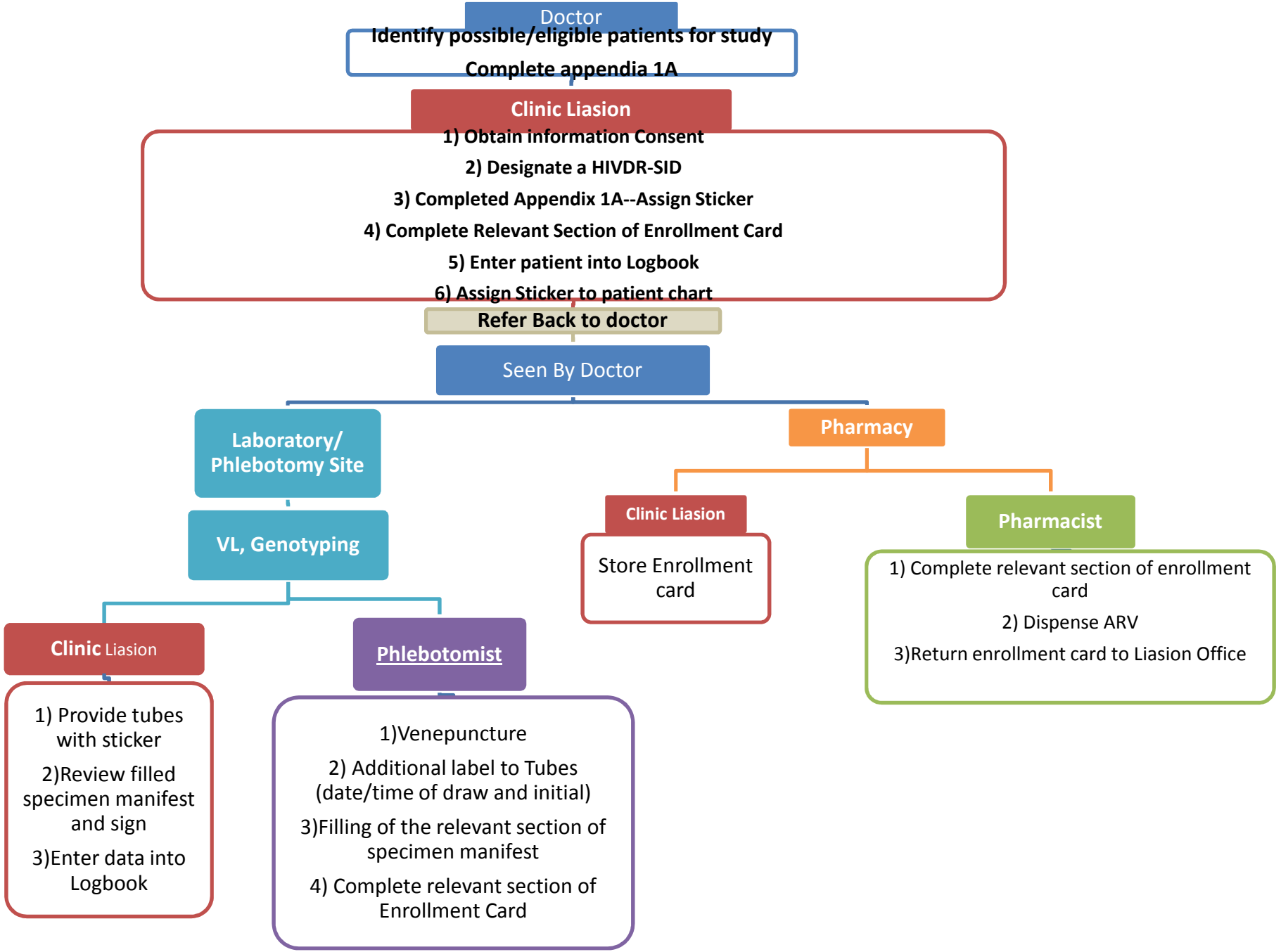
- Individuals transferring in from another ART site who are at the time of transfer currently taking a three- or four-drug first-line ART regimen. (ART)

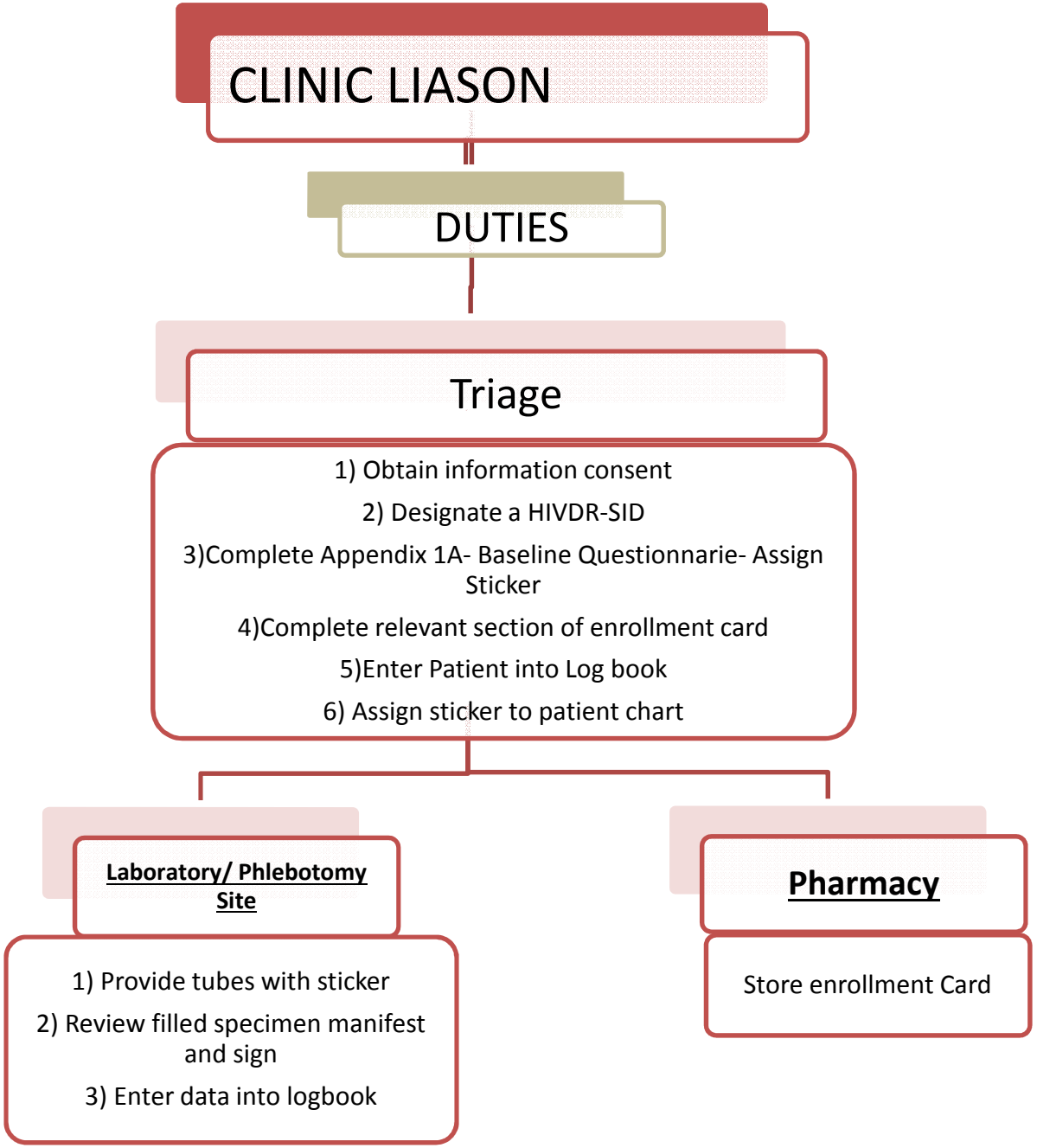
- Individuals who are part of an observational cohort for whom more follow-up efforts are made than for other ART patients treated at the site
  - (Patients enrolled in an observational cohort for whom no additional follow-up procedures are included may be eligible).

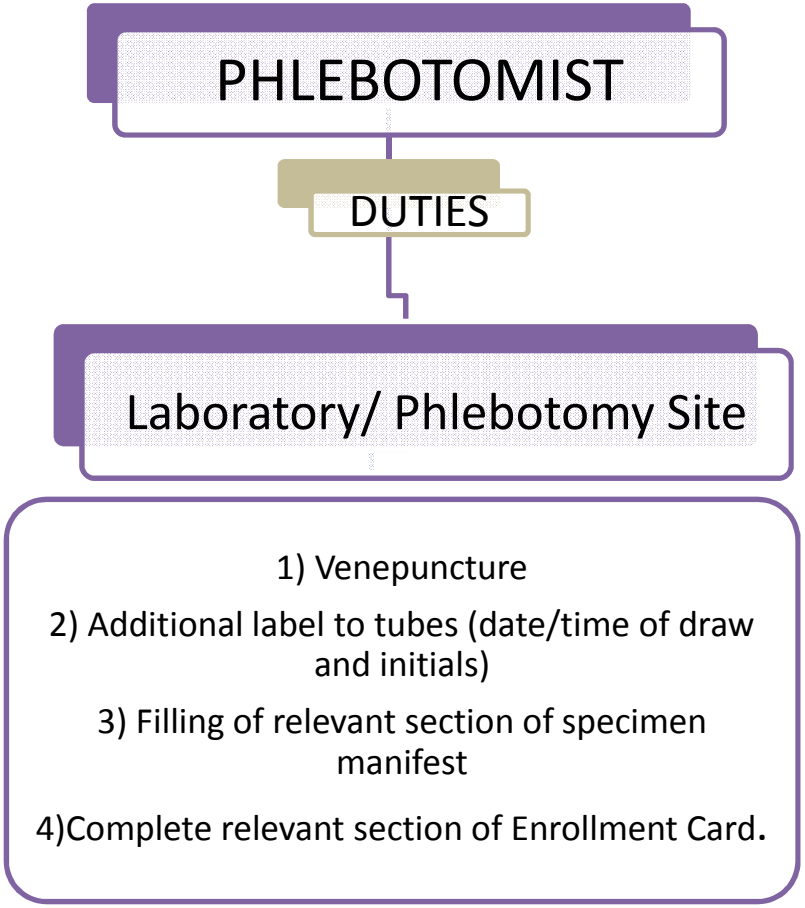
- Individuals reinitiating ART who have previously started and stopped ART at the sentinel survey site.

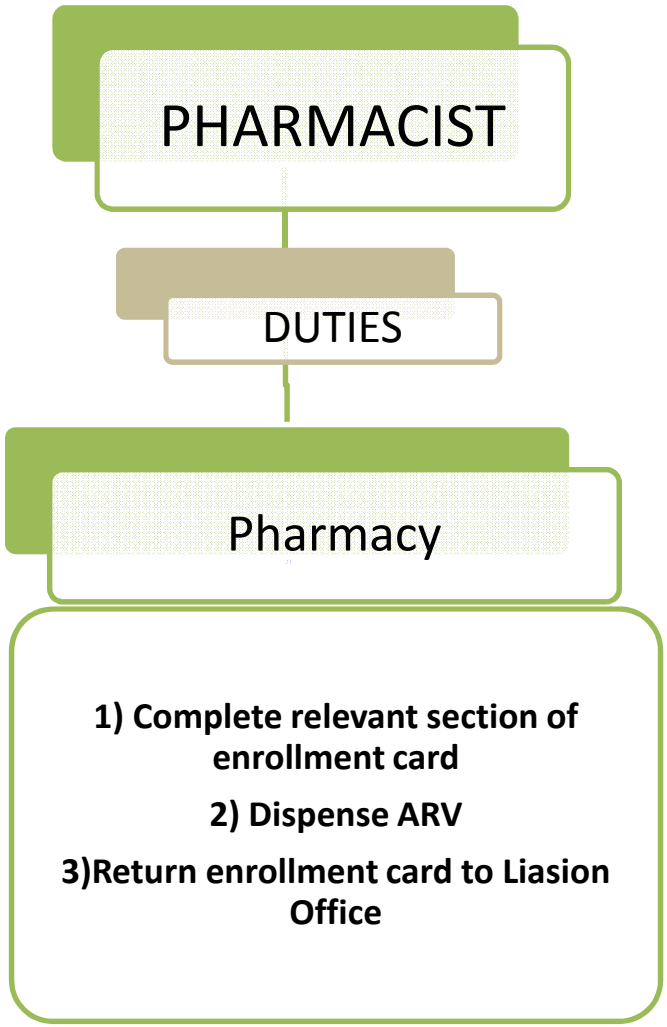
Survey Flow


Clinical Site
Laboratory site
Genotyping Laboratory
HIVDR data base
HIVDR TWG
Dissemination of findings


Doctor
Identify possible/eligible patients for study
Complete appendia 1A
Clinic Liasion
1) Obtain information Consent
2) Designate a HIVDR-SID
3) Completed Appendix 1A--Assign Sticker
4) Complete Relevant Section of Enrollment Card
5) Enter patient into Logbook
6) Assign Sticker to patient chart
Refer Back to doctor
Seen By Doctor
Laboratory/ Phlebotomy Site
VL, Genotyping
Clinic Liasion
1) Provide tubes with sticker
2)Review filled specimen manifest and sign
3)Enter data into Logbook
Phlebotomist
1)Venepuncture
2) Additional label to Tubes (date/time of draw and initial)
3)Filling of the relevant section of specimen manifest
4) Complete relevant section of Enrollment Card
Pharmacy
Clinic Liasion
Store Enrollment card
Pharmacist
1) Complete relevant section of enrollment card
2) Dispense ARV
3)Return enrollment card to Liasion Office


CLINIC LIASON
DUTIES
Triage
1) Obtain information consent
2) Designate a HIVDR-SID
3)Complete Appendix 1A- Baseline Questionnarie- Assign Sticker
4)Complete relevant section of enrollment card
5)Enter Patient into Log book
6) Assign sticker to patient chart
Laboratory/ Phlebotomy Site
1) Provide tubes with sticker
2) Review filled specimen manifest and sign
3) Enter data into logbook
Pharmacy
Store enrollment Card


PHLEBOTOMIST
DUTIES
Laboratory/ Phlebotomy Site
1) Venepuncture
2) Additional label to tubes (date/time of draw and initials)
3) Filling of relevant section of specimen manifest
4)Complete relevant section of Enrollment Card.


PHARMACIST
DUTIES
Pharmacy
1) Complete relevant section of enrollment card
2) Dispense ARV
3)Return enrollment card to Liasion Office

Data Collection

- Base line Questionnaire –filed and signed by the doctor
- Consent form.
- Baseline abstraction form- team led by the HIV Dr. Survey Coordinator
- Log Book at clinical site- clinic liaison
- Specimen Manifest- clinic liaison, phlebotomist, laboratory liaison.
- Laboratory log book
- Sample procession form
- Endpoint questionnaire (VAS), endpoint data extraction form

- **Site: National Care and Treatment Center**
- **HIVDR-SID GYHIVDR-xxx B/Baseline**
- **Date started; (Initial ARV pick-up) (dd/mm/yyyy)**
- **regimen: List of drugs picked up at initial ARV pick-up**
- **Gender: Female/ Male**
- **Date of birth(dd/mm/yyyy)**
- **Age (calculated field if DOB is entered)**
- **Education level**
- **Residence of patient (village/town/city/region)**
- **Occupation**
- **Previous ARV exposure: exposure to PMTCT (yes/no, if applicable; include PMTCT regimen and duration, if available) and/or other ARV exposure (yes/no, if applicable; include ARV drugs taken and duration, if available) [obtained from the baseline questionnaire]**
- **Current pregnancy (yes/no) and date of last pregnancy (for female)**
- **On tuberculosis treatment at start of ART: (yes/no; include TB regimen if available)**
- **CD4 cell count(1,2,3,4) and CD4 assay date (dd/mm/yyyy)**
- **WHO stage: I, II, III, IV**
- **Viral load(1,2,3) and viral load date (dd/mm/yyyy; this will be done as part of the survey)**
- **Date and time of blood draw (dd/mm/yyyy, hh/mm)**
- **Name or initials of staff member drawing blood**
- **Baseline sequence for the protease region and the relevant portion of the reverse transcriptase region of the HIV genome [to be uploaded from genotyping lab]**
- **Data entry person**
- **Data entry date (dd/mm/yyyy)**

Other Clinic variables to be collected at start and at end (12months or switch) and analysis.

- **Catchment area and population groups served**
- **Number of patients started on ART in the past 12 months**
- **Number of patients planned to be started on ART in the next 12 months**
- **Number of months in previous 12 months in which one or more first-line ARV drugs were insufficient for patients already on ART**
- **Number of months in previous 12 months in which one or more first-line ARV drugs were insufficient for patients scheduled to start ART**
  - **Number of ARV stock-outs in previous 12 months**
  - **Method of determining eligibility for ART**
  - **Provider/patient ratio**
  - **Training level for persons who start patients on ART**
  - **Training level for persons who provide routine care during ART**
  - **Location of ARV drug pick-ups (pharmacy in clinic, pharmacy off-site, treatment room in clinic, other (specify)**
  - **Role of staff who dispense ARV drugs (physician, nurse, pharmacist, other (specify)**
  - **Procedures for following up patients who do not return to clinic for ART appointments**

Other Clinic variables to be collected at start and at end (12months or switch) and analysis proposed (2)

- **Costs of care (record 0 if no cost)**
  - **Cost of initial registration at clinic**
  - **Cost of each appointment**
  - **Cost of first-line ARV drugs**
  - **Cost of each routine laboratory test used in ART**
  - **Cost of special laboratory tests used in ART**
- **Days of the week ; clinic opening and closing times for ART clinical appointments**
- **Days of the week' pharmacy opening and closing times for ARV drug pick-ups**
- **Maximum, minimum, and mean distance traveled by patients to clinic; brief description of most commons means of transport**
- **Longest, shortest, and mean waiting times for routine ART appointment at clinic**
- **Longest, shortest, and mean waiting times for ART drug pick-ups**

HIVDR SID	DOB	Date of Specimen Collection	Date Received at NPHRL	Number of EDTA Tubes Received	Volume of specimen received	Accepted: YES or NO	Received By:	Name of Clinician	Results	Date results issued to Site
GYHIVDR-001	…../…../…..	…../…../…… :	…../…../…..							…../…../….
GYHIVDR-002	…../…../…..	…../…../…… :	…../…../…..							…../…../….
GYHIVDR-003	…../…../…..	…../…../…… :	…../…../…..							…../…../…
GYHIVDR-004	…../…../…..	…../…../…… :	…../…../…..							…../…../….
GYHIVDR-005	…../…../…..	…../…../…… :	…../…../…..							…../…../….
GYHIVDR-006	…../…../…..	…../…../…… :	…../…../…..							…../…../….
GYHIVDR-007	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-008	…../…../…..	…../…../…..	…../…../….							…../…../….
HIVDR SID	**DOB**	**Date of Specimen Collection**	**Date Arrived at NPHRL**	**Number of EDTA Tubes Received**	**Volume of specimen received**	**Accepted: YES or NO**	**Received By**	**Name of Clinician**	**Results**	**Date results issued to Site**
GYHIVDR-009	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-010	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-011	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-012	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-013	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-014	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-015	…../…../…..	…../…../…..	…../…../….							…../…../….
GYHIVDR-016	…../…../…	…../…../…	…../…../…							

Time of plasma separation	_ _ : _ _			
Number of aliquots	**1**	**2**	**3**	**4**
Volume in aliquot 1	**ml**			
Volume in aliquot 2	**ml**			
Volume in aliquot 3	**ml**			
Volume in aliquot 4	**ml**			
	Date	**Time**	**Temperature**	
Initial plasma aliquot freeze	_ _ / _ _ / _ _ _ _	_ _ : _ _	**°C**	
Storage temperature for aliquots	**°C**			
	Date	**Time**		
Thaw 1 of plasma aliquots	_ _ / _ _ / _ _ _ _	_ _ : _ _		
Refreeze 1 of plasma aliquots	_ _ / _ _ / _ _ _ _	_ _ : _ _		
Thaw 2 of plasma aliquots	_ _ / _ _ / _ _ _ _	_ _ : _ _		
Refreeze 2 of plasma aliquots	_ _ / _ _ / _ _ _ _	_ _ : _ _		
Thaw 3 of plasma aliquots	_ _ / _ _ / _ _ _ _	_ _ : _ _		
Refreeze 3 of plasma aliquots	_ _ / _ _ / _ _ _ _	_ _ : _ _		
Date sent to Genotyping Laboratory	_ _ / _ _ / _ _ _ _			
Time Sent to Genotyping Laboratory	_ _ : _ _			
Transport method to Genotyping Laboratory	**Dry Ice**	**Liquid Nitrogen**	**Other**	
Description of packaging				

Survey Information-NCTC

- Total Recruited- baselines 130 persons
- 6 died, 2 stopped and 3LTFU.

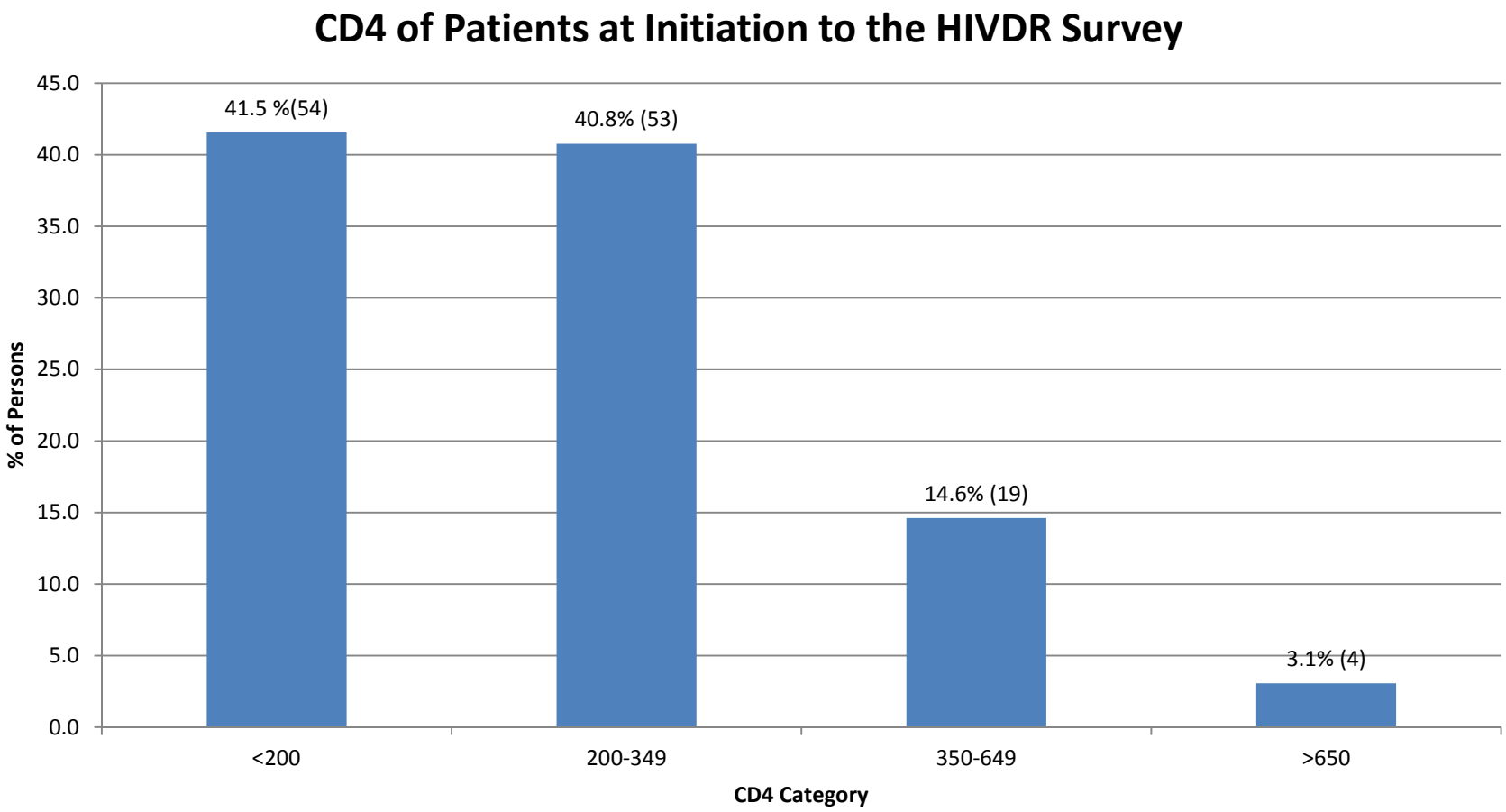
- Endpoint- 56 completed, 63 still being followed up for their end points.
- Anticipated end date of August 2013.

Baseline data-Survey Demographics

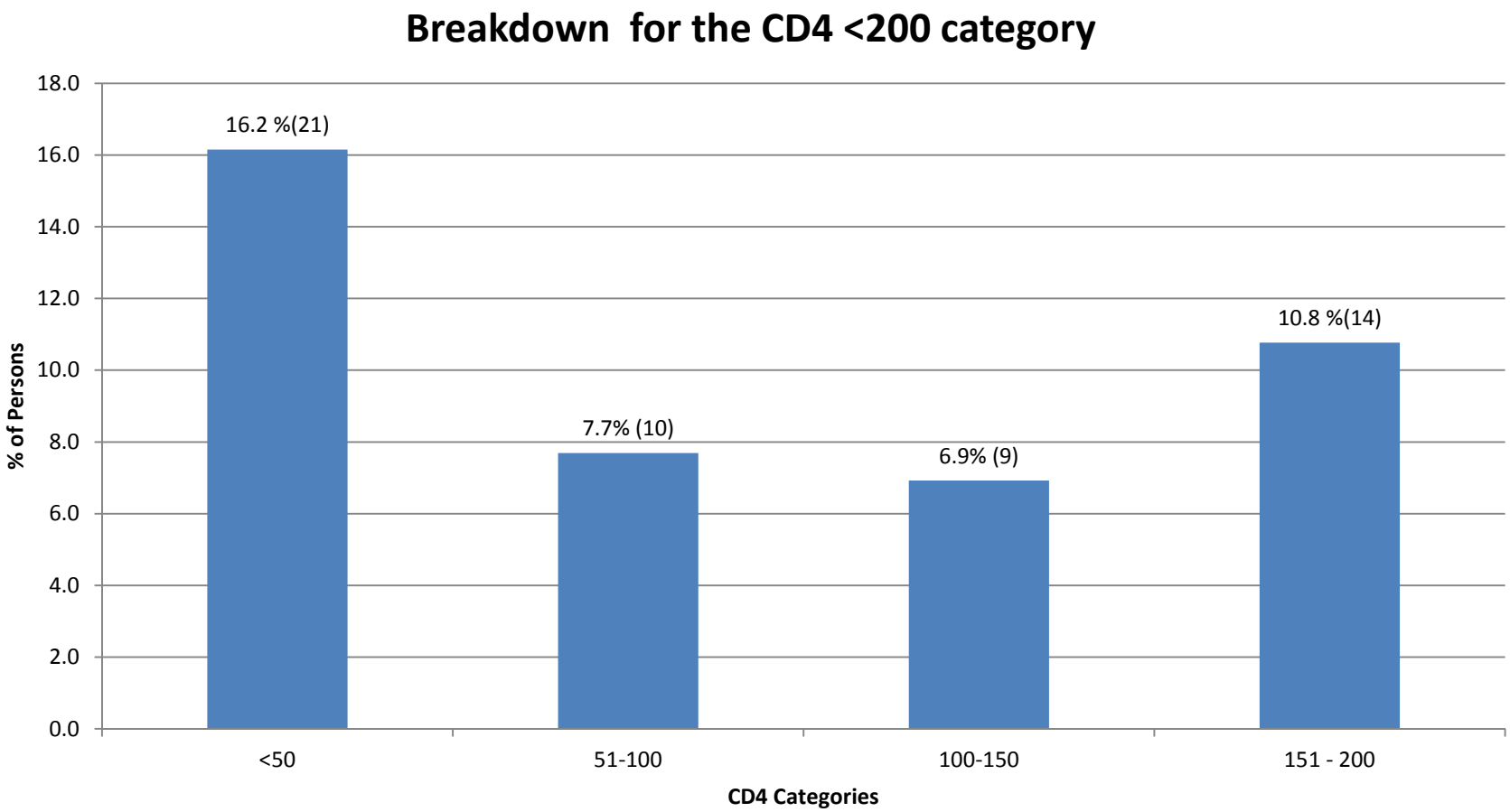
Participants : 130 persons aged between 16 -77 years

- 51% males (66) and 49% females 64
- Education:
  - 43% completed some primary
  - 69% completed some secondary
  - 6% completed some university
  - 12% data is unknown

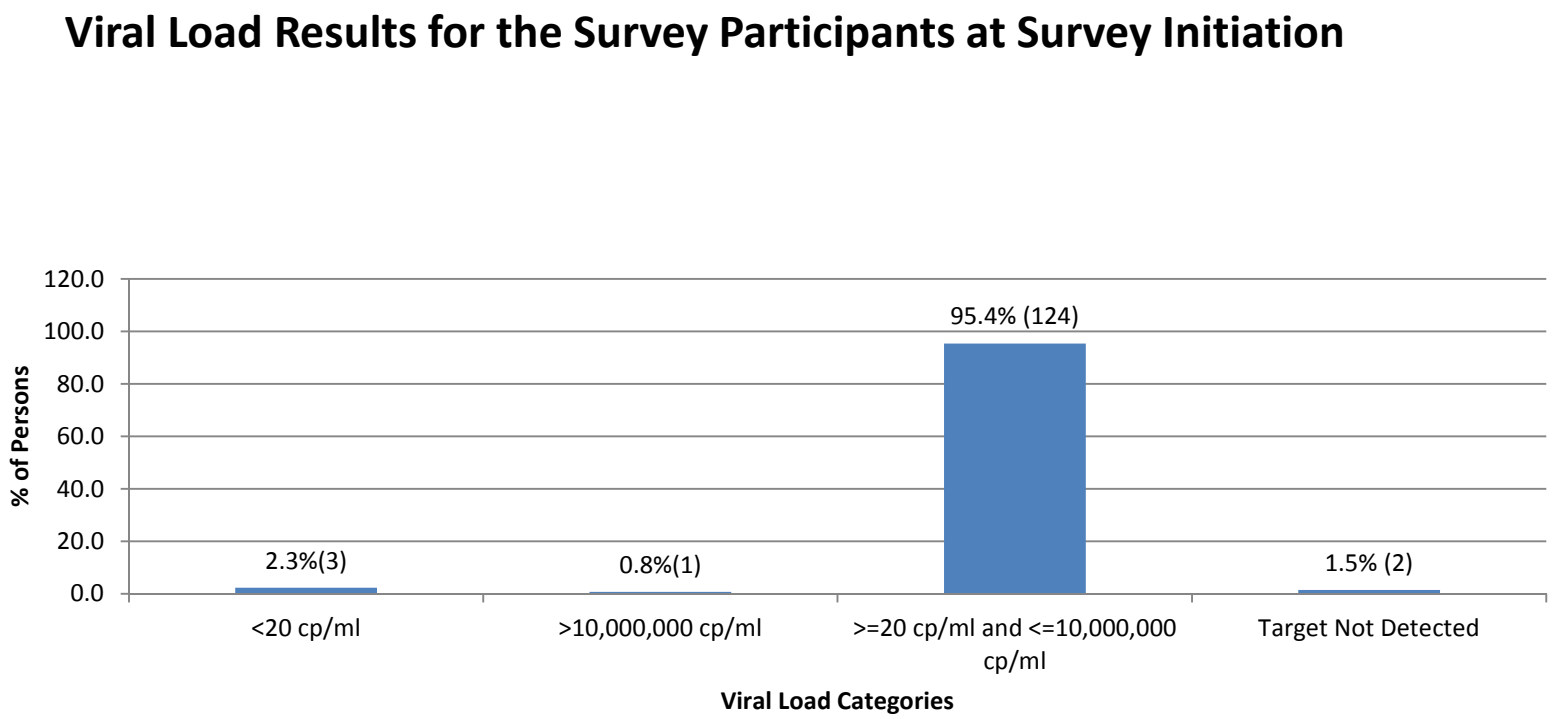
Baseline- Survey Information



Baseline -Survey Information



Baseline- Survey Information



Data dissemination and Use-EWI Data

- National EWI reports produced.
- Highlights of the report are summarised in the National HIV report.
- Updates provided to the HIV DR working group.
- Updates provided to the HIV Treatment working group.
- Feedback provided practitioners at quarterly feedback meetings.

Decisions are made and implemented.

Data dissemination and use HIVDR Survey

National Level

-Status updates in the National Reports.

- Status reports are presented at the TWG on HIVDR and discussed. Presentations for the survey, site and laboratory coordinators.

Site Levels (NCTC)

-Regular updates at Staff meeting.

- Regular updates posted on the Clinic's notice board

Completion of the survey

- Report production and dissemination- among several groups (Patients, HCW, policy makers, media)
- Understand the findings, make the necessary modifications- Rx but also prevention programmes.

Challenges

- HR
- Patient Monitoring System is paper based.
- HIVDR Survey- Data base challenges. Unable to upload FASTA files into the data base.

Next Steps

- Completion of survey.
- Need to HIVDR base fixed- upload the FASTA files.
- Data analysis, dissemination and use.
- Programme consideration and use of the survey results to inform policy and guidelines
- Reviewing the paper base system – pilot an IQ Chart.

Next Steps

- Regular EWI reports.
- Continue and expand the HEALTHQUAL initiative
- Consumer Advisory Group.
- Client Satisfaction Survey
- Addition implementation research to support the treatment programme- reasons for late entry into the treatment, strengthen linkages between testing and treatment, better understanding adherence.

Thank you.