EVALUATION OF EARLY INFANT DIAGNOSIS SURVEILLANCE SYSTEM IN KENYA

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DECLARATION

This research project is my original work and has not been submitted for an award in any other university or college.

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DEDICATION

This work is dedicated to my family for their support and inderstanding during my study period

ACKNOWLEDGEMENT

My sincere appreciation goes to Prof Raphael Nyonje and Dr Angeline Mulwa for their support, guidance insight and encouragement from the beginning of this project up to the end.

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To Busia County, thanks for giving me the opportunity to undertake this course.

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LIST OF ABBREVIATIONS

EID	Early Infant Diagnosis
EID LRF	Early infant diagnosis laboratory request form
ART	Anti-Retroviral Therapy
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
AIDs	Acquired Immunodeficiency Syndrome
HEI	HIV Exposed Infant
DNA	Deoxyribonucleic Acid
RNA	Ribonucleic Acid
PCR	Polymerase Chain Reaction
DBS	Dry Blood Spot
PMTCT	Prevention of Mother to Child Transmission
eMTCT	Elimination of mother to Child Transmission
WHO	World Health Organization
MCH	Maternal Child Health
MOH	Ministry of Health
NASCOP	National AIDS and STI Control Programme
CCC	Comprehensive care clinic
OPD	Out-Patient Department
EID LRF	Early infant diagnosis laboratory request form

PROJECT SUMMARY

Kenya is one of the 22 priority countries focused for lessening of mother-to-Child transmission (mtCt) of Human immunodeficiency virus. The worldwide super-fast-track framework propelled in 2016 points at ending new HIV infections among children (start free) and keeping their mothers alive, adolescents (stay free) and end pediatric and adolescent aids (aidsfree) by 2020. Identifying infants infected early and starting them on Anti-retroviral therapy as soon as possible after diagnosis is fundamental to moderate the movement from HIV infection to AIDS and to prolong the life of the patient. The objective of the assessment was to describe the attributes and process of operation of HIV/AIDS early infant diagnosis surveillance system in Kenya, determine if the set objectives for establishing the HIV/AIDS Early infant diagnosis surveillance system and to make appropriate recommendations for improving the surveillance system in Kenya. On methodology, surveillance evaluation involved qualitative method and review of January-June 2018 early infant surveillance data. A new early infant diagnosis laboratory requisition form was developed after identification comprehensive identification of the gaps. The assesment process was according Center for Disease Control and Prevention (CDC) guidelines on public health surveillance assesment. Key informant (KII) sessions were conducted with health care workers to assess the operation, functionality and key attributes of the surveillance system. Revised early infant diagnosis laboratory request form, piloted the new tool, revision of the new tool after incorporating feed back from the pilot, rolled out of the new tool and updated EID and DHIS2 websites to be in line with the new tool. Data from the EID website before and after the revision of the EID LRF showed an improvement on data quality. Focused mentorship and continuous training on the EID surveillance system is important.

CHAPTER ONE

1.0 INTRODUCTION

The National AIDS and STI's Control Programme (NASCOP) was set up in 1987 to lead in the battle against HIV/AIDS. At the crest of the HIV plague, HIV prevalence was at 30% in various parts of the nation. HIV/AIDS was articulated a national catastrophe in 1999, this lead to a national move towards creating awareness and advocacy for prevention of new infections. This is done inconjuction with implementing partners, regular HIV testing and providing appropriate treatment (NASCOP, 2017).

About 77.3 million individuals have been infected with HIV since the primary case was discovered 1981, and 35.4 million people have died from AIDS-related illness (UNAIDS, 2016a). There were 1.8 million new infections in 2016, of which one hundred and sixty thousand were children aged less than 15 years. One million people died of due AIDS of which 120,000 were children aged less than 15 years (UNAIDS, 2016a). A total of 1,500,000 Kenyans lives with HIV, 110,000 are children aged 0 to 14 years (UNAIDS, 2016b). Kenya has the fifth highest number of Aids infections in the world. South Africa, with a burden of 7.1 million leads, ahead of Nigeria (3.2 million), India (2.1 million), and Mozambique (1.8 Million) according to statistics from the Central Intelligence Agency (USA) in 2016 (CIA, 2017). HIV exposed infants need a timely HIV diagnosis, this is a vital step to reduce mother to child transmission and mortalities in children (WHO, 2007). Maternal HIV antibodies persist in infants exposed to HIV up to the age of 18 months, early HIV diagnosis requires use of virological testing. WHO has recommended screening for HIV-exposed infants in using polymerase chain reaction (PCR) technology at age 4–6 weeks. This aligns to the immunization visits by the mother and is critical in identifying early early postnatal transmissions (WHO, 2007).

World health organizations in 2006 expanded HIV care and treatment and added HIV diagnosis in children (WHO, 2007). Early infant diagnosis (EID) services have been joined into PMTCT programme since 2006 throught out Sub Saharan Africa (Ong'ech *et al* 2012; Weigel et al 2009; UNAIDS, 2014).

A big diagnostic gap exist where by about half, 51% of infants exposed to HIV globally are tested at six weeks after birth as recommended by WHO. Among the infants tested about half will not receive their results and those who test positive and are able get their results, only half are linked to care. Only half of the 150 000 babies born HIV-positive in 2015 were linked to care (UNAIDS, 2016c). In Kenya percentage of HIV exposed infants receiving a virological test for HIV two months after birth was 51% in 2015, 56% in 2016 and 51% in 2017 (UNAIDS, 2015). The Kenyan government through NASCOP in 2006 developed National pediatric EID guidelines, which indicate key time sensitive strategis to analyze and oversee HIV diesase among HIV exposed infants (MOH Kenya, 2009).

Public health surveillance is the persistent, precise collection, examination and illustration of health-related data required for the orchestratin, utilization and assessment of public health practice (CDC, 2001). This guarantees the institution of convenient mediations to control and avoid the malady beneath observation. The usefulness of a surveillance is decided through assessment of the surveillance system. It is imperative in identification of crevices within the framework as well as guaranteeing advancement within the quality, profiency and convenience of the system (CDC, 2001).

1.1 Problem Statement

The Ministry of Health (MOH) presented the EID programme in 2006 to test all HEI to guarantee early screening and linkage of infected newborns to care and treatment hence decreasing dismalness and mortality. However, the system has weakness that needs strengthening. In 2017 high number of confirmatory PCR tests appeared in the system, expected is minimal variation. EID samples that were positive in the initial test turn negative in subsequent analysis, confirmatory test appearing in the system with no trace of an initial test, non- standardized patient's identification/coding system. Longitudinal tracking of an infant is not possible. Various versions of laboratory request sheets; 2011, 2012.2013, 2014 and 2015 still being used by facilities causing variations in the indicator being picked. There was a need to link mothers CCC number and Infant CCC number, description of different variables on the laboratory request form, mother's regimen was standardized thus review on the form. All these complexities affect the overall linkage of the HIV exposed infant to care.

1.2 Justification

During the 2012-2015 period, Kenya implemented the first eMTCT strategic framework and successfully halved mother-to-child transmission of HIV from 16% to 8.3%. The second eMTCT framework for elimination of transmission of HIV and Syphilis from mother to the child, 2016-2021commits the country to be validated in 2021. However, 2018, January to March data shows MTCT of HIV have shot up to 11.5%. Kenya aims to achieve the pre-elimination targets of mother to child transmission of HIV and Syphilis by 2019, towards validation of elimination of Mother-To-child Transmission (eMTCT) of HIV and Syphilis. A newborn who has HIV has the probability of biting the dust from AIDs and related illness. This reduces by 75%, if they are screened early for HIV and started on ART within the first 12 weeks of life. Early screening of HIV among newborns is vital since it permits health care workers the opportunity to identify and give critical care and treatment early enough to such

children and an opportunity to keep all infected infants and their mothers in care to prevent loss to follow-up. Early Infant Diagnosis (EID) moreover grants the linkage of Prevention of Mother-to-Child transmission of HIV (PMTCT) and treatment services so as to decrease child mortality and helps mothers make decisions about infant feeding (Ciaranello *et al*., 2011).

1.3 Objectives

1.3.1 Broad objective

To evaluate early infant diagnosis surveillance system in Kenya and review of the early infant diagnosis laboratory request form

1.3.2 Specific objectives

1. To determine the effectiveness and efficiency of the surveillance system
2. Revise early infant diagnosis laboratory request form
3. Sensitize health care workers new Early infant diagnosis laboratory request form and other revised tools used in HIV exposed infants
4. Align EID system and DHIS-2 to the new tool
5. To make appropriate recommendations to stakeholders for its improvement

1.4 Delimitation of the study

The study was conducted at National AIDS and STI control programme. The study focused on the Early infant diagnosis surveillance system. The researcher focused on the Early infant diagnosis laboratory request sheet, Early infant diagnosis surveillance system dashboard and attributes of the surveillance system.

1.5 Limitations of the study

The study period was not sufficient enough to determine impact of new early infant diagnosis request sheet on the mother to child transmission rates. Delayed response from healthcare workers to participate in the key informant interview due to heavy workload at the hospital.

CHAPTER TWO

LITERATURE REVIEW

2.1 Description of the early infant diagnosis (EID) surveillance system

Early infant diagnosis surveillance is a population based electronic surveillance system that bensures HEI data collection is a continuous and ongoing process. NASCOP) manages and maintains the system. There are over 3000 sites for sample collection and 8 central testing laboratories serving various regions in Kenya (NASCOP-EID, 2017). Recently testing has been de centralized through Point of Care testing in some counties to reduce the turnaround time. EID care and administration incorporates an algorithm and arrangement of intercessions known as the "EID cascade of care". This cascade incorporates the following: [1] Early infant diagnosis testing among HIV-exposed newborn children, [2] precise sample collection, transport, and laboratory analysis; [3] transfer of results to both healthcare workers and mothers/caregivers; and [4] linkage to care and treatment (Ciaranello et al 2011; Sarah et al 2015).

HIV testing algorithm for infants as of 2017: DNA-PCR is carried out at 6-8 weeks or at first contact for all HEI. A positive EID test, the infant is started on ART and if negative, a repeat HIV DNA PCR is done at 6 months. HEI follow up continues for negative infants and a HIV DNA PCR test conducted at 12 months or soonest contact thereafter. If negative, the HIV antibody test is done at 18 months. Testing laboratories process the dried blood spot samples for the country and uploads the results into the early infant diagnosis dashboard.Data from the early infant diagnosis database can be viewed on a national dashboard on the NASCOP website.

2.2 Sample collection

Dried Blood Spots (DBS) are collected as portion of schedule care for newborn children with suspected or known HIV exposure. Tests are collected beneath sterile conditions from newborn children utilizing either a heel prick or finger prick depending on the age newborn child. Tests are collected within the well being officer at different section focuses counting maternal and child well being (MCH)/PMTCT clinics, Comprehensive Care Middle (CCC), maternity, outpatient division (OPD), and in pediatric ward. DBS filter papers are labeled and dried independently on a drying rack. They are at that point bundled utilizing glycine envelopes and fixed plastic sacks beneath sterile conditions and sent to the testing laboratory by a messenger went with the laboratory request form.

HIV automated PCR test methods are conducted on each test. Positive tests are retested to affirm their status and a request for collection of another sample incase testing failed, insufficient sample or to repeat the test or carry out a confirmatory test for positive samples. Laboratory management information system is used for the storage of the results (LMIS), along side laboratory request form showing the number of tests sent to the testing laboratory, date of sample collection/receipt in lab/processed/results, county, sub county, health facility, the age and sex of the infant, feeding method, point of entry, PMTCT intervention to the mother, and prophylaxis given to the infant. Health facilities can access results real-time from the system or via mail. NASCOP regularly analyses the data on the EID system and results of the analysis are posted on the EID dashboard. Feedback is given from the national program through forums such as meetings, support supervision to health facilities, phone calls and E-mails.

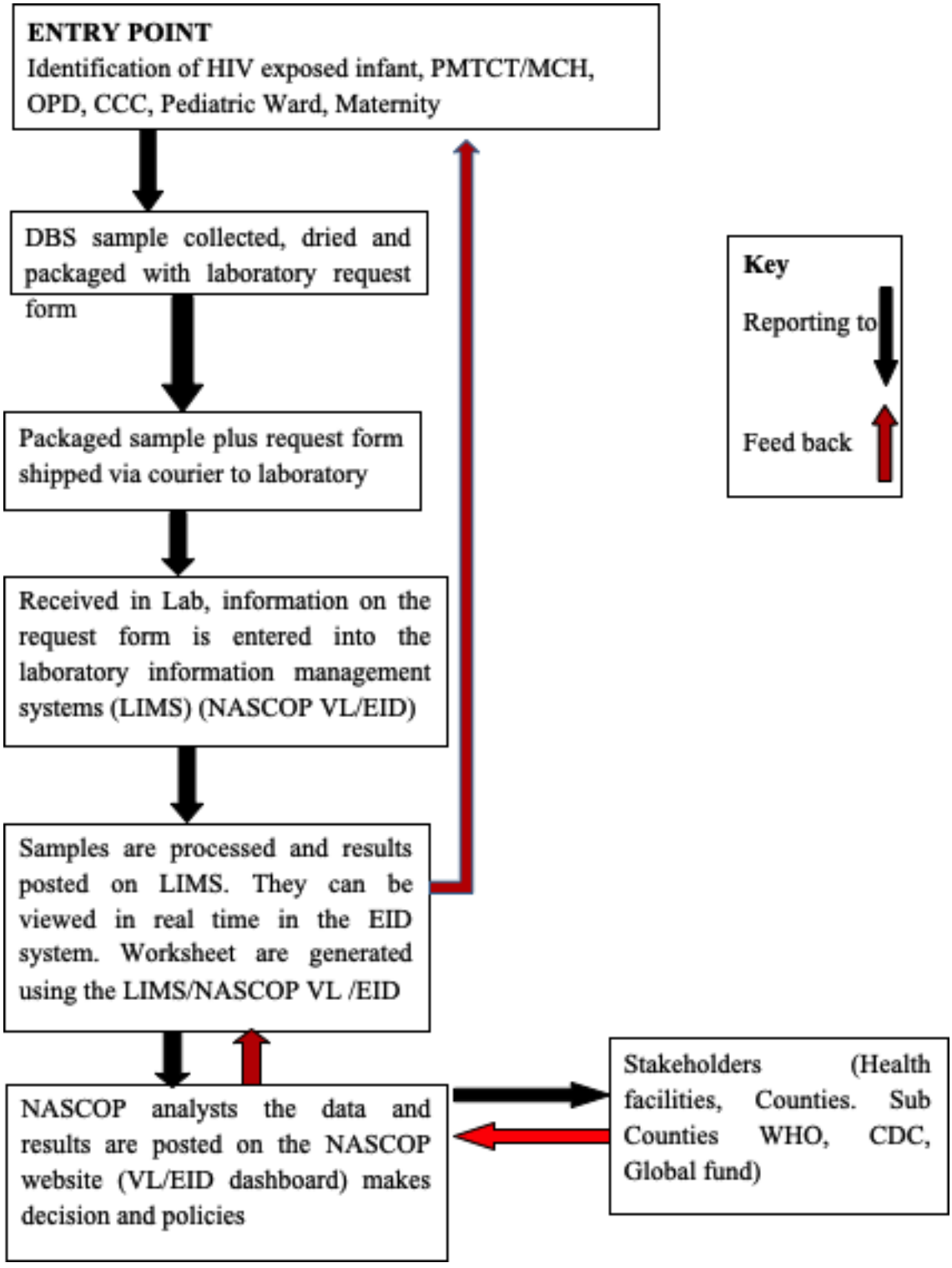


Figure 2.1: Early infant diagnosis surveillance data flow chart (NASCOP)

2.3 Selected factors affecting early infant diagnosis

Mother related factors

1. Mothers delay to take their infants for testing, lack of proper sensitization
2. Stigma related factors
3. Distance to health facilities

Facility related factors

1. Batching of samples
2. Improperly filled request sheet
3. Double collection of samples due to delayed results
4. Inability to retrieve results on the dashboard
5. Poor sample referral network
6. Wrong request forms

Laboratory related factors

1. Lack of reagents
2. Delay in testing thus affecting TAT

CHAPTER THREE

MATERIALS AND METHODS

3.1 Key surveillance issues to be addressed

A stakeholder meeting was be convened. It comprised staff from NASCOP (SI and PMTCT), National HIV reference laboratory, USAID, University of Maryland, UNICEF, WHO and CHAI. Quality of data was compared between 2017 and 2018.

3.2 Core team

Core team of 10 members constituted members from NASCOP SI and PMTCT, National HIV reference laboratory, partners from USAID, CHAI, UNICEF and WHO. The primary goal of the team was to develop tools to be used for evaluation. The core team further selected a team that spearheaded revision of the Early infant diagnosis laboratory request form. The team developed a new early infant diagnosis laboratory request form. All the gaps identified during the problem identification meeting were factored in the new tool. The core team further selected a team that spearheaded piloting of the new early infant diagnosis laboratory request form in facilities in Nairobi

3.3 Methods and procedures

The assessment of early infant surveillance system in Kenya was conducted in line with the CDC overhauled rules for assesing public health surveillance system. The assessment was conducted both retrospectively and prospectively. Both qualitative and quantitave data was analyzed. Information on the operations, functionality and attributes of the EID HIV surveillance system was collected qualitatively using key informant interview sessions. The surveillance information for the time period under assessment was analyzed

The key informant interview (KII) sessions involved health care workers in the health facilities working in the PMTCT and the laboratory department. The interview sessions were

done to survey the operation, capacities and properties of the surveillance system in understanding with the CDC overhauled rules for assessing public health surveillance system. Informed consent was obtained from the key informants prior to the interviews. Data from the surveillance system was re abstracted and analyzed.

3.4 Facility and healthcare workers Sampling

The evaluation was carried out in selected facilities across the country. A total of 12 facilities in 12 counties were sampled through purposive sampling. The informants were purposively sampled to get an understanding on the attributes of the surveillance system.

3.5 Pilot testing of the evaluation tools and the laboratory request form

Evaluation tool the KII was piloted at Riruta health center by the investigator. This was done to ensure that items in the instrument was stated clearly and had the same meaning to all respondents. The investigator administered the tool to the health care worker. Pilot assessed the clarity of the instruments, their ease of use, appropriateness and completeness before actual implementation. The feedback collected from the pilot study was used to correct the KII. The revised early infant diagnosis laboratory request form was piloted in high workload facilities in Nairobi. Selected facilities in Nairobi include, Mama Lucy Hospital, Kenyatta National referral, Riruta Hospital, Mbagathi Hospital and Matter Hospital.

3.6 Review of Early infant diagnosis laboratory request form

A stakeholders (It comprised staff from NASCOP (SI and PMTCT), National HIV reference laboratory, USAID, University of Maryland, UNICEF, WHO and CHAI) meeting was convened to discuss feedback from the pilot of the tool. A final copy of the tool was approved NASCOP.

3.7 Sensitization of Laboratory request form

Partners supporting HIV activities in counties sensitized the healthcare workers on the new EID LRF. They also printed and circulted copies to facilities.

3.8 Roll out and update of early infant diagnosis system and District Health Information System 2

The Early infant diagnosis system and the District health information system was updated to capture the new variable on the laboratory request form.

3.9 Implementation of the evaluation

Evaluation of the early infant diagnosis dashboard by use of the Key informant guide was executed in purposively selected facilities in Nairobi, Kajiado, Nakuru, Meru, Kiambu, Embu, Machakos, Busia, Kisii, Migori, Bungoma, Kilifi and Bomet.

Table 3.1: The SWOT analysis of the EID surveillance system

Strengths	Weakness
EID dashboard up and running Support by MOH and NASCOP Existence of partners Dedicated workforce Traineed personnel in PMTCT clinic Availability of EID tools and materials Good sample referral system in place PMTCT focal person in every facility Reducing HIV prevalence in the country	Poor data quality Lack of basic computer skills among the healthcare workers Weak stakeholder coordination Heavy workload and understaffing Inadequate skilled personnel Lack of computer/tablets in rural facilities Demotivation of staff
Opportunities	**Threats**
Promotion of teamwork across divisions Identify gaps into staff hidden strengths Capture all HEIs to ensure they are tested Increased support from partners	High staff turnovers Funding for HIV and AIDS projects decreasing Competion for resources both internally and externally Increased mother to child transmission rates in the coutnry

3.10 Expected Outcome

1. Increase the efficiency and effectiveness of early infant diagnosis in Kenya
2. Improve the accuracy in data collection and report in early infant diagnosis
3. Facilitate infant follow up and linkages
4. Reduced mother to child transmission of HIV

3.11 Monitoring and evaluation

Monitoring and Evaluation was undertaken throughout process of project implementation. Both qualitative and quantitative indicators were used during the M&E exercise (Table 2.1)

Table 3.2: Monitoring and Evaluation

	Outcomes	**Outputs**	**Indicators**	**Target**	**Means of Verification**	**Assumptions**
1	Project approved by Nascop (PLP)	Approval process undertaken	Number of meetings held as scheduled	100% of meetings are held on schedule	Meeting minutes	No Major competing tasks involving members
		Initiation phase undertaken	Number of sub-committees formed	All departments represented	List of members	Members willing to participate
2.	Reviewed Early infant diagnosis form	Current gaps on EID LRF analyzed and desired future determined	Number of meetings	80% of meetings on schedule	Meeting minutes	
		Piloting of new LRF	Number of facilities visited	95% of scheduled piloting visits undertaken	Piloting feedback reports	Identified sites will be ready to receive teams

	Outcomes	Outputs	Indicators	Target	Means of Verification	Assumptions
		Review of EID LRF from the pilot feedback	Number of meetings	Reviewed EID LRF	Meetings reports	No competing tasks affect process
		Sensitization of Healthcare workers on the new EID LRF	Number of sensitization meetings held	95% of scheduled sensitization meetings undertaken	Sensitization meeting reports	Availability of health care workers to be sensitized
3	Updated EID dash board, DHIS-2 and New EID LRF rolled out	EID dash board/DHIS-2 up date EID LRF circulated in facilities	Updated EID dashboard/DHIS-2 New EID LRF in use	Update EID dashboard Circulate	Updated EID dashboard active New EID LRF in use	Availability of cooperation form partners to print the EID LRF
4	Evaluated EID LRF	Evaluation of EID LRF	Evaluation report	Draft document ready within draft period	Availability of draft document	Draft team will work in a cohesive manner
5	EID surveillance	Data collection in	Number of filled Key informant	60 health care	Filled KIIs	Availability of health care

	Outcomes	Outputs	Indicators	Target	Means of Verification	Assumptions
	system evaluated	different facilities	guides	workers		workers
		Re abstraction of data form the EID dashboard	Abstracted data from the EID dash board	Re abstract data for July to Sept 2017 and July to Sept 2018	Re abstracted data	EID system active
6	Comprehensive evaluation report developed	Draft document done	Number of days taken	Draft evaluation report ready within the required period	Availability of draft document	Draft team will work in a cohesive manner

3.12 Data management and Analysis

The quantitative component of this evaluation involves retrospective review of the data before and after the new laboratory request sheet. Data was re-abstracted from early infant diagnosis dashboard for sampled facilities in October 2017 and compared with October 2018. All filled data collection instruments were kept in a closed, locked file cabinets with restricted access.

Data quality was assessed by the presence of data supervision, data quality assurance reviews and the completeness of the data. Examine the percentage of “unknown” or “blanks” responses to items on the laboratory request form. Data set were reviewed before and after

the laboratory request form. Qualitative data from KII was analyzed through themes, Stability of the surveillance system was assessed by finding out the presence of a devoted staff for data activities and the level of interruption of the system due to insufficient human resources and finances.

Simplicity was determined by the ease which data collectors filled the laboratory request form and the EID dashboard and were able to retrieve results from the system. Acceptability was decided by the willingness of the surveillance data collectors and users to continue to participate in the system and depend on data from it. Representativeness was evaluated using the distribution of data in person and place. Flexibility was assessed by retrospectively examining the ease by which the system accommodated new laboratory request sheet.

Sensitivity of the surveillance system was assessed based on the screening tool used for defining a case of HIV. Usefulness was assessed by the value, practicality of information generated from the system, can it help users to detect trends, magnitude of HIV among infants. Representativeness was assessed if the system can be able to identify person, place and time. Timeliness was assessed through time duration between sample collection to processing at the laboratory, facility receives results and time mother receives the results. Predictive value, positive was assessed by the capacity of the surveillance system is able to distinguish extent of reported cases that actually have health related event beneath surveillance. Descriptive statistics, including frequencies, percentages, medians, and ranges were used to summarize the data, and 95% confidence limits for all statistics were computed. Qualitative data from interviews were transcribed, coded, and thematically analyzed.

3.13 Sustainability

The project was entirely be undertaken by staff at NASCOP, National HIV reference laboratory and partners. Identification of gaps on the dashboard and Revision of early infant diagnosis laboratory request form by NASCOP, NHRL and partners, piloting of the tool and final revision of the EID LRF ensured sustainability. The KII was administered in health facilities inconjuction with medium term fellow, staff at NASCOP. This ensured appropriate knowledge and skills transfer is done during the process. Members of staff participated and there was ownership, commitment and a smoother execution process since they are final project implementers. Three members of staff were trained for the medium term fellowship and two were part of the evaluation process.

3.14 Ethical Issues

All data collected was kept private and confidential, no any patient identifying information was collected. Participation for the KII was on voluntary basis and no inducement whatsoever. Participation was also based on informed consent.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Evaluation Report

4.1.1 Early infant diagnosis laboratory request form

The PMTCT program in Kenya made tremendous progress in reducing the MTCT rates of HIV from 16% in 2012 to 8% in 2015. However the rates increased to 11.5% in 2017. Early infant diagnosis has to be strengthened to ensure HIV exposed infants access diagnosis on time as scheduled. The early infant diagnosis was revised from version 01 October 2016 to version 02 May 2018. All the gaps identified from the EID dash board were addressed. The new early infant diagnosis laboratory request form was piloted in five facilities in Nairobi County.

4.1.2 Pilot of new early infant diagnosis laboratory request form

The new tool was piloted in several facilties within Nairobi county, Riruta Satelitte County Hospital, Kenyyata National Hospital, Mama Lucy Hospital, Mater Hospital and Mbagathi County Hospital. All the inputs from the pilot were factored into the new tool (Table 3.1).

Table 4.1: Pilot feedback for revised Early infant diagnosis laboratory request form

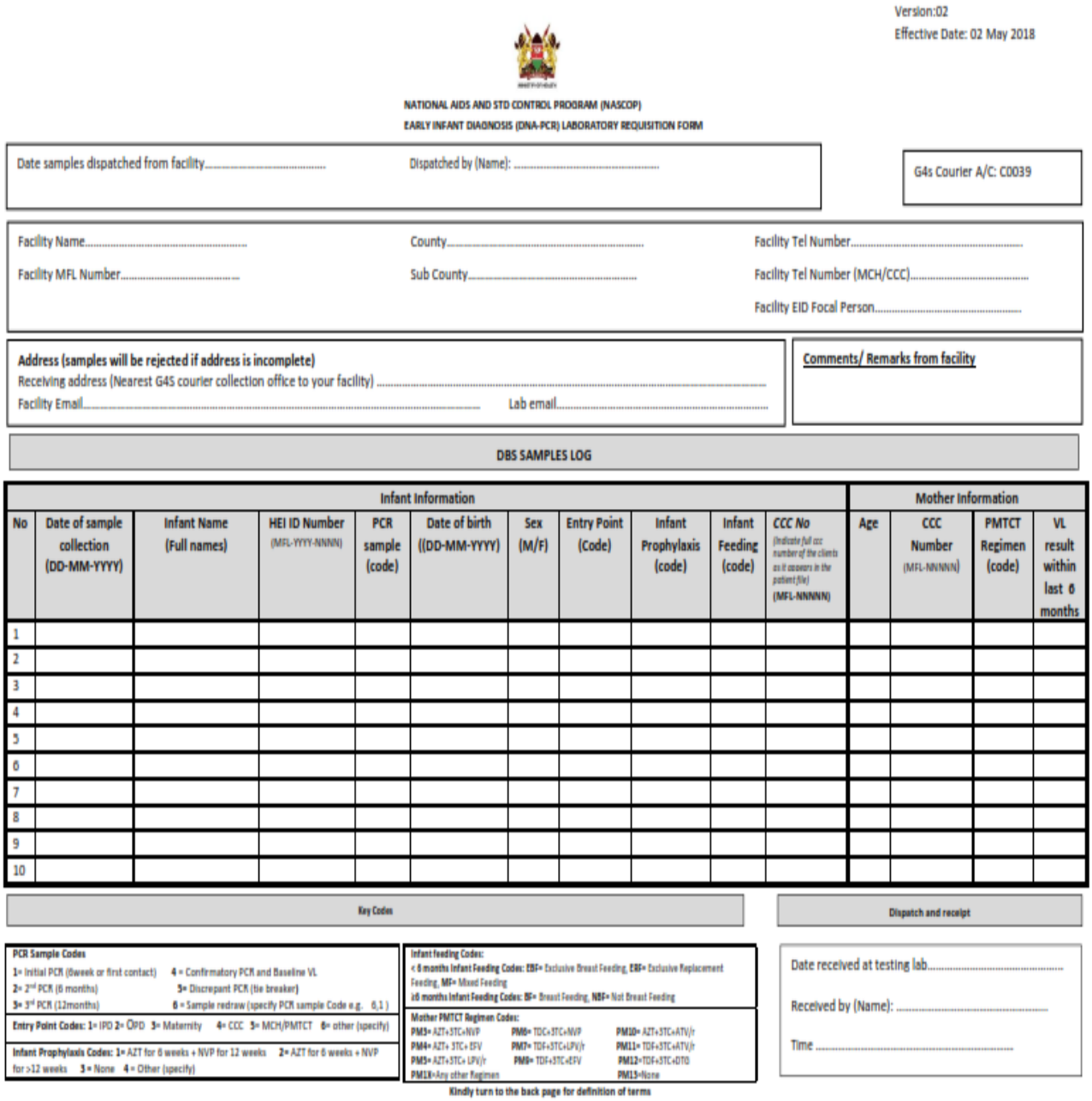
Facility	**Unit**	**Current EID LRF forms in use at the facility**	**Recommendations**
RIRUTA	MCH and lab	Version 2016	Space for HEI ID to be expanded
			Add phone number of focal person
			Define discrepant and indicate lab (NHRL) to refer samples
			Which lab to tie break if discrepancy is from NHRL

Facility	Unit	Current EID LRF forms in use at the facility	Recommendations
			Define confirmatory PCR
			Add space for infant and mother's CCC number
KNH CCC	MCH	Use of customised laboratory requisition form for individual infant, thus none of the staff had direct contact with the tool	None
	Lab	Receiving different versions from different facilities	Add reasons for rejection and the codes
			Text orientation
			KNH code of Ethics, does not allow use of names
			Consistency in filling the HEI ID, different for various facilities
Facility	**Unit**	**Current EID LRF forms**	**Recommendations**
MAMA LUCY	MCH	2015 version	Confusion on arrangement of the columns, PCR code column has been shifted next to the date, rather confusing
			HEI ID column is small, can't fit all the digits
			Infants prophylaxis column to be reduced

Facility	Unit	Current EID LRF forms in use at the facility	Recommendations
			"Last VL results in last 6 months"
			Increase the column size for the mothers CCC number
			The facility does not have a number, will instead use the CCC
Matter Hospital	CCC	2013 version	Increase space for baby's names
			Reduce PCR code
			Space for HEI ID code is small
			Infant feeding codes
			Space for CCC number for mother
			VL last 6 6 months
			Supplies, how to order
			No code for **"none"** for the mothers prophylaxis
			The example for HEI ID number "MMMM" to be changed to "MFLCODE"
Mbagathi	MCH/ANC	2015 version	PCR code column confusion
			Column for HEI ID column to be increased
			Mothers CCC number

4.2 Early infant diagnosis laboratory request sheet version 02 May 2018

The new early infant diagnosis laboratory request sheet had new revison on the PCR sample codes, infant prophylaxis codes. Mother alive or dead and date of ART initiation for the mother were dropped on the new tool. CCC number for the infant was introduced for confirmatory samples only **(Fig 3.1 Early infant diagnosis laboratory request form version 02 May 2018).**



Version:02
Effective Date: 02 May 2018

NATIONAL AIDS AND STD CONTROL PROGRAM (NASCOP)
EARLY INFANT DIAGNOSIS (DNA-PCR) LABORATORY REQUISITION FORM

Date samples dispatched from facility..... Dispatched by (Name): .....

G4s Courier A/C: C0039

Facility Name..... County..... Facility Tel Number.....
Facility MFL Number..... Sub County..... Facility Tel Number (MCH/CCC).....
Facility EID Focal Person.....

Address (samples will be rejected if address is incomplete)
Receiving address (Nearest G4S courier collection office to your facility) .....
Facility Email..... Lab email.....

Comments/ Remarks from facility

DBS SAMPLES LOG

Infant Information											Mother Information			
No	Date of sample collection (DD-MM-YYYY)	Infant Name (Full names)	HEI ID Number (MFL-YYYY-NNNN)	PCR sample (code)	Date of birth ((DD-MM-YYYY)	Sex (M/F)	Entry Point (Code)	Infant Prophylaxis (code)	Infant Feeding (code)	CCC No (Indicate full ccc number of the clients as it appears in the patient file) (MFL-NNNNN)	Age	CCC Number (MFL-NNNNN)	PMTCT Regimen (code)	VL result within last 6 months
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														

Key Codes

PCR Sample Codes
1= Initial PCR (6week or first contact) 4 = Confirmatory PCR and Baseline VL
2= 2nd PCR (6 months) 5= Discrepant PCR (tie breaker)
3= 3rd PCR (12months) 6 = Sample redraw (specify PCR sample Code e.g. 6,1)

Entry Point Codes: 1= IPD 2= OPD 3= Maternity 4= CCC 5= MCH/PMTCT 6= other (specify)

Infant Prophylaxis Codes: 1= AZT for 6 weeks + NVP for 12 weeks 2= AZT for 6 weeks + NVP for >12 weeks 3 = None 4 = Other (specify)

Infant feeding Codes:
<6 months Infant Feeding Codes: EBF= Exclusive Breast Feeding, **ERF**= Exclusive Replacement Feeding, **MF**= Mixed Feeding
≥6 months Infant Feeding Codes: BF= Breast Feeding, **NBF**= Not Breast Feeding

Mother PMTCT Regimen Codes:
PM3= AZT+3TC+NVP PM8= TDC+3TC+NVP PM10= AZT+3TC+ATV/r
PM4= AZT+ 3TC+ EFV PM7= TDF+3TC+LPV/r PM11= TDF+3TC+ATV/r
PM5= AZT+3TC+ LPV/r PM9= TDF+3TC+EFV PM12=TDF+3TC+DTG
PM13=Any other Regimen PM15=None

Kindly turn to the back page for definition of terms

Dispatch and receipt

Date received at testing lab.....
Received by (Name): .....
Time .....

Figure 4.1: Early infant diagnosis laboratory request form version 02 May 2018

Definations and terms was added to early infant diagnosis laboratory request form so as to guide healthcare workers on how to fill it (**Table 3.2**).

Table 4.2: Early Infant Diagnosis Instructions/Definition of terms

Date of sample collection	This is the date PCR sample was drawn from the infant or child.
Infant Name	Enter the three names of the infant as they appear on the birth
HEI ID Number	Enter HIV exposed Infant's number in the format MFL- YYYY-NNNN. Where: MFL is the master facility list (MFL) Code; YYYY is the year of registration; NNNN is the client serial counter within each facility in that year; Example: 18008/2016/0001 is sample number **0001** in the year **2016** at Mutulani Dispensary (**MFL 18008)** in Kilome Sub-county
PCR sample (code)	Indicate whether this is: **1**- Initial PCR (6week or first contact) **2**= 2nd PCR (6 months) 3= 3rd PCR (12months) **4** = Confirmatory PCR and Baseline VL **5**= Discrepant PCR (tie breaker) **6** = Sample redraw (specify PCR sample Code e.g. 6,1)
Date of Birth	Enter the Infants Date of Birth in the format DD-MM-YYYY. This should be copied from the birth notification or certificate.
Sex(M/F)	Enter infant's or child's sex. Use "M" for males and "F" for Females. For this data element, the provider should ask the guardian for the infant's/ child's sex.

Entry Point(Code)	Use the information on the HEI Card under the label "source of referral" and use the corresponding code for the source as given below. For example, if **OPD** is checked on the card, write "2" in the register. 1=IPD 2=OPD 3=Maternity 4=CCC 5=MCH/PMTCT 6. Others (Specify) **Note**: Infants, who are already on the program but get transferred to this facility, will bring with them the mother baby booklet or the HEI card (with source of referral already completed. Transfer the code into this column.).
Infant Prophylaxis(code)	Infant Prophylaxis Codes: **1=** AZT for 6 weeks + NVP for 12 weeks **2=** AZT for 6 weeks + NVP for >12 weeks **3 =** None **4** = Other (specify)
Infant Feeding(code)	< 6 months Infant Feeding Codes: EBF= Exclusive Breast Feeding, ERF= Exclusive Replacement Feeding, MF= Mixed Feeding
Infant CCC NO	Indicate full CCC number of the infant as it appears in the patient file) (MFL-NNNNN) (For confirmatory samples only). Don not leave blanks. **Use NA**= not applicable for infants who are not legible for confirmatory PCR.
Mother's Age	Indicate mother's age in years
Mother's CCC number	Indicate full CCC number of the mother as it appears in the patient file (MFL-NNNNN)
PMTCT regimen code	PM3= AZT+3TC+NVP PM4= AZT+ 3TC+ EFV PM5= AZT+3TC+ LPV/r PM6= TDC+3TC+NVP PM7= TDF+3TC+LPV/r PM9= TDF+3TC+EFV PM10= AZT+3TC+ATV/r PM11= TDF+3TC+ATV/r PM12=TDF+3TC+DTG PM13=None PM1X=Any other Regimen
VL Results	Fill the viral load results for the mother within the last 6 months. Do not leave blank. Indicate ND= Not done if was eligible or NA=Not applicable if client was not eligible. .
Comments/ Remarks from facility	Example: Urgent (specific y sample ID),

A Memo through head NASCOP was circulated to all health care facilities through county directors of health to notify them of updated early infant diagnosis (DNA PCR) laboratory requisition form **(Appendix II).** Sensitization for the new EID LRF was supported by partners supporting HIV AIDS activities in various counties.

4.3 Early infant diagnosis dashboard

The early infant diagnosis dashboard and Kenya health information system (DHIS 2) were updated to align to the new early infant diagnosis laboratory request form that was rolled out. Letter requesting data from the EID dashboard was sent to CHAI the host of the system (Appendix IV). Data was abstracted from the early infant diagnosis dash board before the new EID LRF October 2017 and after the new EID LRF October 2018. Data completeness during the two periods were compared.

In October 2017, 3,367 early infant diagnosis samples did not have sample identification as compared to only 100 in October, 2018. This shows a tremendous improvement from October, 2017 **(Fig:…).**

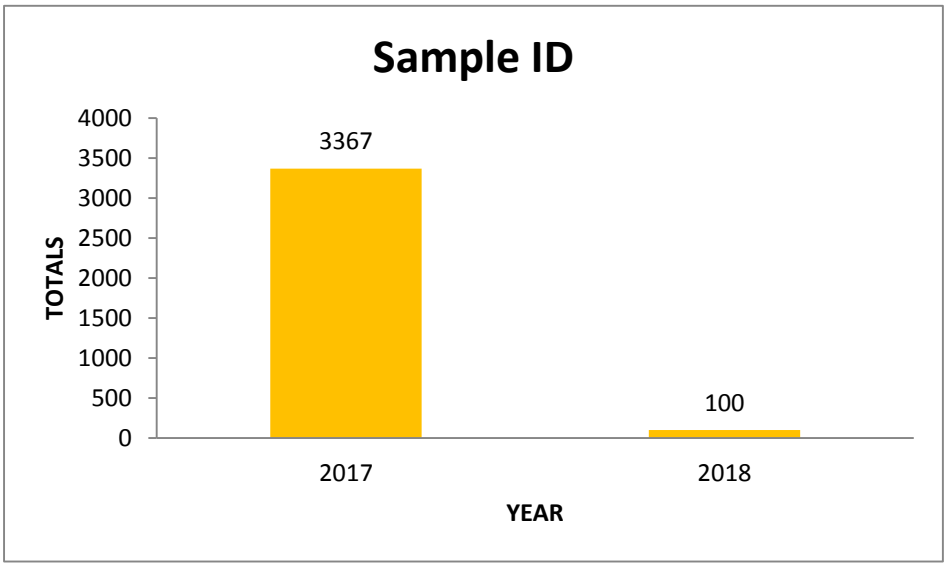


Figure 4.2: Sample identification

A total of 38 early infant diagnosis samples did not have infants date of birth in October, 2017 against 5 in October, 2018. **(Fig…)**

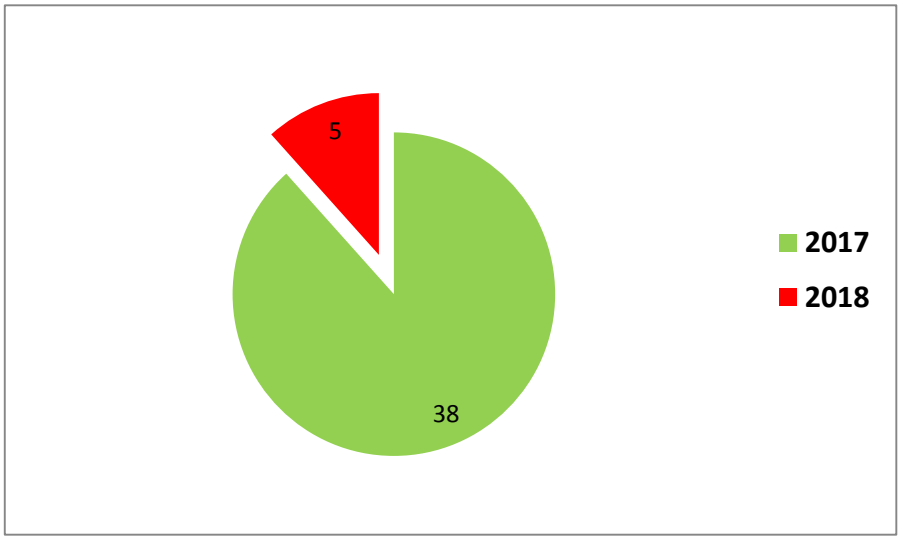


Figure 4.3: Date of birth

Among the early infant diagnosis samples sent to testing laboratory for screening in October 2017, seventy infants did not have their gender indicated, this reduced to only 4 in October 2018 **(Fig…).**

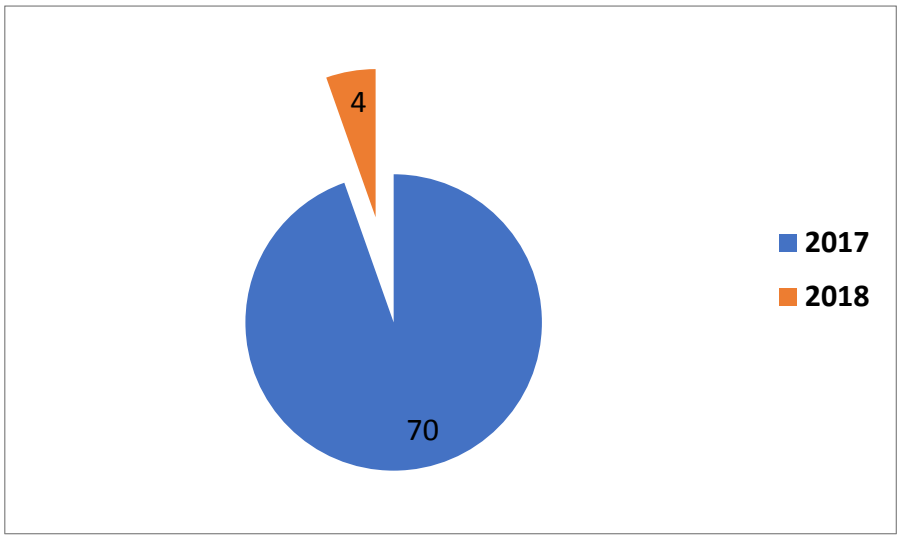


Figure 4.4: Gender

One hundred and forty eight early infant diagnosis samples sent for DNA PCR did not have infant prophylaxis indicated in October 2017, the number reduced to 65 in October 2018. Follow up of facilities still not providing this necessary (**Fig…..**).

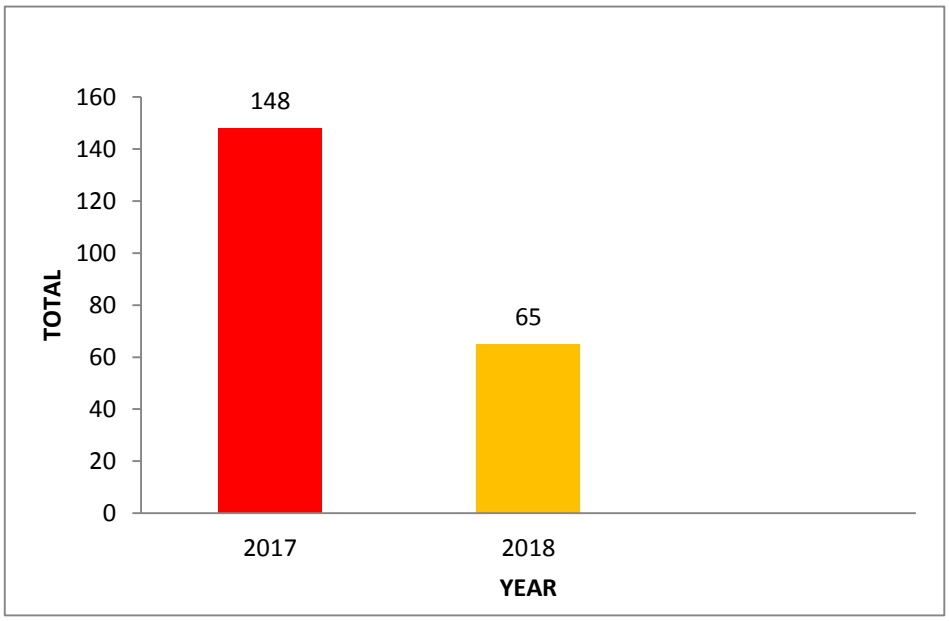


Figure 4.5: Infant prophylaxis

In October 2017, 314 EID DNA PCR samples did not have mothers PMTCT intervention indicated the number slightly reduced to 144 in October 2018 **(Fig 3.6).**

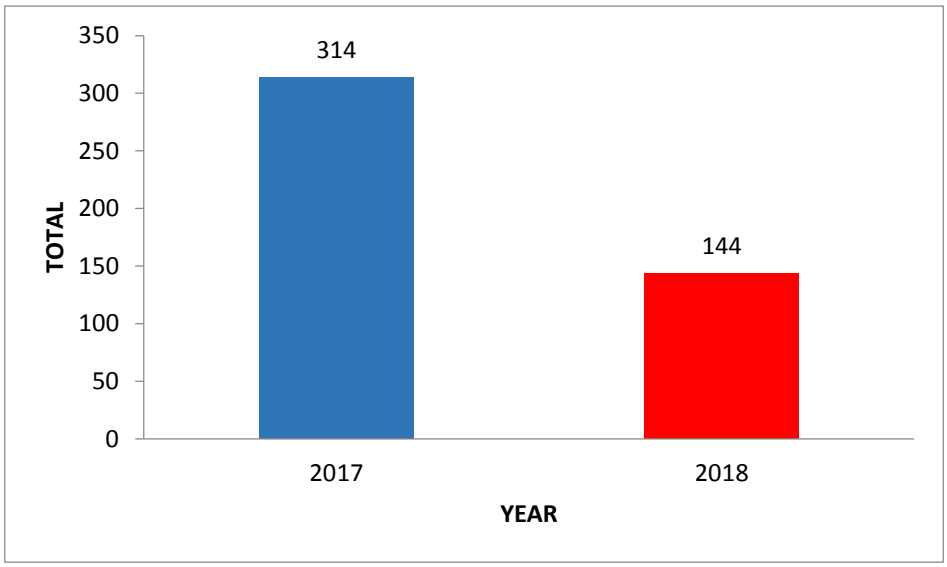


Figure 4.6: PMTCT Intervention

Eight thousand six hundred and four EID samples in October 2017 did not have mothers age indicated, this figure dropped to 2,738 in 2018 **(Fig 3.7).**

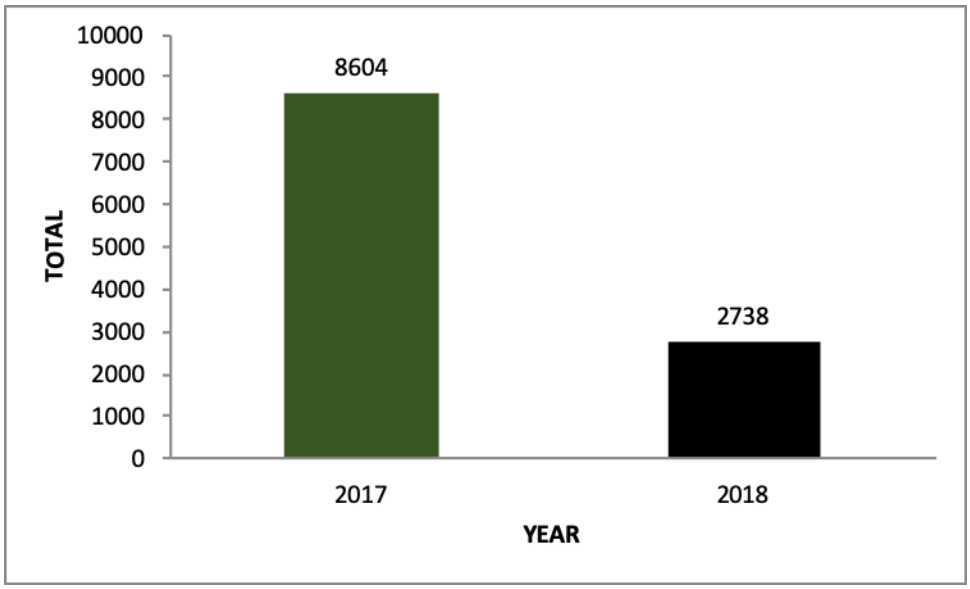


Figure 4.7: Mothers age

4.4 Findings on the attributes of the early infant diagnosis surveillance system

Key informant interviews were conducted with different stakeholders in different hospitals working in the PMTCT section.

Usefulness: Data is used by multiple interest groups, PMTCT NASCOP, MOH and HIV partners to direct resources towards interventions tomprevent transmission of HIV from mother to infant. The system is able to provide trends and magnitude of HIV infected infants in Kenya. Early infant diagnosis surveillance is very useful in managing HIV exposed infants. Its able to provide early detection which allows intervention measures for management of exposed infants and help reduce disease progression thus significantly reducing infant mortality from HIV and other opportunistic diseases.

Simplicity: The sessions with the health care workers also revealed that filling of the necessary documents is easy and straight forward. It does not need complicated equipment. It only requires a filter paper and you prick the Childs finger/heel and collect the DBS sample. The use of dried blood spots for sample collection and test makes it easy for sample shipment and storage even in the remote set up. Samples are able to reach the testing lab while still viable. Any HCW can do the procedures without lots of guidance. The presence of a web-based laboratory information system ensures results are available to the clinician wherever they are immediately they have been dispatched at the testing lab. Its easy to understand and operate for first time users

Flexibility:Adjustments on the EID LRF were updated on the EID surveillance system. Diagnosis can happen at different entry points including the out/in patient department, maternity, MCH etc. The surveillance system is flexible and can easily adapt to change be it the way it is reported or change of staffs assigned to the department that deals with

Data Quality: For years there was inconsistency with the unique patient identifiers (HEI numbers) however Nascop directed facilities to use a standard way for generating the unique identifiers. There has been a remarkable improvement since 2018 March when this directive was effected. The information system has been improved over time and loopholes have been

closed in such a way that data capture is done 100%. No entry can be completed with missing information/data. Data is excellent, compared with other PCR results, EID surveillance system data quality is reliable and easy to interprete

Acceptability: The healthcare workers are willing to continue to participate in the surveillance system.

Sensitivity: The EID surveillance system defines a case based on DNA PCR analysis**.** The national early infant diagnosis program majorly uses two platforms for DNA PCR. These two platforms, Roche CAP/CTM and Abbott m2000 have been validated and verified by the national office prior to the testing roll out. This certifies that the machines are able to reproduce the true results. Addition of Genexpert point of care has reduced the turn around time for facilities which are very far from testing laboratories.

Predictive Value Positive: Positives are true positives and same to negative cases. All the positive cases are refered to national HIV reference laboratory for restesting.

Representativeness: All HIV exposed infants are included in the surveillance system and are subjected to the same standards of care and treatment regardless of the gender, race or socioeconomic status. They all have equal access to the services available. The early infant diagnosis surveillance system is only available to children 18 months and below.

Timeliness: The time taken between testing and confirmation of diagnosis is well within the national set timelines of less than 2 weeks. Introduction of point of care testing in the EID surveillance system has tremendously reduced the turn around time for facilities which were very far from the testing laboratories. The DNA PCR is done at birth, 6 months or at first contact,12 months and finally at 18 months.

Stability: The system is stable and rarely occurs any outages in the program and there is an account for sending samples to KEMRI. Extensive back up security and appropriate software upgrade procedures. All materials are provided on time and there are continuous training and updates to staff when necessary. The availability of a robust network of testing lab ensures that facilities have a testing lab nearer to them that they can refer samples to for testing. Management of supplies to support testing is done at national level, which allows for standardization in terms of procurement of commodities and supplies.

4.5 PROJECT IMPACT

Improved data quality on the EID dashboard, gaps identified on the EID dashboard, high number of confirmatory tests, more than initial tests thus poor data was observed. Revision of the early infant diagnosis laboratory request sheet improved the quality of data on the EID dashboard

Reduced mother to child transmission rates, this was through longitudinal tracking of HEIs. Previously it was not easy to follow up the babies, this was due to a lot of samples which were sent to testing laboratories without sample ID.

Early screening thus improved linkages for infants who turn positive. Infants who turn positive are linked on care on time it was easy nto track.

Retesting at 6 months, 12 months, facilitate timely management for infants who are exposed to HIV. The laboratories were able differentiate at which stage the samples were thus contious follow up of the infants

Negative tests for infants encourage mothers to maintain prevention measures and maintain the negative status for their infants through prohylaxis for the infant and mother. Mothers received their results on time and were encouraged to continue with infant prophylaxis.

Improved antenatal care, safe delivery practices counselling and nutritional support for both mother and infant. The improved services in the PMTCT department.

Linkages for mothers who are living with HIV to care and treatment, prolong their lives and enhance the survival of their child. Mothers who turn positive at antinatal clinic, Maternity or post natal clinic were linked to care on time.

4.6 LESSONS LEARNT

Team work is imperative. NASCOP, National HIV reference laboratory and HIV partners worked as a team that lead to the updating of the new tool.

Poor data on the EID dashboard in 2017, data was retrieved from esarly infant diagnosis system for October 2017, infant sample id, date of birth, gender were missing for most of the samples which were referred for testing.

Sensitization and refresher trainings are play a vital role in improving health care delivery. After the revision of the early infant diagnosis laboratory system, healthcare workers were sensitized on the new tool which played a big role in improving the quality of data.

PMTCT has to work together with laboratory to reduce MTCT rates, the labotory plays a vital role in early infant diagnsosis.

4.7 Conclusion

Early infant diagnosis system evaluation reveals that its achieving the purpose of a public health surveillance in identifying and monitoring the trends of HIV infection in infants. This is important in planning public health activities towards PMTCT services in Kenya. The surveillance system is usefull, simple, flexible, sensitive, representative, stable, timely acceptable, and has improved data quality.

4.8 Recommendations

Focused mentorship for health facilities that have EID LRF that are incompletely filled. Some facilities are still submitting early infant diagnosis laboratory request sheets with missing variables. Identification of this facilities is important and the health personel trained proper filling of the request sheets.

Encourage remote logging of samples to reduce missing variables through use of EID LRF. Remote logging of samples helps in reducing errors on the EID dashboard. The request sheet is filled online at the health facility and samples sent to the testing laboratories.

Demand creation strategies for EID testing to increase uptake. Many infants are still not able to access infant diagnosis and NASCOP through partners have to carry out strategies that will increase coverage. Community health workers play a vital role in the demand creation especially for mothers who give birth at home through use of traditional birth atendants

Train more personnel on how to navigate the EID platform, during the execution of the study, in most facilities there was only one or two healthcare personnel who were able to navigate the system. More healthcare workers have trained to increase the utilization of the dasb board

Conduct a data quality assessment from the dashboard biannually, a continuous assessment of the EID is necessary to monitor the quality of data generated on the system.

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Appendix I Consent Form for Interviews with Healthcare Workers

Study title: **EVALUATION OF EARLY INFANT DIAGNOSIS SURVEILLANCE SYSTEM IN KENYA**

INTRODUCTION AND PURPOSE

My Name is Moseti Wycliffe Makori from University of Nairobi and National AIDS and STI control program, Ministry of Health. I am conducting an evaluation of early infant diagnosis surveillance system in Kenya. Access to timely HIV diagnosis for HIV-exposed infants is a critical step to close the treatment coverage gap for children and reduce HIV-associated mortality for children

You are being invited to take part in a study to find out your experiences and satisfaction with the early infant diagnosis surveillance system in Kenya. The goal of this evaluation is to better understand early infant diagnosis in Kenya and to identify gaps and barriers to the provision of early infant diagnosis in Kenya.

The duration of the interview is approximately 15 mins.

PROCEDURES

If you choose to be in this study, you will be asked questions regarding your experience with early infant diagnosis in Kenya. We will not record your personal details but will assign the KII a unique number for the purpose of study.

Risks or Discomforts

The interview will take some of your time to complete. There are no risks in participating in this interview. You may interrupt the interview process at any time.

Benefits

Please note that there is no direct benefit for your participation. There is no monetary compensation or any other material incentive to you for being in this study. The results of this evaluation will help the Kenya Ministry of Health to better understand the early infant diagnosis in Kenya. The evaluation will help to identify, develop and plan strategies to improve the system for early infant diagnosis surveillance system in Kenya.

Confidentiality

The information gathered in this interview will be kept strictly confidential. No information will be recorded and this information will not be linked to you at all.

Compensation

There will be no compensation for participating in this interview.

Voluntary Participation

You are being invited to participate in a series of interviews concerning provision of early infant diagnosis surveillance system in Kenya, which will take approximately 15 minutes. Your participation is completely voluntary and you have the right to leave the interview at any time. You do not have to answer any questions, or contribute to the discussion on an issue that makes you uncomfortable. There are no risks associated with not participating in this interview.

Consent and contact

Do you have questions that you would like to ask? Are there any things you would like me to explain again or say more about? Do you agree to participate in the interview?

If you agree to take part in the interview question, I would like you to sign on this form indicating that you have voluntarily given your consent.

Participant's signature _____ Participant's name _____

Interviewer's signature _____ Interviewer's name _____

If you have any other questions, contact Moseti Wycliffe Makori 0723641595, wycliffemakori@gmail.com

Key informant guide

Can you describe the early infant diagnosis surveillance system in terms of the following attributes…?

1. Usefulness:……..
2. Simplicity:……
3. Flexibility:……
4. Data Quality: ……
5. Acceptability: ……..
6. Sensitivity: ……...
7. Predictive Value Positive: ……...
8. Representativeness: …….....
9. Timeliness: ……..
10. Stability: ……..

Appendix II Memo to counties

MINISTRY OF HEALTH

Telephone: (020) 2630867
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E-mail : head@nascop.or.ke
Office Mobile: 0775-597297

National AIDS & STI Control Program
Kenyatta National Hospital Grounds
P.O. Box 19361, 00202
Nairobi

Ref:NASCOP/ADMIN/eMTCT/2018/05 **Date:** 13th April 2018

All County Directors for Health

RE: UPDATED EARLY INFANT DIAGNOSIS (DNA-PCR) LABORATORY REQUISITION FORM

The National AIDS and STI Control Program (NASCOP) and National Public Health Laboratories (NPHLS) in collaboration with partners coordinate the implementation of Early Infant Diagnosis (EID) for HIV through HIV DNA PCR testing in Kenya. To ensure sustained high quality HIV prevention, diagnosis and treatment programs NASCOP and NPHLS regularly reviews and updates National Policies, Guidelines and Standard Operating Procedures to reflect the WHO requirements.

As a result of these, NASCOP and NHRL together with partners have reviewed and updated the "Early Infant Diagnosis (DNA - PCR) Laboratory Requisition Form" to Align it with the current ART and PMTCT guidelines, Align it with the updated PMTCT indicators and to improve data quality for use in decision making at all levels and also to reduce redundancy.

The updated form has also incorporated inputs from the County leadership (CHMT) and health care workers providing EID services. The NASCOP EID website has also been updated to reflect the structure of the new form.

The purpose of this letter is to inform you on the following;-

1. The updated "Early Infant Diagnosis (DNA-PCR) Laboratory Requisition Form" version 02 (attached) which will be in use at all facilities providing EID services from 2nd May 2018.
2. The use of previous versions of forms will cease from 4th June 2018, the date by which they should all have been withdrawn from the EID sites. Thereafter, no older version EID forms will be accepted by the testing laboratories.

ISO 9001:2008
Certified

3. All EID sites in line the national guidelines, as they send a sample for confirmatory EID testing for HIV they concurrently request for baseline viral load testing on the same form.
4. The county leadership and implementing partners to ensure that the updated forms are available to all EID sites on time.

Thank you for your continued support.

Dr. Kigen B. Bartilol
Head: National AIDS & STI Control Program

Encl

Copy to: County Medical Laboratory Coordinators
County AIDS & STI Coordinator
All implementing partners

Appendix III Letter to the counties

MINISTRY OF HEALTH

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E-mail: head@nascop.or.ke
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NATIONAL AIDS & STI CONTROL PROGRAM
Kenyatta National Hospital Grounds
P.O. Box 19361, 00202
Nairobi

When replying please quote
Ref: NASCOP/ADMIN/C&T/2019/016

Date: 2nd April 2019

County Directors of Health

- **Kajiado** - **Busia**
- **Nakuru** - **Kisii,**
- **Meru** - **Migori**
- **Kiambu** - **Bungoma**
- **Embu** - **Kilifi**
- **Machakos** - **Bomet**
- **Nairobi**

RE: SUPPORT TO CONDUCT EVALUATION OF EARLY INFANT DIAGNOSIS SURVEILLANCE SYSTEM

The National AIDS & STI Control Program (NASCOP) collaborates with University of Nairobi to implement HIV Capacity Building Fellowship Programme. Moseti Makori Wycliffe is a University of Nairobi (UNITID) Monitoring and Evaluation Fellow attached to NASCOP. He is undertaking an evaluation of early infant diagnosis surveillance system in Kenya.

The global super-fast-track of Elimination of Mother to Children Transmission (EMTCT) framework was launched in 2016 and aims at ending new HIV infections among children (start free) and keeping their mothers alive, adolescents (stay free) and end pediatric and adolescent aids (AIDS free) by 2020.Kenya is one of the 22 priority countries that has been prioritized for elimination of mother-to-child transmission of HIV(EMTCT). Currently, maternal HAART coverage for EMTCT is estimated at 80% with about 79% of HIV positive women receiving ARVs for prophylaxis However, only 54% of HIV exposed infants receive a polymerase chain reaction test at 6 weeks after birth and many are lost through the HEI follow-up cascade and cannot be

accounted for by 18 months. Identifying infants infected early and initiating them on Anti-retroviral therapy as soon as possible after diagnosis is essential to slow the progression from HIV infection to AIDS and to prolong the life of the patient. Evaluation of a surveillance system is significant learning tool and forms a basis for improving the existing system. Tremendous progress has already been made by the PMTCT program in reducing the Mother to child transmission (MTCT) rate of HIV from 16% in 2012 to 8% in 2015. Unfortunately, in 2018 estimates, the MTCT rate rose to 11.5%. In order to achieve EMTCT, the country will need to consistently lower MTCT rates of HIV to less than 5% for at least 2 years.

As part of routine programme review, 13 counties have been identified for further assessment to gain understanding of the factors that are related to low early infant diagnosis and health system contributors to a leaky HEI cascade facilities and additionally carry out key informant interviews with the health care workers working in the PMTCT and laboratory departments.

Wycliffe will carry out this activity and this is to request that you accord him the necessary support as this evaluation has the potential of informing future early infant diagnosis surveillance system that ensure reduced mother to child transmission rates of HIV to less than 5% for the country to be validated.

Thank You for Your Continued support

Dr. Kigen B. Bartilol
Head; National AIDS & STI Control Program

Appendix IV Request for data form early infant diagnosis system

MINISTRY OF HEALTH

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Nairobi

When replying please quote
Ref: NASCOP/SI/2019/038

Date: 10th April, 2019

Gerald Macharia
Country Director
Clinton Health Access Initiative - Kenya
Timau Plaza Argwis Kodhek Road
Nairobi

Dear Sir

RE: REQUEST FOR DATA FROM EARY INFANT DIAGNOSIS SYSTEM

The National AIDS & STI Control Programme collaborates with University of Nairobi to implement HIV capacity building fellowship programme.
Moseti Makori Wycliffe is a University of Nairobi (UNITID) monitoring and evaluation fellow attached to NASCOP. He is undertaking an evaluation of early infant diagnosis surveillance system in Kenya.

The global super-fast-track of Elimination of Mother to Children Transmission (EMTCT) framework was launched in 2016 and aims at ending new HIV infections among children (start free) and keeping their mothers alive, adolescents (stay free) and end pediatric and adolescent aids (AIDS free) by 2020.Kenya is one of the 22 priority countries that has been prioritized for elimination of mother-to-child transmission of HIV(EMTCT). Currently, maternal HAART coverage for EMTCT is estimated at 80% with about 79% of HIV positive women receiving ARVs for

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A new early infant diagnosis laboratory requisition form was developed after identification comprehensive identification of the gaps on the EID dashboard. The new early infant diagnosis laboratory request form (EID LRF) was implemented in May 2018 within the country. There is a need to evaluate the new EID LRF from the previous versions.

The purpose of this letter is to request you to provide data sets to Wycliffe from EID dashboard for October 2017 before revision of EID LRF and October 2018 after rolling out EID LRF. Kindly accord him the necessary support as this evaluation has the potential of informing future early infant diagnosis surveillance system that ensure reduced mother to child transmission rates of HIV to less than 5% for the country to be validated.

Thank You for Your Continued support

Dr. Kigen Bartilol
HEAD NATIONAL AIDS & STI CONTROL PROGRAM

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