



ELIMINATION OF MOTHER TO CHILD TRANSMISSION OF HIV AND SYPHILIS

NATIONAL VALIDATION REPORT
SRI LANKA 2019

ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV AND SYPHILIS

National validation report of Sri Lanka

2019



Acknowledgements

The report for validation of elimination of mother-to-child transmission (EMTCT) of HIV and syphilis programme of Sri Lanka was compiled by the report writing committee representing the National STD/AIDS Control Programme (NSACP) in collaboration with the Family Health Bureau (FHB) under the guidance of the Ministry of Health (MoH), Sri Lanka.

Scaling up services throughout the country within four years was no mean task. This was possible because of the contribution of the provinces and districts under the guidance of regional and provincial authorities. The active role played by the public health team of the MOH units at the grassroot level under the guidance of the Consultant Community Physicians and MO MCHs in the districts is highly appreciated. The dedication and commitment shown by the STD clinic staff representing clinical, preventive and laboratory components under the guidance of the Consultant Venereologists/MO STDs facilitated achieving the objectives of the EMTCT programme.

Pregnant women with HIV or syphilis and the exposed infants were managed in secondary or tertiary care hospitals by the obstetricians and paediatricians supported by hospital directors with supportive staff representing various sections including the infection control unit.

The programme was a good example of a successful multidisciplinary approach, covering many organizations in the health and non-health sectors and UN agencies sitting together with key populations, NGOs and PLHIV taking decisions applicable to the country.

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Finally, the report writing team wishes to thank all staff at the NSACP and FHB who worked together as a team to reach the targets of EMTCT of HIV and syphilis.

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July 2019

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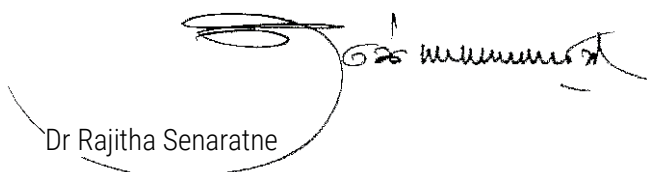
Message from the Minister of Health, Sri Lanka

It is indeed a great pleasure to write this message for the report on validation of elimination of mother-to-child transmission (EMTCT) of HIV and syphilis in Sri Lanka.

I know very well the strenuous and extensive work carried out by the National STD/AIDS Control Programme (NSACP) in collaboration with Family Health Bureau (FHB) together with stakeholders to achieve EMTCT of HIV and syphilis. Scaling up of the EMTCT programme commenced in 2013 and in three years, by end-2016, nationwide coverage of required services was achieved. Currently, health services offer HIV and syphilis testing facilities for all pregnant women and treatment for all positive pregnant women.

The effort to achieve EMTCT of HIV and syphilis in Sri Lanka is commendable, but it needs to be sustained. I have no doubt that our health systems are equipped to face that challenge. The most important strength of the EMTCT programme is that it is almost entirely funded by the Government of Sri Lanka assuring the sustainability.

I wish to take this opportunity to express my gratitude to NSACP, FHB, and all other stakeholders for the work well done.



Dr Rajitha Senaratne

Minister of Health, Nutrition and Indigenous Medicine

Message from the Secretary, Ministry of Health, Sri Lanka

The elimination of mother to child transmission of HIV and syphilis will help Sri Lanka to improve a broad range of maternal and child health (MCH) outcomes that include reducing child mortality and improving maternal health.

Children living with HIV or congenital syphilis face several complex social, psychological and ethical issues in addition to the medical problems. Ministry of Health has been providing services to prevent mother to child transmission of syphilis and HIV since long ago and from 2013 and, services have been strengthened further aiming elimination of mother to child transmission of HIV and syphilis.

Elimination of mother to child transmission of HIV and syphilis in 2018 is another pleasing achievement for Sri Lanka. This achievement is an example of multidisciplinary approach as governmental, non-governmental and international partners worked together with community and People living with HIV (PLHIV) organization to achieve a common cause. This was possible because of the dedication and commitment of many partners of the programme at the national, provincial and district levels under the guidance of the Family Health Bureau and the National STD AIDS Control Programme of Ministry of Health.

I would like to congratulate all who contributed to the programme to achieve another milestone in the delivery of health services in the country



Wasantha Perera

Secretary, Ministry of Health

Foreword

It is with great pleasure I pen a few words to introduce the report on validation of elimination of mother-to-child transmission (EMTCT) of HIV and syphilis programme in Sri Lanka. During the month of July, we learnt that Sri Lanka has been declared by WHO to have eliminated measles. In the same month submitting the validation report on EMTCT of HIV and syphilis programme doubles our pride on the health system of the country.

Achieving global indicators to be eligible to apply for elimination of mother-to-child transmission of HIV and syphilis is not an easy task. The dedication and commitment of health-care workers, be it the PHM at the grassroot level or the highest level health administrator in the country, has paved the way to achieve these brilliant outcomes. The multidisciplinary approach and the involvement of all for a common cause is clearly evident in this programme. Meaningful participation of key populations, PLHIV and NGOs, further facilitated the implementation and the sustainability of the programme.

I wish to congratulate the NSACP and FHB for the successful efforts under the guidance of DDG PHS who worked with multiple stakeholders including the health sector at the Central and provincial levels, the private sector and the community.

I wish to congratulate all those who worked tirelessly during the last two months to finalize the report, especially the report writing team headed by the coordinators of working groups of the four main domains.

I thank the members of the NVT and NVC for their contribution and the UN agencies such as UNICEF, WHO, GAFTM and UNFPA for the support extended.



Dr. Anil Jasinghe

Director General of Health Services

Abbreviations

3TC	lamivudine	IOM	International Organization for Migration
AFASS	acceptable, feasible, affordable, sustainable and safe	IUD	intrauterine device
AIDS	acquired immune deficiency syndrome	IYCF	infant and young child feeding
ANC	antenatal clinic	KP	key population
ANC1	at least one visit to antenatal clinic	M&E	monitoring and evaluation
ART	antiretroviral therapy	MCH	maternal and child health
ARV	antiretroviral (drug)	MLT	medical laboratory technologist
AVDC	Anti-Venereal Disease Control Campaign	MMR	maternal mortality rate
AZT	zidovudine	MoH	Ministry of Health
CBO	community-based organization	MOH	Medical Officer of Health
CD4	cluster of differentiation 4	MO MCH	Medical Officer, Maternal and Child Health
CDC	Centers for Disease Control and Prevention	MSD	Medical Supplies Division
CHE	current health expenditure	MSM	men who have sex with men
CMAI	Christian Medical Association of India	MTCT	mother-to-child transmission
CMC	Christian Medical College, Vellore, India	NAC	National AIDS Committee
CS	Congenital syphilis	NARI	National AIDS Research Institute
CSF	cerebrospinal fluid	NAT	nucleic acid-amplification test
CSW	commercial sex worker	NBTS	National Blood Transfusion Service
DDG LS	Deputy Director General of Laboratory Services	NCPA	National Child Protection Authority
DDG-PHS	Deputy Director General of Public Health Services	NDDCB	National Dangerous Drugs Control Board
DGHS	Director General of Health Services	NEQA	national external quality assurance
DHS	Demographic Health Survey	NGO	non-governmental organization
DMPA	depot medroxyprogesterone acetate	NRL	National Reference Laboratory
DNA PCR	deoxyribonucleic acid polymerase chain reaction	NRMA	National Medicinal Regulatory Authority
EFV	efavirenz	NSACP	National STD and AIDS Control Programme
EIBF	early initiation of breastfeeding	NSP	National Strategic Plan
EID	early infant diagnosis	NVC	National Validation Committee
EIMS	electronic information management system	NVP	nevirapine
ELISA	enzyme-linked immunosorbent assay	NVT	National Validation Team
EMTCT	elimination of mother-to-child transmission	NYC	National Youth Council
EPF	Employees' Provident Fund	OCP	oral contraceptive pill
e-RHMIS	electronic reproductive health information management system	PCR	polymerase chain reaction
FDA	Food and Drug Administration	PDHS	Provincial Director of Health Services
FEFO	first expired, first out	PHI	public health inspector
FHB	Family Health Bureau	PHLT	public health laboratory technician
FP	family planning	PHM	public health midwife
FPA	Family Planning Association	PHNS	public health nursing sister
FSW	female sex worker	PHSRC	Private Health Service Regulatory Council
FTC	emtricitabine	PITC	provider-initiated testing and counselling
GAM	Global AIDS Monitoring	PLHIV	people living with human immunodeficiency virus
GBV	gender-based violence	PMTCT	prevention of mother-to-child transmission
GFATM	Global Fund for AIDS, TB and Malaria	POA	period of amenorrhoea
GoSL	Government of Sri Lanka	PWID	people who inject drugs
GVAC	Global Validation Advisory Committee	PWUD	people who use drugs
HIV	human immunodeficiency virus	RAL	raltegravir
HPP	Health Protection Plan	RDHS	Regional Director of Health Services
IBBS	Integrated Biological and Behavioural Surveillance	RGD	Registrar General's Department
ICD PM	International Classification of Diseases (perinatal mortality)	RHMIS	reproductive health management information system
IEC	information, education and communication	RMNCAYH	Reproductive, Maternal, Newborn, Child, Adolescent and Youth Health
IMR	infant mortality rate	RMSD	Regional Medical Supplies Division
		RNA	ribonucleic acid
		RPR	rapid plasma regain (test)

RVT	Regional Validation Team
SIM	Strategic Information Management
SLIPTA	stepwise laboratory improvement process towards accreditation
SLMC	Sri Lanka Medical Council
SPC	State Pharmaceutical Corporation
STD	sexually transmitted disease
STI	sexually transmitted infection
TDF	tenofovir
ToR	terms of reference
TPPA	treponema pallidum particle agglutination (test)
TTI	transfusion transmitted infection
UDHR	Universal Declaration of Human Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Fund for Population Activities
UNICEF	United Nations Children's Fund
VDRL	venereal disease research laboratory test
VOG	visiting obstetrics and gynaecology doctor
WHO	World Health Organization

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Executive summary

The elimination of mother-to-child transmission (EMTCT) of HIV (human immunodeficiency virus) and syphilis in Sri Lanka builds on strong foundations of public health services that have facilitated declining transmission of sexually transmitted infections (STIs) over several decades. High level commitment is evident throughout EMTCT programme implementation. The country has assigned high priority to EMTCT, allocating resources, assigning a coordinator, engaging key stakeholders and meeting frequently to review progress and data. The Ministry of Health (MoH) issued circulars for public and private sectors promoting antenatal clinic (ANC) attendance, early screening for HIV and syphilis, and monitoring of key indicators.

With recent improvements in detection and management of HIV and syphilis in pregnant women, rates of mother-to-child transmission (MTCT) for both diseases have fallen well below global elimination targets – consistently less than five per 100 000 live births. The performance of the EMTCT programme currently meets or exceeds 95% targets for ANC attendance, early screening and treatment for both HIV and syphilis. Pregnant women diagnosed with HIV were started on lifelong antiretroviral treatment (ART) and have shown satisfactory adherence and retention.

Sixteen women living with HIV and 36 women with syphilis delivered during 2018. All pregnant women with HIV received treatment following national protocols, and the new-borns remain free of infection. Among pregnant women with syphilis, 97% received treatment and annual rate of congenital syphilis was 1.5 per 100 000 live births. Process indicators have improved with 97.5% in 2017 and 96.4% in 2018 for coverage of ANC attendance. These figures have been achieved through the government services. The screening coverage of pregnant women for HIV was 95.2% in 2017 and 95.9% in 2018 and for syphilis was 96.9% in 2017 and 99.3% in 2018 (Table 1).


Table 1. Impact and process indicators for 2017 and 2018

Impact Indicators	2017	2018
MTCT rate of HIV	0%	0%
Annual rate of new paediatric HIV infections per 100 000 live births	0	0
Annual rate of congenital syphilis per 100 000 live births	1.5	1.5
Process indicators	2017	2018
Antenatal care coverage	97.5%	96.4%
HIV testing coverage of pregnant women	95.2%	95.9%
Syphilis testing coverage of pregnant women	96.9%	99.3%
ART coverage of HIV-positive pregnant women	100.0%	100.0%
Treatment coverage of syphilis-positive pregnant women	100.0%	97.2%

All four prongs (P1–P4) of the EMTCT strategy are strongly implemented through well-integrated services for the community including pregnant women, their partners, key populations, adolescents and others at risk of STI/HIV. A background of steadily declining adult bacterial STI incidence over several decades reflects strong primary prevention and effective treatment services, leading to fewer women having infection during pregnancy.

Prongs 1 and 3 in particular are sufficiently developed to ensure that elimination is sustained in the future (Fig. 1). HIV/STI prevention efforts (P1) prioritize key populations and other vulnerable populations with targeted services, while the general population has easy access to a range of preventive service. All these services are provided free of charge by the government. Family planning services (P2) are available to any female who needs them. The unmet need for contraception was 6.1% in 2017. All pregnant women are provided with EMTCT services during pregnancy, delivery and postpartum period to ensure screening and treatment for HIV infection (P3) as detailed in this report. Finally, although the number of women living with HIV are few, a comprehensive package of HIV-related services for them and their families (P4) are provided free of charge, as for other PLHIV in Sri Lanka.

Fig 1. EMTCT critical pathways in Sri Lanka

Prong objective	Current status	Programmatic Progress	Evidence
1. Transmission low / declining among adults	Very low HIV prevalence (0.03%*)	Appropriate prevention focus on key population	Very good: through STD clinic reports
→ Very low transmission among adults means few maternal infections.			
3. Detection of maternal infection	>95% ANC >95% HIV Screening >95% Syphilis screening	Scale-up since 2013 with close monitoring	Excellent FHB and NSACP monitoring
→ Universal ANC attendance with complete HIV and syphilis screening means no missed cases			
 <p>Systems in place for individual case management of any pregnant woman found with HIV or syphilis</p> <p>Extremely small numbers of cases permit complete care and follow-up of infected mothers and infants</p>		Prong objective	Current status
		2. Prevention of Unwanted pregnancies	Available for positives
		4. Management of maternal infection	100% of positives
		4. Follow-up and management of newborn	100% of exposures

*Spectrum data, SIM Unit, NSACP, 2018

There is an adequate service delivery system to achieve and maintain EMTCT of HIV and syphilis with good linkage of MCH and STI services in all 25 districts in Sri Lanka. Data from the Family Health Bureau (FHB) show that in 2018, 96.4% of pregnant women presented for ANC services in the government health services. According to the Demographic and Health Survey (DHS) in 2016, institutional deliveries were reported by 99.5% of the sample and of them 5.4% of pregnant women delivered in private sector facilities. Private hospital survey data in 2018 showed that more than 80% of pregnant women had documented evidence of screening for HIV and syphilis at the time of delivery, and the national case management guidelines were followed.

Screening for syphilis among pregnant women in government sexually transmitted disease (STD) clinics increased from 60% in 2012 to 99.3% by the end of 2018, while HIV testing improved from 5.6% to 95.9% during the same period. These results follow an impressive national scale-up of services since the launch of the EMTCT programme in 2013.

After carefully reviewing the evidence presented in this report, the National Validation Committee (NVC) confidently submits it for the recommendation for validation of EMTCT of HIV and syphilis in Sri Lanka.

1. Country context

1.1. Geography

Sri Lanka is an island in the Indian Ocean, which is separated from peninsular India by the Palk Strait. The total area of the country is 65 610 sq. km with about 2905 sq. km of inland water. The country has a maximum length of 432 km from north to south and a maximum width of 224 km east to west. The south-central part of Sri Lanka, which is known as the central highlands, is the heart of the country. The highest elevation in the central highlands is 2.5 km and contains many complex topographical features such as ridges, peaks, basins, plateaus and valleys. The remainder consists of plains between 30 and 200 metres above the sea level. The coastal belt is about 30 metres above the sea level and surrounds the island. It consists of sandy beaches indented by coastal lagoons.

Fig 1.1. Geographical location of Sri Lanka



Source: <http://tourallseasons.com/index.php/tour-guide>

Colombo is the largest city and the commercial capital of the country and is situated on the western coast of the island.

Passenger transport within the country is mostly by road and to a lesser extent by rail. Any part of the country can be reached from the commercial capital Colombo within half a day by public transport and within eight hours by vehicle.

1.2. Demography

According to the last Population Census and Statistics report, the population of Sri Lanka was 20 359 439, with a population density of 325/km². The female population was 51.6% of the total population and 62.4% of the total population was between the ages of 15–59 years. The major ethnic groups are Sinhalese 74.9%, Tamils 15.4% and Sri Lanka Moor 9.3% (DoCS, 2012). Sri Lanka has a high life expectancy of 75.5 years with a male life expectancy at 72.43 years and a female life expectancy at 79.59 years (Central Bank, 2018a; MoH, 2016a).

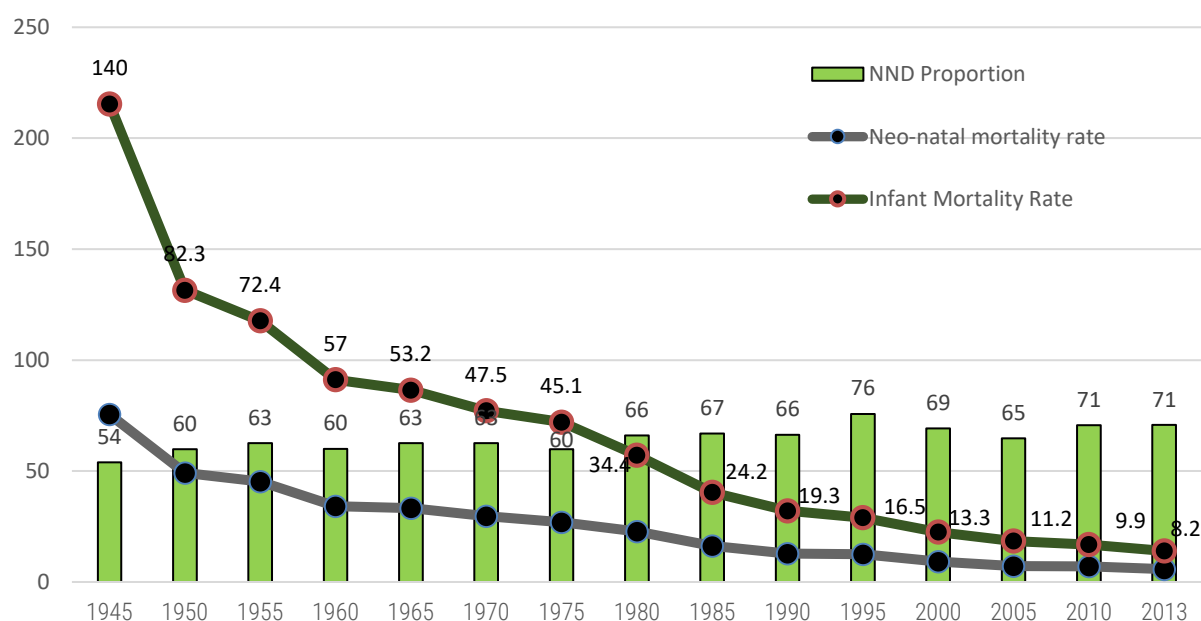
1.3. Basic health indicators, including MCH indicators

Sri Lanka has achieved marked improvements in health-related indicators during the past six decades. Despite the low national income and low level of health expenditure, Sri Lanka has improved basic health indicators, which are comparable to those of more developed countries in the region (Central Bank, 2018a; Central Bank, 2018b).

Maternal mortality ratio (MMR) is an overall quality index of a country's socioeconomic development and health care. Sri Lanka reported an MMR of 1964 per 100 000 live births in 1947 and has gradually reduced it over the past few decades to achieve the best in the South Asian region. In 2017, the MMR was 39.3 per 100 000 live births.

Sri Lanka has shown a steady decline in neonatal, perinatal, infant and child mortality over many decades (Fig. 1.2). Rapid decline shown in the mid-20th century could be attributed to the expansion of hospital and public health infrastructure, increase in skilled birth attendance, control of malaria, introduction of antibiotics and social policies in providing free health and free education. However, the infant mortality rate (IMR) seems to have stalled at around 8/1000 live births in recent years (FHB, 2016).

Fig.1.2. Trends in Infant and Neonatal Mortality Rates 1945 -2013



Source: M&E unit- FHB, 2018

These improvements have been attributed to a combination of factors. Significant contributory factors are listed below:

1. Provision of preventive and curative health services free of charge at the point of delivery by the public sector.
2. Public provision of free education for all is also an important, cost-effective welfare measure established in 1947 and continued by successive governments thereafter. Universal access to free education with continuation of free higher education has increased opportunities for employment and raised social status for many. Empowerment of girls and women through equal access for free education helps in effective health education, which has contributed significantly for successes in

the public health sector, especially for reduction in maternal and child morbidity and mortality in Sri Lanka.

3. Introduction of a health unit system since 1926, thus mainstreaming public health-care delivery at the grassroot level with a framework for accountability and governance.
4. Introduction of a large number of curative care centres throughout the country, with both in- and outpatients' care at the primary level, gave the public access to health care without travelling long distances.
5. Introduction of income transfer programmes that have allowed higher consumption by the poor.

All of the above factors may have contributed to the provision of good health care (health promotion, disease prevention and early detection and treatment) at a low cost in Sri Lanka. However, it is important to note that discrepancies exist between geographical regions in terms of indicators of health status and availability of resources for health care. Hence, improving the quality of care and minimizing inequities in access to care are major challenges to be addressed in the future in order to further improve health indicators (Gunasekera, 2014; Fernando et al., 2003; Pathmanathan et al., 2003).

Table 1.1. Key Health Indicators in Sri Lanka

Indicator	Data	Source/Year
Crude birth rate (per 1000 population)	16.0	Registrar General/2016
Crude death rate (per 1000 population)	6.3	Registrar General/2016
Women in reproductive age group (15–49 years)	51%	Census of population and housing/2012
Neonatal mortality rate (per 1000 live births)	5.6	Registrar General/2014
Infant mortality rate (per 1000 live births)	8.0	Registrar General/2014
Under-5 mortality rate (per 1000 live births)	9.4	Registrar General/2014
Maternal mortality rate (per 100 000 live births)	39.3	Registrar General/2013 Family Health Bureau/2017
Low birth weight (per 100 live births) in government hospitals as a %	15.5	Medical Statistics unit/2016
% of under-5 children		Demographic and Health Survey/2016
Underweight (weight for age)	20.5	
Wasting (weight for height)	15.1	
Stunting (height for age)	17.3	
Life expectancy at birth (years)		
Female	78.6	Census and Statistics/2016
Male	72.0	
Literacy rate (%)		
Total (10 year or more)	95.7	Census and Statistics/2016
Female	94.6	
Male	96.9	
Singulate mean age at marriage (years)	23.4	Census and Statistics/2016

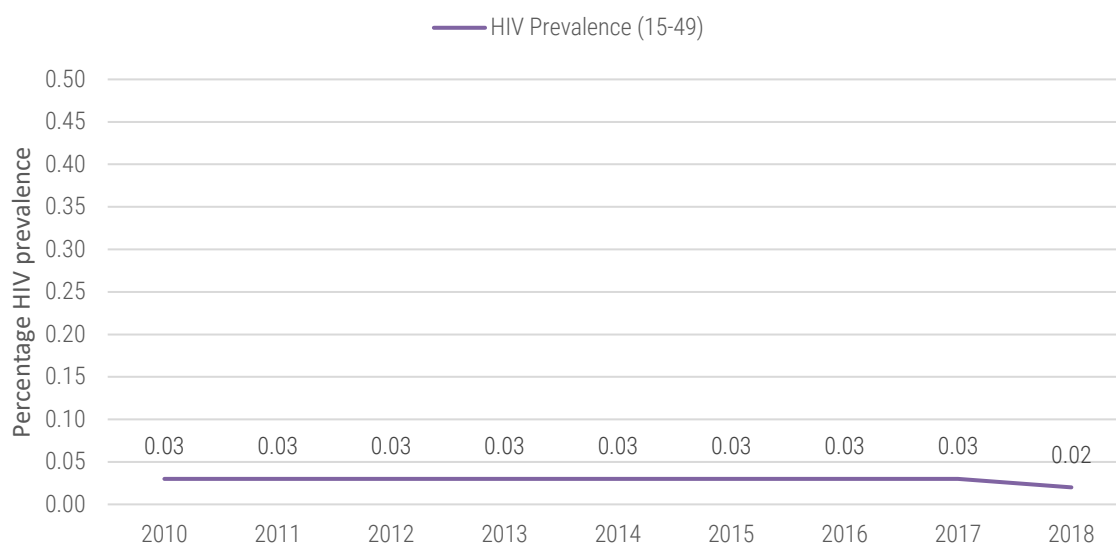
Source – [Central Bank Annual Report 2018](#)

1.4. Epidemiological profile of HIV and syphilis prevalence and incidence trends in the general population and in Antenatal clinic (ANC) population

1.4.1. HIV prevalence trends in general population

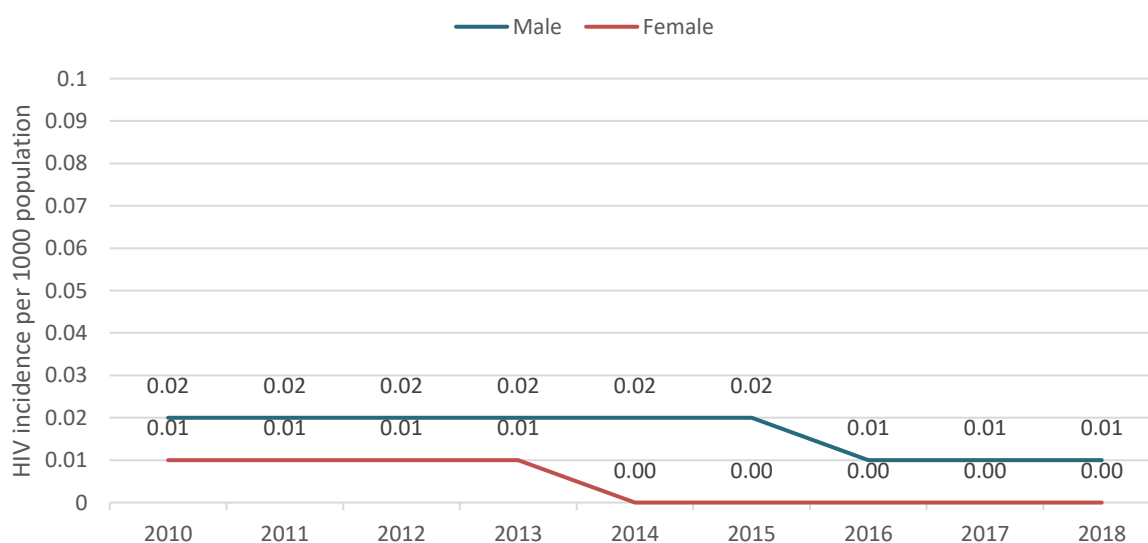
HIV infection was first reported in Sri Lanka in a foreign national in 1986 and in a Sri Lankan the following year. By end-2018, the total number of reported HIV diagnoses were 3192. The estimated numbers of adults living with HIV as of 2018 was 3500 (3100–4000) and estimated new infections were less than 200 (UNAIDS, 2019). Sri Lanka continues to be a low prevalence country for HIV. HIV incidence also remains at a very low level (Figs 1.3, 1.4).

Fig.1.3. Estimated HIV prevalence trends in the general population, by age group 15 -49 years, 2010-2018



Source – Spectrum 2018/2019.(SIM Unit, NSACP)

Fig.1.4. Estimated HIV incidence trends in the general population per 1000 uninfected population, 2010–2018



Source – Spectrum 2018/2019. (SIM Unit, NSACP)

Figure 1.5 shows different patterns when HIV infections are disaggregated by sex. Over three male HIV infections per 100 000 male population were reported in Colombo and Gampaha in 2017. During 2018, in addition to these two districts, Galle, Matale and Vavuniya districts also had over three infections per 100 000 male population. None of the districts had over three female HIV infections per 100 000 female population. Colombo, Polonnaruwa and Vavuniya had higher rates during both 2017 and 2018 for female HIV infections. During 2017, most of the districts of the Northern province showed a higher rate of HIV infection among females. However, this pattern was not seen in 2018.

Fig.1.5. Rates of newly reported HIV infections per 100 000 male and female population in 2017 and 2018

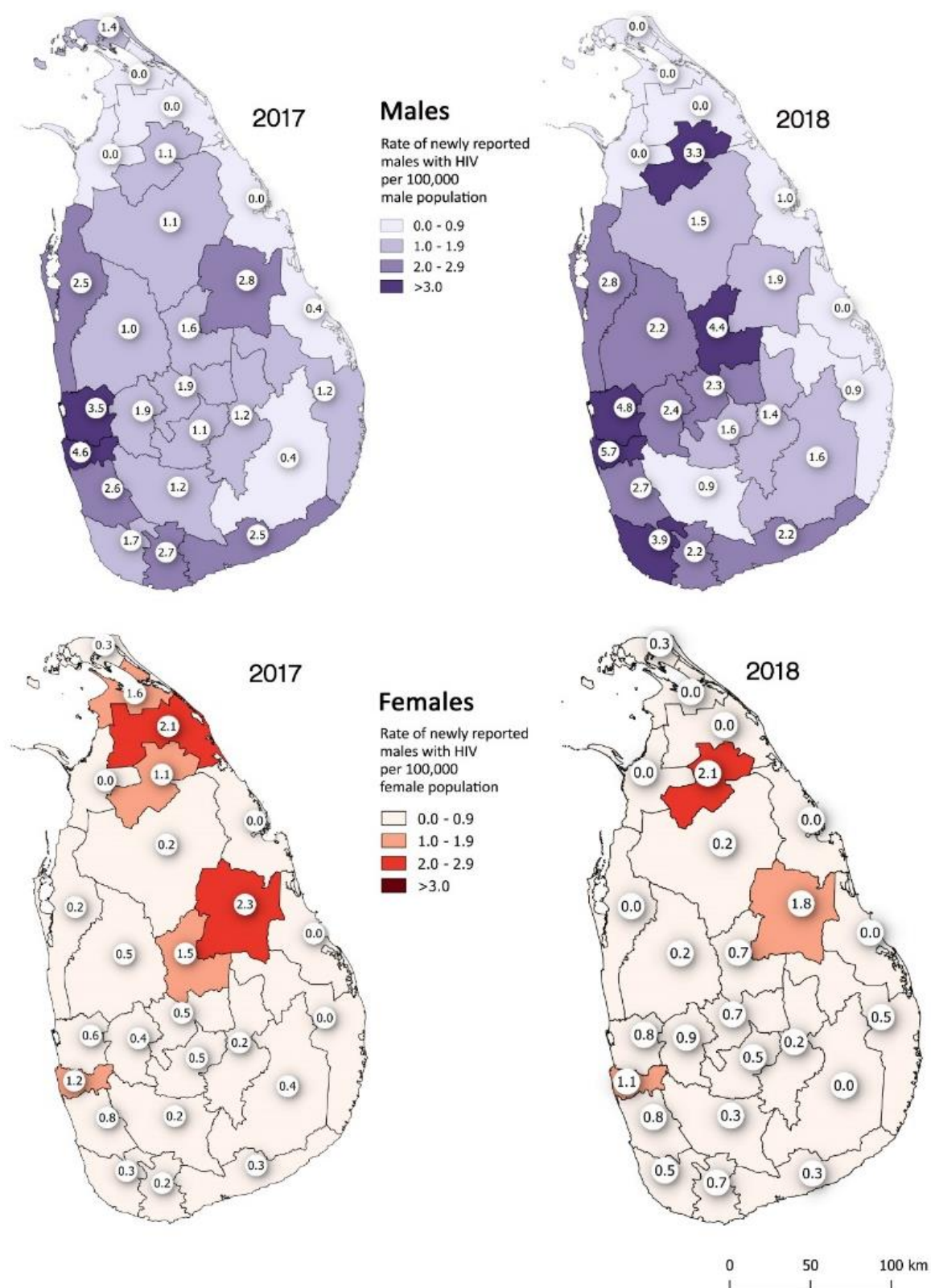
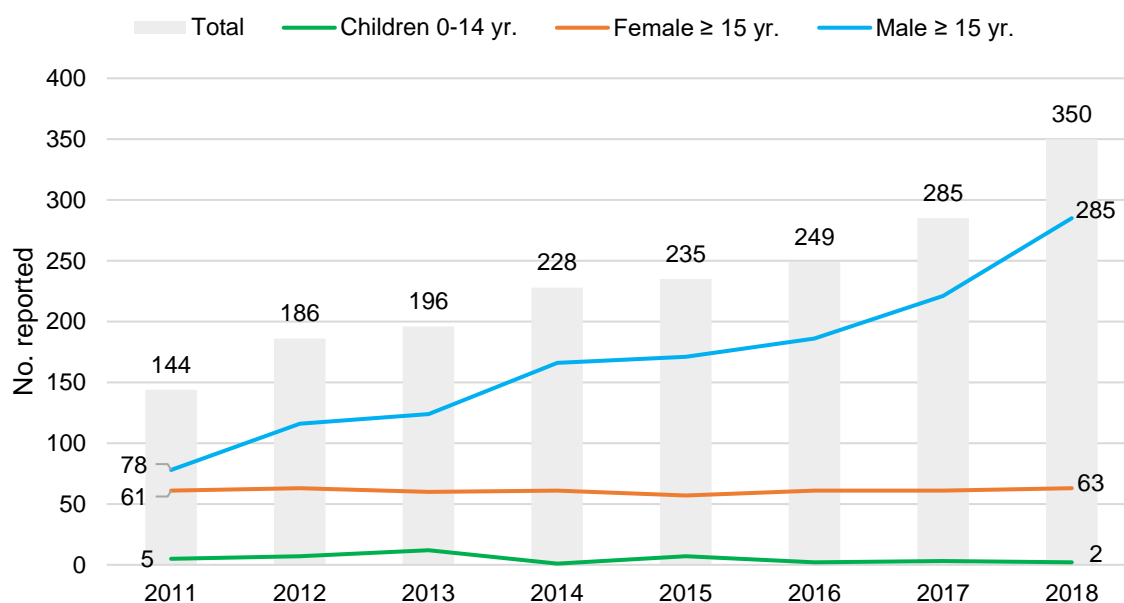
Source – [NSACP Annual Report 2018](#)

Fig.1.6. Trends of annual reported cases of HIV infection by age and sex 2011 – 2018

Source – [NSACP Annual report 2018](#)

The numbers of HIV-positive cases have been slowly rising over the years and this increase was mainly due to increased infections among males (Fig. 1.6). Among the reported cases, the numbers of HIV infections among men who have sex with men (MSM) have been rising gradually with close to half of all positive males reporting male-to-male sex.

1.4.2. HIV prevalence among key population

According to the Integrated Biological and Behavioural Surveillance (IBBS) conducted in 2017/2018, the overall prevalence among key populations (KPs), which include female sex workers (FSWs), MSM, beach boys, people who use drugs (PWUD) and people who inject drugs (PWID) was <1% except in the transgender women (TGW) population (Table 1.2). TGW and MSM had a higher HIV prevalence than other population groups (NSACP, 2018)

Table 1.2. Percentage seroprevalence of HIV among key populations

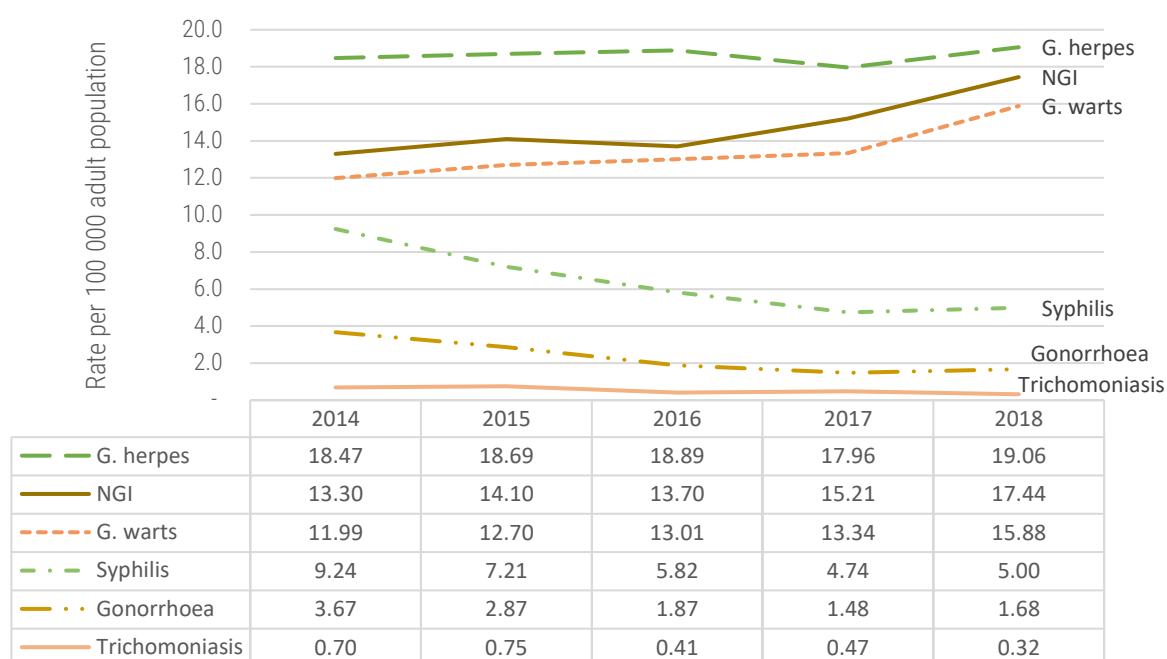
Key indicator	MSM	TGW	FSW	PWID	Beach boys
HIV prevalence	0.6	1.2	0.24	0	0.2
HIV and hepatitis coinfection	0	0	0	0	0

Source – [IBBS, 2018](#)

Sexually transmitted infections (STIs) have been in decline in Sri Lanka since the mid-1970s due to sustained public health efforts implemented mainly through district-level sexually transmitted disease (STD) clinics. All components of STI preventive and curative services are well supported and backed by a simple but reliable surveillance system. The annual report of the National STD/AIDS Control Programme

(NSACP) 2018 gives in detail how different STI programme components contribute to a comprehensive and highly effective national response to HIV as well as other STIs. Perhaps unique to the region, the NSACP retained its broad STI focus, incorporating HIV prevention, care and treatment activities within existing STI programme structures. Moreover, the slow growth of HIV in Sri Lanka has been attributed to the high level of STI control in the country when HIV first appeared (Rajapaksa, 2012; WHO, 2013) (Fig. 1.7).

Fig.1.7. Trends of STI rates per 100 000 adult population (15+ years), 2014-2018



Source – NSACP Annual report 2018

1.4.3. Syphilis trends in general population

To eliminate mother-to-child transmission (MTCT) of syphilis, the prevalence of syphilis among pregnant women as well as in the general population needs to be reduced.

Since STIs are not notifiable in Sri Lanka, data on syphilis are generated from STD clinics of the Ministry of Health (MoH). Although this may not indicate the exact magnitude of the problem, the trend data gives valuable insight into the epidemiology of syphilis.

Syphilis prevalence data are also available for pregnant women, donor blood (Table 1.3) as well as surveillance data from HIV sentinel surveys and [IBBS](#) (Table 1.4).

The National Blood Transfusion Service (NBTS), which comes under the MoH, is the sole supplier of blood and blood products to all state hospitals and to some private hospitals registered under the MoH. Currently, it supplies blood/blood products to 100 blood banks distributed in 19 clusters. All blood donations are from voluntary and non-remunerated donors. In 2018, over 450 000 units of blood were screened for syphilis, HIV and other transfusion transmitted infections (TTIs) and the prevalence of HIV and syphilis among donors for the year 2018 was 0.01% and 0.02%, respectively (Table 1.3).

Table 1.3. Prevalence data for TTI s in donated blood from 2012-2018

	No. of donated samples	HIV +Ve	HIV prevalence	TPPA +ve	Syphilis prevalence	HBsAg +ve	Hep B Ag prevalence	HCV Ab +ve	HCV sero prevalence
2012	351,605	16	0.00%	170	0.05%	405	0.12%	1025	0.29%
2013	380,808	16	0.00%	180	0.05%	273	0.07%	953	0.25%
2014	380,367	26	0.01%	152	0.04%	394	0.10%	657	0.17%
2015	395,500	21	0.01%	175	0.04%	409	0.10%	800	0.20%
2016	417,175	25	0.01%	152	0.04%	505	0.12%	847	0.20%
2017	423,668	28	0.01%	152	0.04%	618	0.15%	905	0.21%
2018	450,640	29	0.01%	107	0.02%	513	0.11%	898	0.20%

Source – National Blood Transfusion Service, 2018

1.4.4. Syphilis prevalence among key populations

According to the IBBS results, prevalence rates of syphilis were 1.7% and 1.4% among FSWs and MSM, respectively. It is noteworthy that even among populations at high risk, the prevalence of syphilis was low (NSACP, 2018) (Table 1.4).

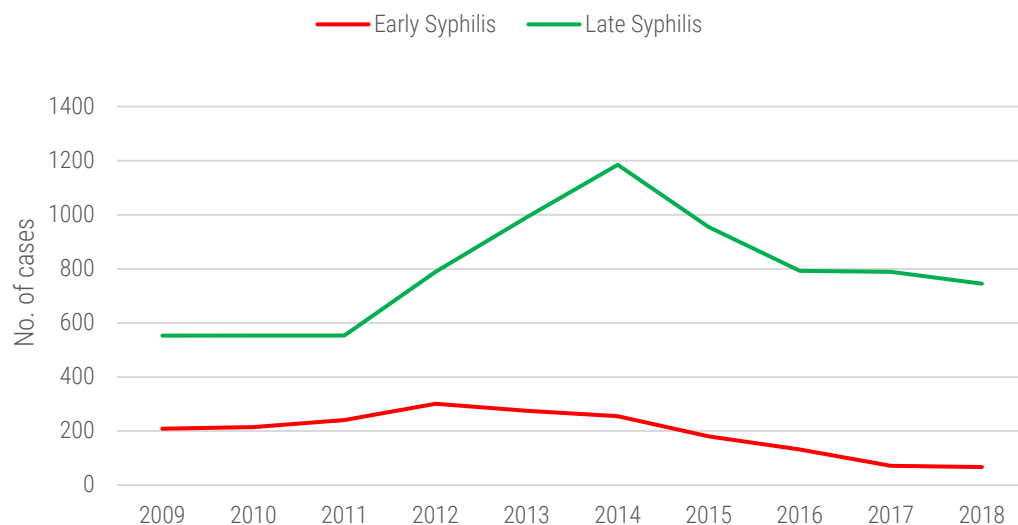
Table 1.4. Percentage Seroprevalence of STIs among key populations in 2018

Survey indicator	MSM	TGW	FSW	PWID	Beach boys
Active syphilis*	1.4	0.4	1.7	0.3	0.2
Hepatitis B surface Ag-positive	0.6	0	0.37	0.1	0
Hepatitis C Ab-positive	-	-	-	6.2	-
Herpes Ab-positive	-	-	-	-	5

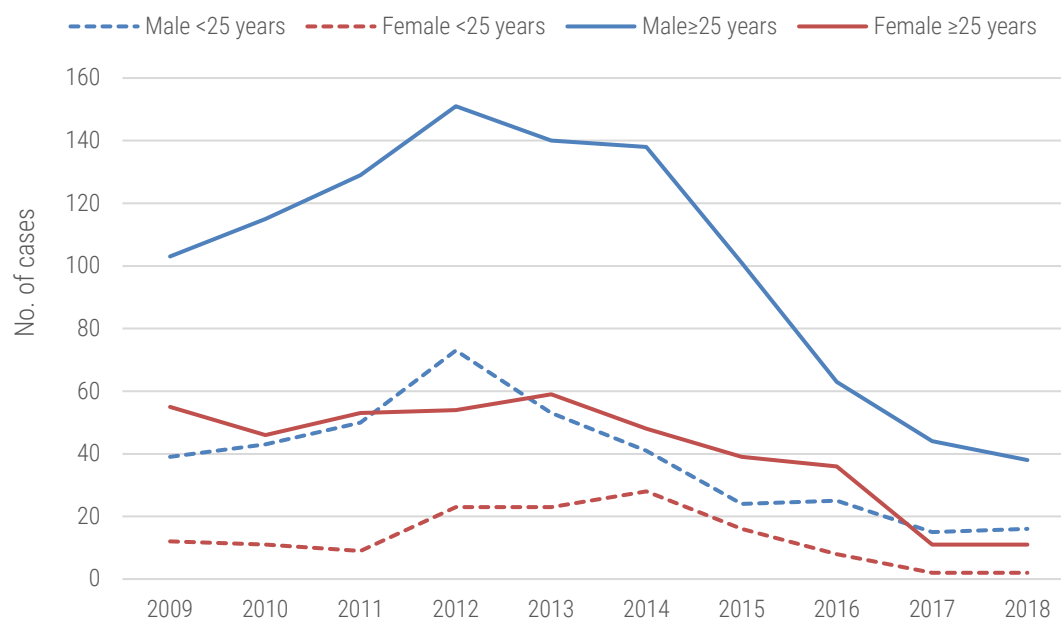
*Active syphilis – Primary, secondary and early latent syphilis

Source – [IBBS 2018](#)

The number of newly reported cases of syphilis (early and late syphilis) diagnosed in STD clinics shows an increase from 2012 to 2014, followed by a decline. The increase was mainly due to increase in late syphilis cases (Fig. 1.8). Early syphilis refers to syphilis diagnosed within two years of infection and late syphilis is infection diagnosed two years or more following possible acquisition. Early syphilis is also known as infectious syphilis and persons with infectious syphilis can transmit the infection to their sexual partners and thereby to children, if the infected pregnant women are not adequately treated. Figure 1.9 shows the declining trend of early syphilis in the different age groups.

Fig.1.8. Reported cases of early and late syphilis, 2009-2018

Source – SIM Unit NSACP, 2018

Fig.1.9. Reported cases of early syphilis by age and sex, 2009-2018

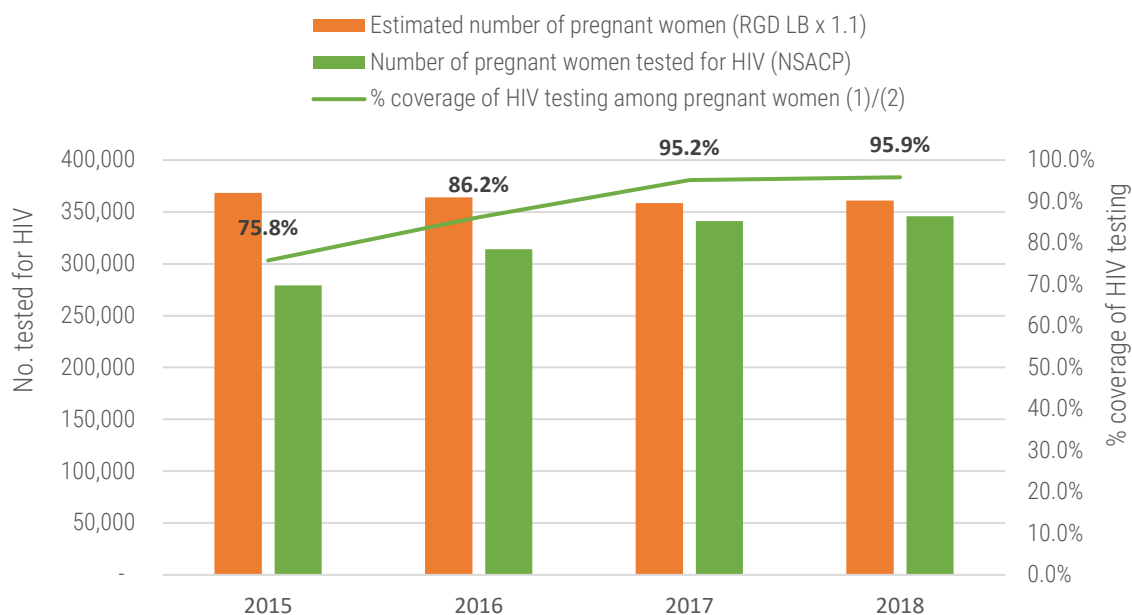
Source – NSACP Annual report 2018

1.4.5. HIV Prevalence Trends among Pregnant Women

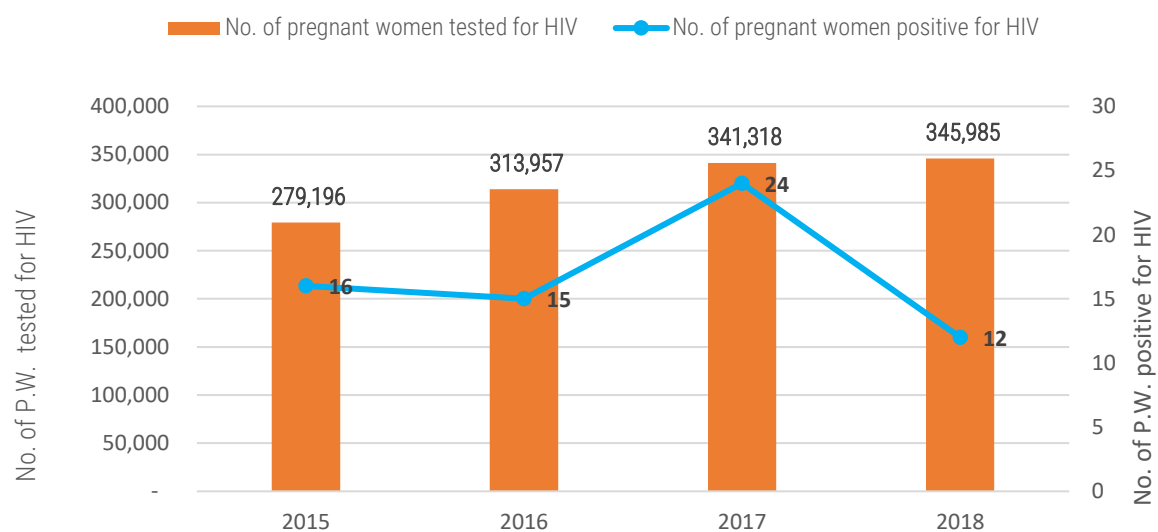
The first case of HIV infection in a pregnant woman in Sri Lanka was reported in 1990. The programme for prevention of mother-to-child transmission (PMTCT) of HIV was formally established in 2002 and provided services to all pregnant women identified as HIV-positive. Initially, a pilot project was carried out at the district general hospitals in Gampaha, Kalutara and the De Soyza hospital in Colombo. The PMTCT service package was improved including antiretroviral therapy (ART), obstetric management and infant feeding options.

In early 2013, the MoH re-assessed the PMTCT programmes for HIV and syphilis and decided to amalgamate the two as one programme called the elimination of mother-to-child transmission (EMTCT) of HIV and syphilis programme. The NSACP collaborated with the Family Health Bureau (FHB) to initiate the scaling up of antenatal HIV and syphilis testing services across the country, through government STD clinics and maternal and child health (MCH) services with the assistance of the UNICEF, WHO and World Bank to cover the entire country by 2016. In 2018, government STD clinics offered HIV testing services for 95.9% of pregnant women. According to the government policy of free health services for all, these services were offered free of charge as part of the maternal care package. (Fig. 1.10)

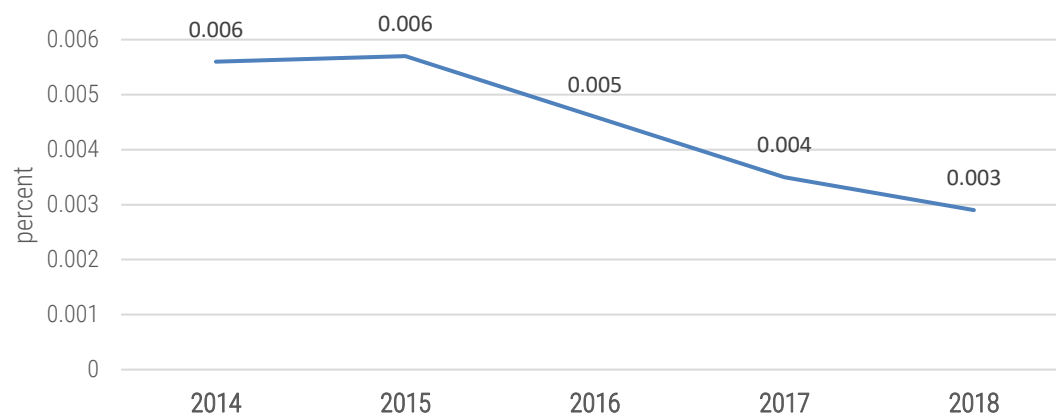
Fig.1.10. Coverage of HIV testing among pregnant women



Source – NSACP Annual report 2018

Fig.1.11. Annual reported numbers of pregnant women tested and found positive for HIV, 2015 - 2018

Source: NSACP Annual report 2018

Fig.1.12. HIV Prevalence among pregnant women

Source –SIM Unit, NSACP , 2018

The number of new HIV diagnoses among pregnant women has remained stable over the years (Fig. 1.11). Despite scaling up of HIV testing among pregnant women, the prevalence of HIV infection has declined over the years (Fig. 1.12).

The NSACP data gave an HIV prevalence of 0.003 among pregnant women in 2018.

1.4.6. HIV estimates

Sri Lanka uses HIV estimates to compare against the reported prevalence including HIV surveillance data. Currently, HIV disease burden is estimated using the Spectrum software. The latest estimation was done in 2018 using the Spectrum software version 5.755. Table 1.5 summarizes PMTCT of HIV estimates for the period 2015–2018.

Table 1. 5. Spectrum estimates for PMTCT indicators, 2015-2018

	2015	2016	2017	2018
Mothers needing PMTCT	17	18	16	16
Mothers receiving PMTCT	11	16	16	16
Single-dose nevirapine	0	0	0	0
Dual ARV therapy	0	0	0	0
Option A: maternal	0	0	0	0
Option B: triple prophylaxis from 14 weeks	0	0	0	0
Option B+: ART started before current pregnancy	4	4	6	7
Option B+: ART started during current pregnancy >4 weeks before delivery	6	12	10	9
Option B+: ART started during current pregnancy <4 weeks before delivery	1	0	0	0
% PMTCT coverage	63.92	91.25	97.70	99.86
% PMTCT coverage of more efficacious regimens	63.92	91.25	97.70	99.86
% MTCT rate at 6 weeks	10.87	4.63	2.71	1.95
% Final transmission rate including breastfeeding period	24.77	4.63	2.71	1.95
Number of HIV+ breastfeeding women at 3 months	6	0	0	0
Number of HIV+ breastfeeding women at 12 months	5	0	0	0
Number of new child infections due to mother-to-child transmission				
Total	4	1	0	0
Male	2	0	0	0
Female	2	0	0	0
% treatment coverage for HIV+ pregnant women	63.92	91.25	97.7	99.86

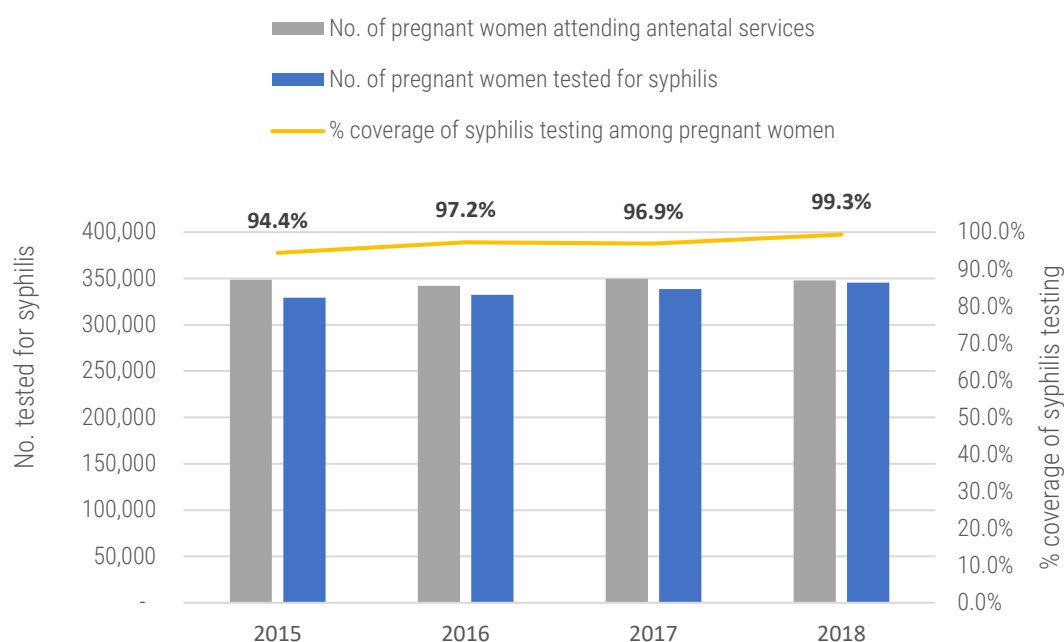
*Spectrum version 5.557 done in May 2019. (SIM unit, NSACP)

1.4.7. Syphilis prevalence trends in antenatal population

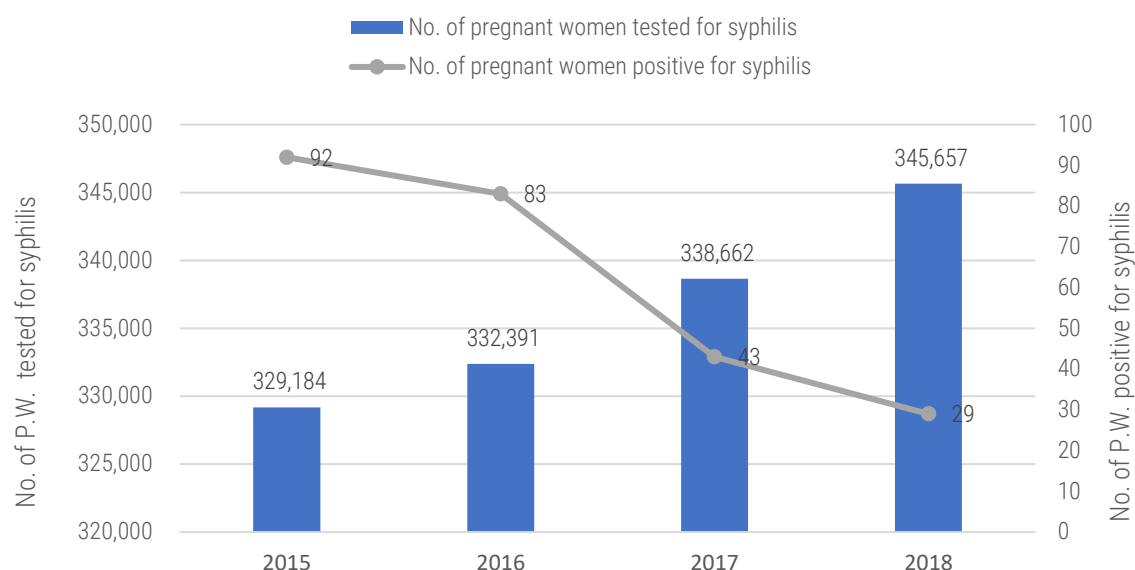
Syphilis is a bacterial STI with a potential for *in utero* infection resulting in adverse pregnancy outcomes. Highly effective treatment is available, which reduces the risk of MTCT. Pregnant women should be screened for syphilis at the first antenatal visit preferably before 12 weeks of gestation to prevent adverse outcomes including congenital infection. Because adverse outcomes from syphilis are preventable, screening and treatment in pregnancy are highly cost-effective. As far back as 1952, Sri Lanka adopted universal syphilis screening of pregnant women. Therefore, all pregnant women who attend antenatal care services, be it in the field ANCs or in MoH and non-MoH and private hospitals are offered screening tests for syphilis.

In 2018, the percentage of pregnant women who attended ANCs in the government sector at least once during pregnancy was 96.4%, and of them 99.3% were tested for syphilis (Fig. 1.13). Twenty-nine pregnant women were diagnosed with syphilis in 2018, giving a prevalence of 0.08 per 1000 (Fig. 1.14).

Fig.1.13. Coverage of syphilis testing among pregnant women, 2015 -2018



Source: NSACP Annual report 2018

Fig.1.14. Reported cases of pregnant women newly diagnosed with syphilis and the number tested, 2015–2018

Source – SIM unit, NSACP, 2018

1.4.8. Estimated syphilis data

The NSACP estimated the burden of syphilis among pregnant women using the WHO tool to “Estimate syphilis in pregnancy and associated adverse outcomes” and the results are given in Table 1.6.

Table 1. 6. Estimated syphilis in Pregnancy and Associated Adverse outcomes (2015 – 2018)

Year	2015	2016	2017	2018
Infant status				
Total number of adverse birth outcomes due to congenital syphilis	8	6	3	3
Number of stillbirths	3	2	1	1
Number of neonatal deaths	1	1	1	1
Number of premature/low birth weight	1	1	0	1
Number of infants with clinical congenital syphilis	2	1	1	1
Total number of congenital syphilis cases (clinical and asymptomatic)	15	10	5	6
Clinical congenital syphilis case rate per 100 000 live births for all pregnant women	4	3	1	2

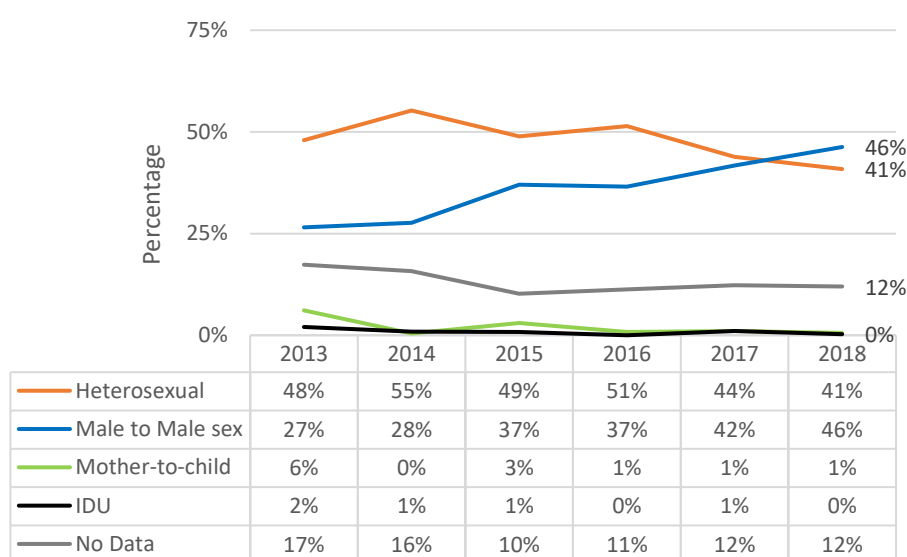
Source – SIM Unit, NSACP, 2018

It was encouraging to note that the numbers derived from the estimates were found to be compatible with the surveillance data.

1.5. Modes and drivers of HIV transmission

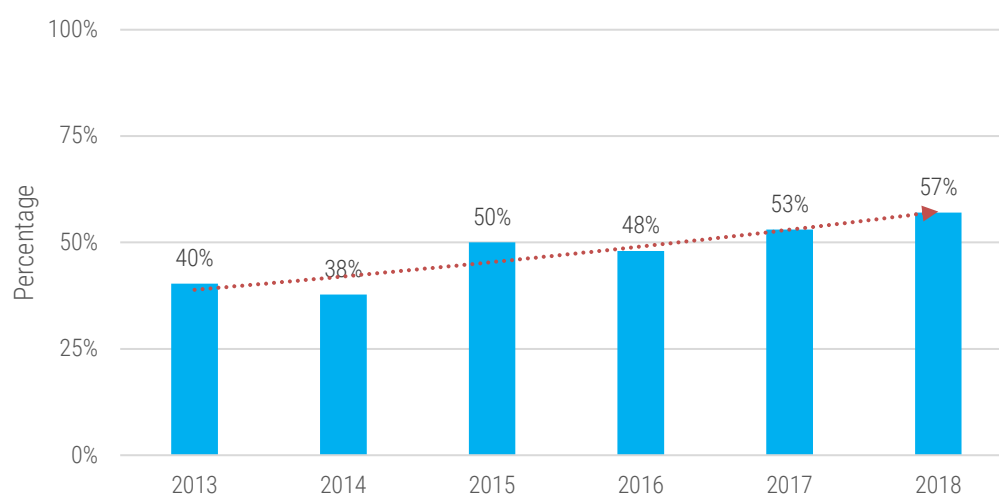
Three hundred and fifty new HIV infections were reported in 2018. The main mode of transmission was unprotected sexual exposures (Fig. 1.15). From 2013 to 2018, there is an increase of transmission related to MSM exposures (Fig. 1.16). MTCT accounted for <1% in 2018. However, there were no infants diagnosed with HIV among the birth cohorts of 2017 and 2018. (Fig 1.17)

Fig. 1.15. Probable mode of transmission among reported HIV infections, 2013–2018

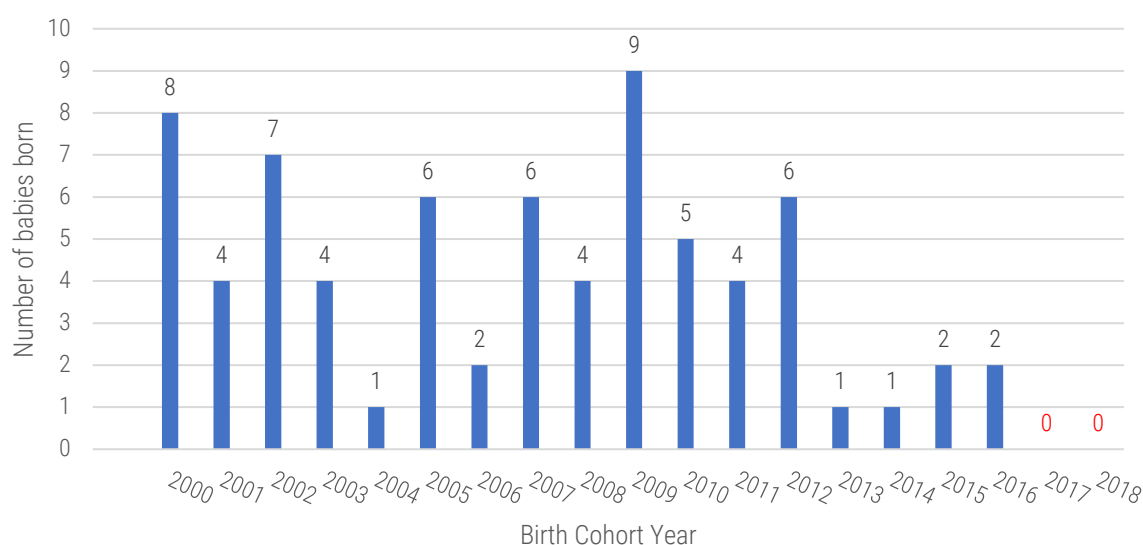


Source – NSACP Annual Report 2018

Fig. 1.16. Percentage of male-to-male transmission of HIV among reported males



Source – NSACP Annual report 2018

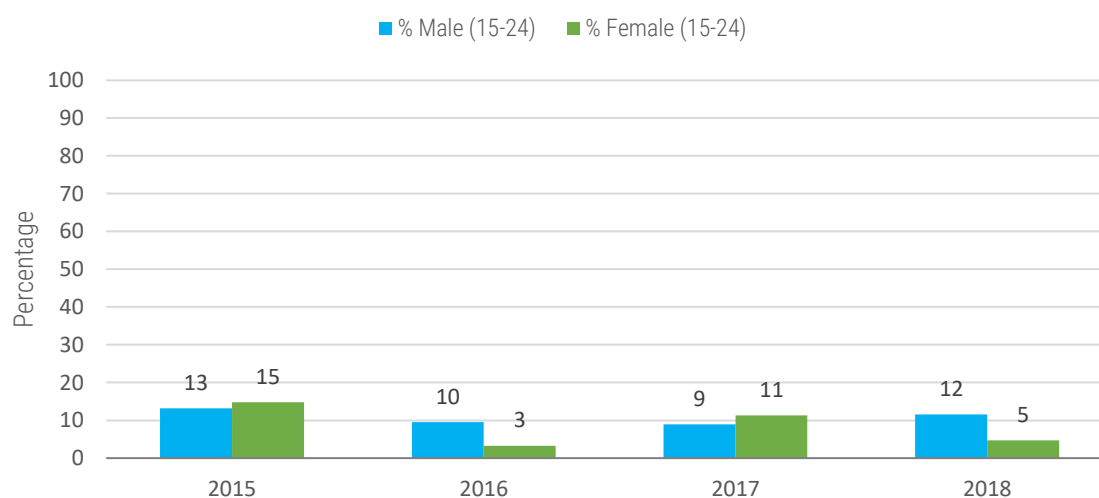
Fig. 1.17. Cases of Mother-to-child transmission of HIV, according to the birth cohort, 2000-2018

Source – SIM unit, NSACP, 2018

1.6. HIV Trends in Children and Adolescents

Since 1990, the cumulative number of HIV infections diagnosed among children and infants is 85 and all were due to MTCT. However, details are available only for 78 cases.

Of these 78 children, 68 were identified in WHO stage I and II, and 63 are living currently. In 2018, there were two children diagnosed with HIV of two-and-a-half and four years of age.

Fig. 1.18. Percentage of young adults among newly reported male and female HIV cases, 2015-2018

Source: SIM unit, NSACP, 2018

In 2018, close to 8% of newly diagnosed PLHIV were young adults in the 15–24 age group and all these cases were due to sexual transmission. Where incidence testing is not available to measure new infections,

HIV infection among young people 15–24 years has been used as a proxy measure for new infections. There was no clear trend seen over the years (Fig. 1.18). There were 33 males and three (3) females in the age group 15–24 years among the total 350 newly reported cases in 2018. Among these 33 males, 25 (75%) probably acquired the infection through MSM exposures. There was only one injecting drug user among them.

1.7. Rates and Trends of Adolescent Pregnancy in Sri Lanka

Pregnancy rates by age groups are not routinely calculated and reported in Sri Lanka, but the percentage of pregnant women who are teenagers is reported. About 5% of all pregnancies registered are among teenagers and this percentage has remained close to 5% over the past several years with no evidence of a secular trend. The percentage of teenage pregnancies in 2014, 2015 and 2016 were 4.9%, 5.3% and 4.9%, respectively (National Statistics, FHB). In 2018, there were 16 105 pregnant women in <20 years age group. This included 325 pregnant teenagers of <16 years and 2947 in 16–17 years.

According to the General Circular No. 01-25/2015 (MoH), on providing sexual and reproductive services to adolescents, the best interest of the child should be the basic concern of medical officers who provide such services. Decisions on best interest should be assessed by the medical officers on a case by case basis. Reproductive health services can be provided even in the absence of parental or guardian consent in the best interest of the child (Annexure 14).

In 2017, a 17-year-old unmarried pregnant girl with HIV infection was diagnosed during screening in prisons. She was managed while she was in the prison by STD clinic Negombo. She was linked to NSACP Colombo after her release from the prison. She continued ART and delivered an uninfected baby. Currently, she is living with her partner.

1.8. Stillbirth trends

In Sri Lanka, the legal meaning of "stillbirth" is "death prior to complete expulsion or extraction from its mother of a product of conception which has had a duration of not less than 28 weeks of gestation, death being indicated by the fact that after such separation, the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles" as defined in the Births and Deaths Registration Act, 1954.

Antepartum hypoxia was the commonest case of stillbirth while congenital malformation was the commonest case in intrapartum and neonatal deaths. Low birth weight and prematurity were the other important reasons for stillbirth (Priyani et al., 2017).

In 2006, a perinatal mortality surveillance system was implemented at specialized hospitals. Individual stillbirth data were available at the hospital level. Stillbirths in the hospitals were subjected to a monthly review. Till 2015, stillbirths were registered under the vital registration system only in certain parts of the country where the registrar of vital events is a medical registrar.

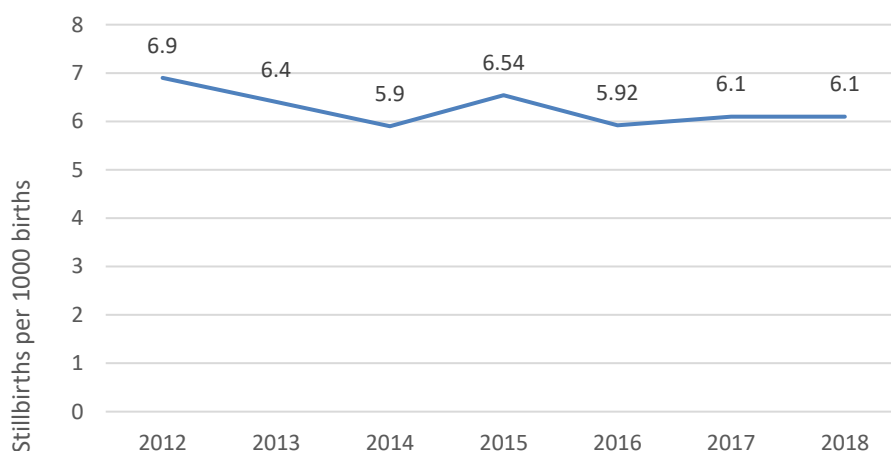
From 2015, the MoH initiated the collection of individual stillbirth data from the specialized hospitals to the national level. The International Classification of Diseases – perinatal mortality (ICD-PM) was introduced. Stillbirths are subjected to a pathological postmortem if a valid cause of death is not available. Pathological postmortems are conducted at all specialized hospitals. As such, quality data on cause of deaths due to stillbirths are available in the country. At present, individual stillbirth data are available at the national level. A web-based stillbirth surveillance system is already finalized.

The MoH is facilitating the registration of stillbirths with the vital registration system since 2015. All specialized hospitals send completed “certificate of the stillbirth” for each stillbirth (>28 weeks of gestation) fast track to the Registrar General’s Department (RGD).

The stillbirth rate (per 1000 total births) is given in Fig. 1.19 (National Statistics, FHB).

A circular was issued in 2016 (General Circular No. 01/59-2016) by the MoH recommending screening of all pregnant women reporting abortions or stillbirths for HIV and syphilis if not done in early pregnancy (Annexure 10).

Fig. 1.19. Stillbirth trends from 2012 to 2018



Source – National statistics, Family Health Bureau, 2018

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2. Description of the health systems present in the country

2.1. Health services

The Sri Lankan health system comprises of different systems of medicine: Traditional, Western, Ayurvedic, Unani, Siddha, Homeopathy and Acupuncture. Of these, the western or allopathic medicine is the main sector catering to the needs of the majority. Allopathic medicine is provided through both public and the private sectors, the share of care being different for inpatients and outpatients. Over 90% of inpatient health-care services are provided by the public sector. In 2017, 55 million outpatient visits and 6 million hospitalizations occurred in government health-care institutions (MoH, 2017).

The private sector provides access to all types of care at a cost while the public sector provides free health facilities.

The public health sector is organized as two parallel streams:

- community health services focusing mainly on promotive and preventive health
- curative care services ranging from non-specialized primary care to specialized care delivered through a variety of hospitals

The government health system has been partially decentralized to provincial councils since 1987 according to the 13th amendment to the constitution. The Ministry of Health, Nutrition and Indigenous Medicine (MoH), at the Central level is responsible for formulation of health-related policies and regulating services for both public and private sectors and maintaining the health services through national-level health institutions. The nine provincial health ministries are responsible for effective implementation of curative and preventive health services in their respective provinces (Fernando, 2000).

2.1.1. Provincial and District Health Services

The nine provinces have 25 administrative districts in the country. The Provincial Director of Health Services (PDHS) leads health services in the province and the Regional Director of Health Services (RDHS) is responsible for organizing, managing and ensuring smooth delivery of services within the administrative district.

Provincial councils and local governing bodies are entrusted with playing a decisive role in the provision of health services. Provincial administrations are entrusted with delivery of majority of preventive and primary curative care services and a substantial proportion of secondary care (Fernando, 2000). Sri Lanka has a well-established network of primary care, especially for MCH at the provincial and district levels.

2.1.2. Public Sector Curative Services

There are 48 national level curative health-care institutions under the supervision of the Central ministry and 1070 health-care institutions under the provincial ministries of health. Public sector curative services are provided through a series of health-care institutions ranging from the Central dispensaries to the

teaching hospitals including the National Hospital of Sri Lanka. Hence, the provision of health care in the public sector is the responsibility of both the Central government and nine provincial councils. Health-care institutions are divided into primary, secondary and tertiary care levels on the basis of the size and the facilities offered. Facilities that offer non-specialist inpatient and/or outpatient care are categorized as primary level hospitals (maternity homes, Central dispensaries, rural hospitals, peripheral units and divisional hospitals). Secondary care institutions include base hospitals, district general hospitals which have general medical and surgical units and the outpatient department. Tertiary care institutions include the National Hospital, teaching hospitals and provincial general hospitals. They have all the facilities as available in secondary care institutions as well as other specialties (MoH, 2003; MoH, 2017; Fernando, 2000) (Table 2.1).

Table 2.1. Types of Public Sector Hospitals

Type of Institution	No. of Hospitals	Bed Strength
Teaching hospital	16	20,310
Provincial general hospital	03	5,076
District general hospital	19	12,080
Base hospital (Type A, B)	74	17,851
Divisional hospital (Type A, B, C)	480	22,322
Primary medical care units/maternity homes	11	145
Other health-care institutions	25	5,491
Total	628	83,275

Source: [Annual Health Statistics 2017](#)

In addition to the above, the Ministry of Local Government is responsible for the provision of health care in the larger local government bodies such as municipal councils (Fernando, 2000).

2.1.3. Private sector services

There are 145 private hospitals in the country, which provide point-of-care services comparable to those of the public system. In addition, the private sector in Sri Lanka provides outpatient services or family care through general or family practitioners. There are also clinical laboratories, diagnostic centres and private pharmacies (Policy, 2018)

2.1.4. Public Sector Preventive Services

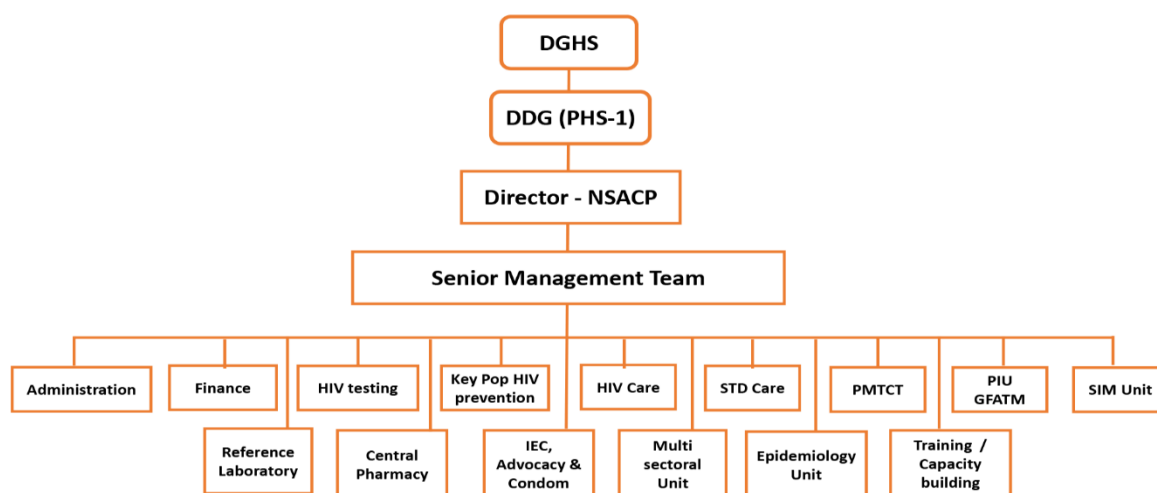
Technical units and prevention programmes under the Central MoH (such as FHB, Epidemiology Unit, NSACP) are responsible for formulating policies and strategies, providing technical guidance and monitoring and evaluation of the programme at the national level.

2.2. STI and HIV care services

The Anti-Venereal Disease Control Campaign (AVDC) of the MoH was established in 1952. This was a vertical programme till 1987 (Rajapaksa, 2012).

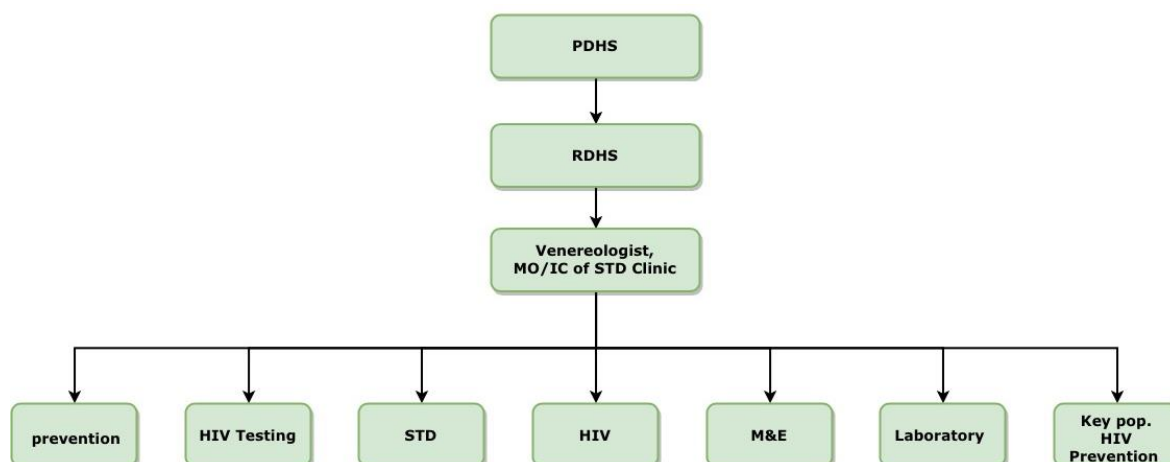
The AVDC was restructured and named as the National STD/AIDS Control Programme (NSACP) in 1987 by assigning the additional responsibility of HIV AIDS control and prevention (Rajapaksa, 2012). The NSACP is the focal point for the prevention and control of STIs including HIV. Therefore, the NSACP is responsible for planning, coordination, implementation and monitoring and evaluation of the national response for the prevention and control of STIs/HIV. The NSACP has its headquarters in Colombo, which houses the Central STD clinic, main HIV clinic and the National Reference Laboratory (NRL). The senior management team comprising consultants provides technical support to programme areas (NSACP, 2017c) (Fig. 2.1).

Fig. 2.1. NSACP Organogram



*PIU – Project Implementation Unit, SIM – Strategic Information Management unit, IEC – Information, Education and Communication *Source:* NSACP [Annual Report 2017](#) (NSACP, 2018c)

Fig. 2.2. Organization of district STD clinic



Source: NSACP [Annual Report 2017](#)

There is a well-established network of STD clinics at the district level. The staff consists of specialist medical officers (consultant venereologists), medical officers, nursing officers, public health staff including PHIs (public health inspectors) and PHNS (public health nursing sisters), who have both clinic and community outreach responsibilities. A district STD clinic is under the administration of the RDHS within the provincial health system (Fig. 2.2).

During 2018, a total of 33 STD clinics and 21 branch clinics functioned across the island; of these, 22 full-time clinics had specialist services (Fig. 2.3). The NSACP provides technical support, supervision, antiretroviral (ARV) drugs, laboratory test kits and reagents, IEC (information, education and communication) material and condoms to district STD clinics while other services are provided by the provincial ministries of health (NSACP, 2017).

In addition to the clinical responsibilities, the STD clinic staff also conducts awareness and risk reduction programmes in the community. The district STD clinic staff supports non-governmental organizations (NGOs) to carry out targeted interventions among KPs such as sex workers, MSM, transgender population, beach boys, prisoners and drug users.

All STD clinics are under the MoH and there are no STD clinics in the private sector. ART services in Sri Lanka are available only through government STD clinics and the National Institute of Infectious Diseases. ARV drugs are distributed throughout the country by the NSACP. There were few pregnant women with HIV who received MCH services from the private sector. They were provided ART and syrup nevirapine for neonatal prophylaxis from the NSACP. Hospitals, venereologists and obstetricians in the private sector worked closely with the NSACP to provide EMTCT services to these few pregnant women.

Fig. 2.3. Map of STD clinics in Sri Lanka



Source; SIM unit NSACP, 2018

STD clinics are open clinics and encourage people to seek services voluntarily. Irrespective of the presence of symptoms, anyone can access STD clinics anywhere in the country and referral notes are not required. Every patient is managed by a specialist or a medical officer with the assistance of trained staff. KPs are encouraged to visit STD clinics regularly for screening and to collect condoms freely.

STD clinics provide comprehensive care services including screening for syphilis and other STIs, HIV testing and counselling, management of patients with STIs and HIV infection, condom distribution, partner notification and defaulter tracing. The ART programme, which was initiated in late 2004, is closely integrated with STI services.

ARV drugs are procured by the Government of Sri Lanka (GoSL) and provided free of cost to PLHIV (people living with HIV). The NSACP is responsible for the distribution of ARV drugs to STD clinics. For procurement and supply of ARV drugs, the NSACP gives its requirement to the Medical Supplies Division (MSD) which then forwards this to the State Pharmaceutical Corporation (SPC). Once the orders are placed, the suppliers send the drugs to the MSD, which in turn provides them to the NSACP.

Treatment for syphilis has been implemented successfully over the years. Benzathine penicillin is the drug of choice to treat adults and benzyl penicillin is used to treat babies diagnosed with congenital syphilis.

2.3. MCH services

Sri Lanka, a non-industrialized country with limited resources, has been able to achieve MCH indicators including MMR that is markedly lower than the ratios of similar countries.

MCH services in Sri Lanka have a long history, which dates back to the early 20th century. An organized effort to provide MCH services commenced with the introduction of the Health Unit System in the mid-1920s, which was thereafter extended to cover the entire country. The Reproductive, Maternal, Newborn, Child, Adolescent and Youth Health (RMNCAYH) programme is a collection of several packages of interventions that are aimed to promote health of families with a life cycle approach (FHB, 2018).

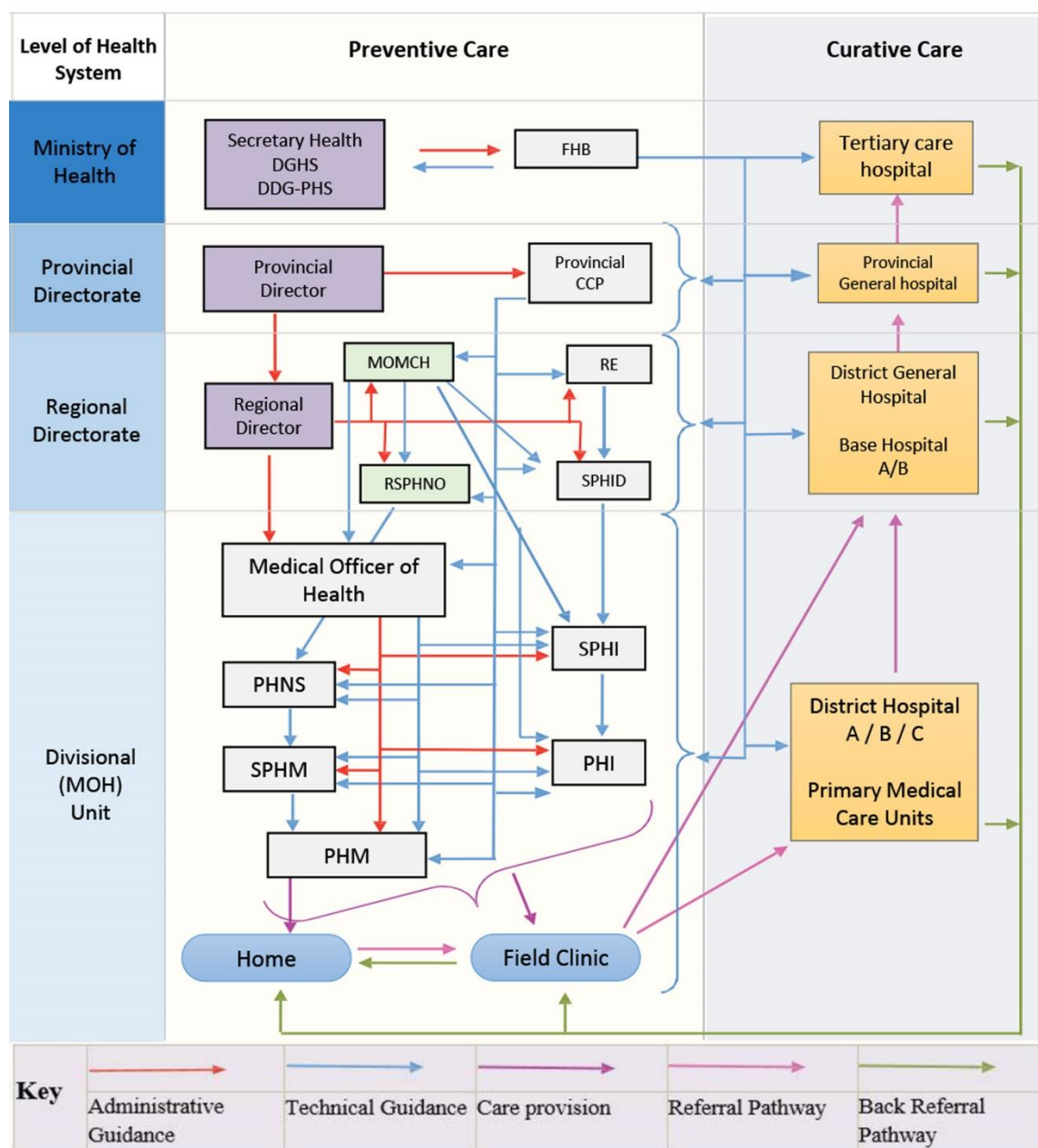
The FHB of the MoH is the focal point for MCH services in Sri Lanka since 1968. It is responsible for planning, coordination, monitoring and evaluation of the MCH and Family Planning Services of the National Family Health Programme. The main components of the Family Health Programme are maternal health, child health, women's health and family planning (FHB, 2018).

In Sri Lanka, the main maternal health-care provider is the public sector. National studies have shown that more than 99% of pregnant women received antenatal care during pregnancy and received trained assistance at delivery (DHS, 2016). According to FHB sources, during 2018, the number of deliveries which happened outside healthcare institutions was 248.

Antenatal care services in the government sector are provided through the RMNCAYH programme. The implementation of the RMNCAYH programme is carried out by the Medical Officer of Health (MOH) teams under the administrative supervision of the Provincial and Regional Directorates of Health (FHB, 2018) (Fig. 2.4).

The country is divided into 340 MOH divisions. The MOH areas are manned by medical officers and primary health-care staff such as public health midwives (PHM), PHIs and PHNS. Their duty is to oversee the well-being of the population of the area with more emphasis on preventive and health promotive activities. There should be on an average 65 000 population per MOH and 3500 population per PHM. However, maldistribution of cadre positions within districts and shortage of staff categories are noted. The services provided by MOH clinics consists of MCH, family planning, immunization, school health, women's health, occupational and environmental health, food and sanitation and communicable and non-communicable disease surveillance and control (DHS, 2016).

Fig. 2.4. Organization of RMNCAYH Programme at Different Levels of Health System



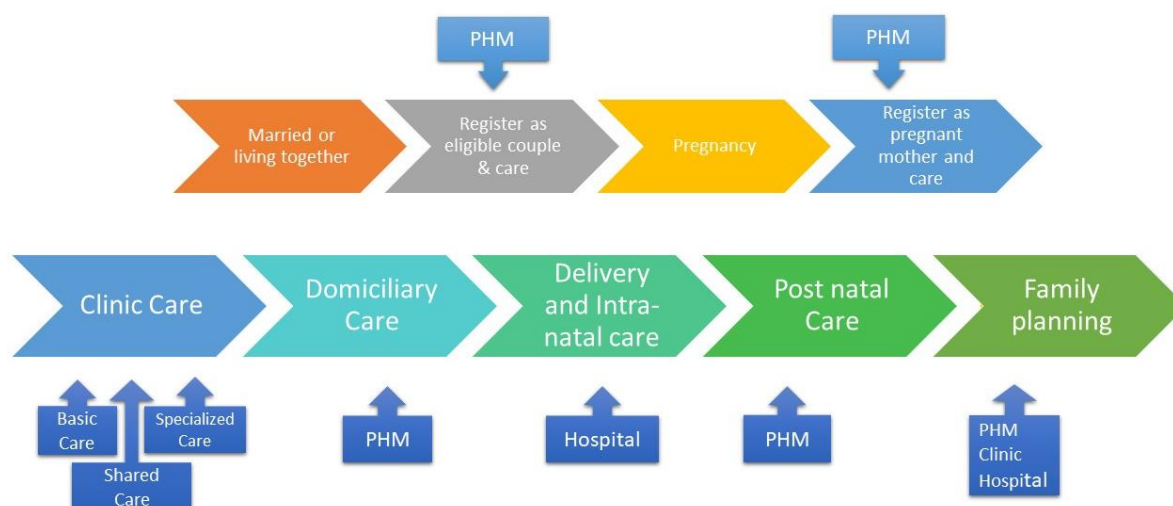
Source: FHB, 2018

The target population for the RMNCAYH programme is identified by the grassroots-level health worker PHM. PHMs identify “eligible families” and register them in the Eligible Family Register. Preconception care for newly married couples is offered to promote health of women and their partners to enter pregnancy in optimal health. This package of preconception care for newly married couples was introduced in the RMNCAYH programme in 2012 (FHB, 2016).

Antenatal care begins with the registration of the pregnant woman by PHM either in the field or in clinics. Every pregnant woman is expected to be registered and receive antenatal care services. Registration needs to be done preferably before 8 weeks. The percentage of pregnant women registered before 8 weeks of pregnancy was 79.8% in 2018 (FHB, 2018). In the same year, 93.4% were registered for antenatal care services before 12 weeks. Antenatal care services are provided as shared care, at the field clinic and at the institutional obstetric clinics under specialist care. In 2018, 96.4% of pregnant women had attended

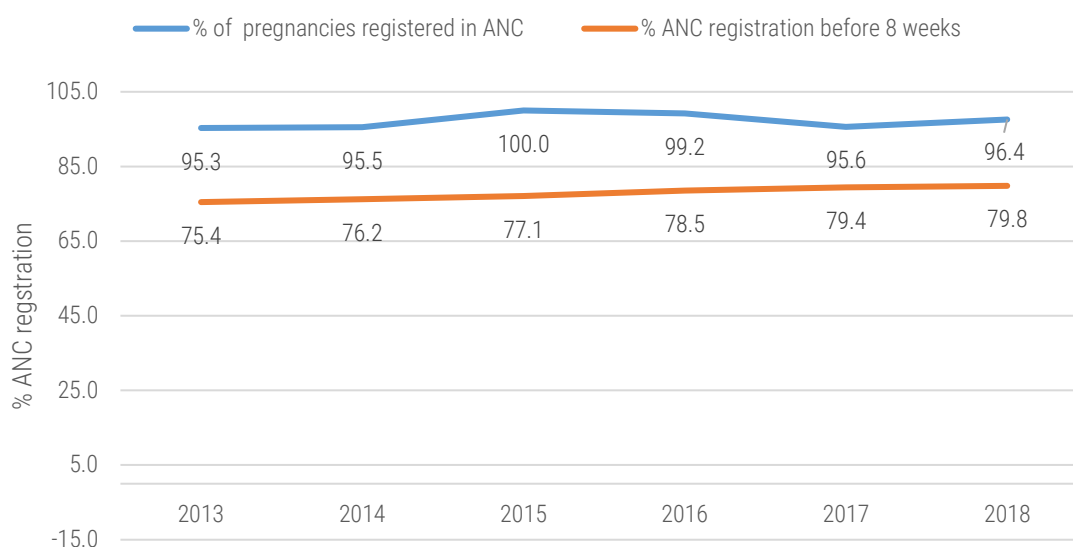
government field ANCs at least once during their pregnancy. Domiciliary care is provided to each antenatal mother at home setting and in 2018, 91.1% of pregnant women have been visited at least once by her area PHM (Fig. 2.5)

Fig. 2.5. Care services provided for pregnant women



Source: FHB

Fig. 2.6. Percentage of pregnant women registered for antenatal care services, 2013 -2018



Source: M&E unit, FHB, 2018

Figure 2.6 shows the trend for percentage of pregnant women registered for maternal care services from 2013 to 2018.

MCH services through non MoH hospitals

The military (Sri Lanka army, navy and air force) and Sri Lanka police have their own hospitals which are managed through their own administrative structures. These hospitals also provide MCH services.

However, pregnant women receiving antenatal care services at these hospitals are registered at the field ANC as well.

Private sector MCH services.

A proportion of pregnant women seek services from private sector hospitals. All these hospitals provide specialist obstetric and paediatric services. The overall percentage of pregnant women who delivered in private sector facilities was 5.4% across the country (DHS, 2016). Certain districts such as Colombo, Gampaha and Kalutara reported having >10% of deliveries in private hospitals but these deliveries took place in ten major private hospitals in Colombo. A survey (NSACP, 2018) conducted among pregnant women (n=656) in these private hospitals in Colombo found that >80% of women had documented evidence of screening for HIV and syphilis at the time of delivery. Out of the sample, 34% have received antenatal care services from both the private and public sectors.

2.3.1. Family Planning Services

At the national level, the FHB is the central organization of the MoH, responsible for coordinating, monitoring and evaluating the family planning programme within the country. The MOH and his team including the PHM are responsible for providing family planning services. Family planning services include counselling and provision of modern temporary methods of family planning, as well as management of subfertility. Both specialist and non-specialist hospitals have family planning clinics.

The National Family Planning Programme of FHB ensures the delivery of quality assured contraceptives for clients, free of charge from the government sector clinics and domiciliary care. The methods provided are: combined oral contraceptive pills (OCP) containing ethinylestradiol and levonorgestrel, injectables containing depot medroxyprogesterone acetate (DMPA), copper-containing intrauterine devices (CuT 380A-IUD), male condom, implants-containing etonogestral (one-rod implant) or levonorgestrel (two-rod implant). Emergency contraceptive pills are available with the field staff and in clinics for free and can be bought over the counter from private pharmacies costing less than one dollar. Female sterilization and male sterilization are performed as permanent methods of contraception by the obstetrics and gynaecology units (female sterilization), surgical units in hospitals (male sterilization) and at the FHB. Family planning services are provided to clients based on their informed choice.

Main recommendations of the National Family Planning Programme are to delay the first pregnancy until 20 years of age of the female, maintaining at least a 3-year gap between two deliveries, completing the family before 35 years and emphasizing the increased risk after four pregnancies.

All contraceptive commodities are procured by FHB at the national level and distributed to the periphery. Only quality assured products with WHO pre-qualification are procured for use in the government sector. Family planning equipment are also procured at the central level. From the central level both contraceptive commodities and equipment are sent to Regional Medical Supplies Divisions (RMSD) for distribution to hospitals and the field. Few hospitals in Colombo receive them directly from the FHB.

Different modalities have been used for capacity building, which include pre-service training, induction training/orientation, in-service training, postgraduate training and continuous professional development.

Data are gathered routinely by the National Family Health Programme of the FHB. The Reproductive Health Management Information System (RH MIS) obtains its family planning data monthly, quarterly and annually. The RH MIS is regularly assessed for data quality using timeliness and completeness indicators. During district review meetings and biannual workshops of Medical Officer Maternal and Child Health (MOMCH), data are reviewed and shared, challenges and gaps are identified, and strengthening interventions and

follow-up actions are identified. There is also a logistic management information system for management of contraceptive commodities and equipment.

According to the RHMS, 67.7% of eligible couples were practising a family planning method, of which 58.4% were practising a modern method in 2018. The unmet need for contraceptives was 6.1% (FHB, 2016). According to the DHS survey in 2016, the percentage of eligible couples who have their need for FP satisfied with modern contraceptive methods was 74.2% (DHS, 2016).

Family Planning Services at STD clinics

All women of child-bearing age attending STD clinic services including sex workers and women living with HIV are counselled on family planning services and offered services including modern family planning methods in addition to condoms (NSACP, 2016a).

Related activities are described below:

- Women living with HIV who indicate their desire to have more children are counselled regarding planning their families, spacing and available services for EMTCT of HIV. They are encouraged to maintain undetectable viral load by adhering to ART. Each year few women who are known to be HIV-positive become pregnant. In 2017, there were 10 women with known HIV infection who became pregnant. All of them received EMTCT services and they delivered uninfected babies.
- Medical officers and consultants attached to STD clinics are trained to provide family planning services by the FHB. Women living with HIV are provided counselling on family planning services and appropriate contraception services are offered based on their choice. They are encouraged to use condoms in addition to modern family planning methods.
- *A Guide to Antiretroviral Therapy* includes a chapter on family planning (NSACP, 2016a). The EMTCT MCH guide for health-care workers gives information on family planning services following delivery (NSACP, 2). Patient information booklets for PLHIV give details on family planning services.
- The NSACP conducts awareness programmes for PLHIV organizations annually with the help of NGO, Family Planning Association (FPA), which covers many aspects including family planning services.
- In the study "Situation assessment of women and children infected and affected by HIV in Sri Lanka" conducted among women with HIV (n=206) in 2015, 49.5% were using modern contraception. In the sample, 59.7% were in the age group 15–45 years. (NSACP, 2015)

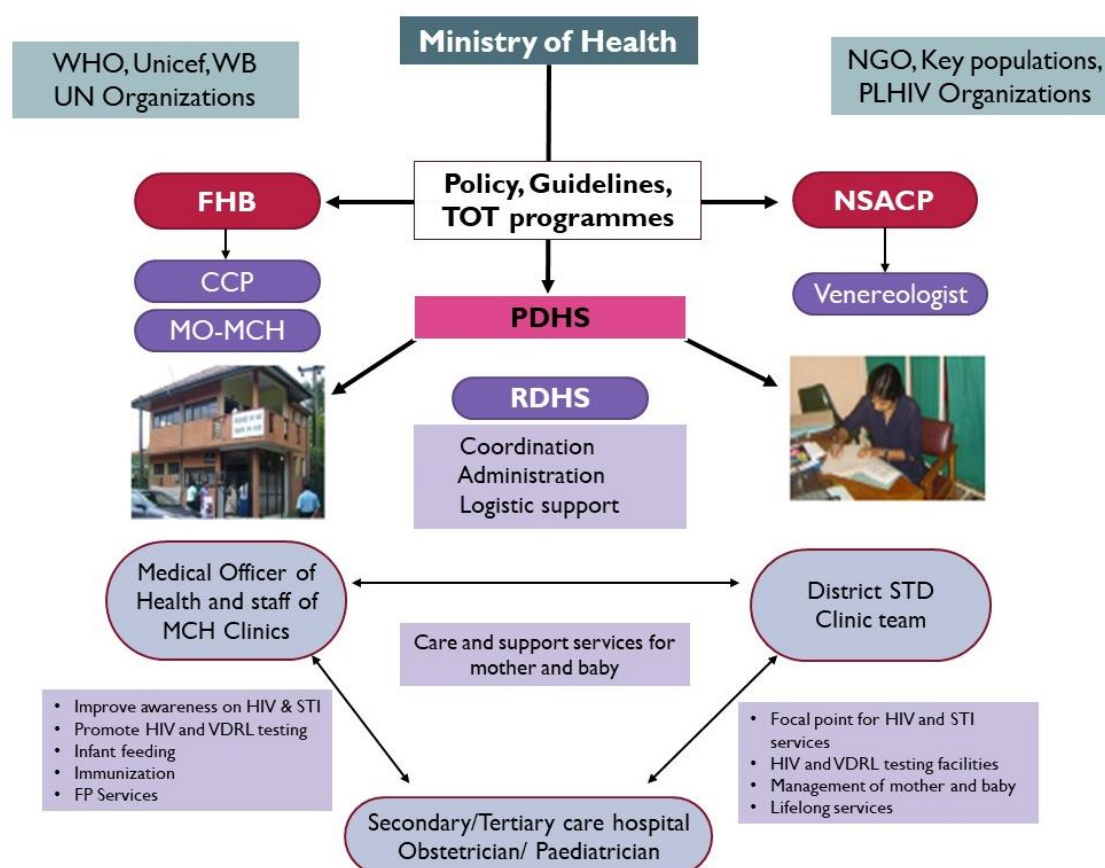
2.3.2. Link between STI and MCH services

EMTCT of congenital HIV and syphilis programme is coordinated by the FHB and NSACP at the central level and through MOH clinics and STD clinics at the district level. Screening for HIV and syphilis and the management of infected women during pregnancy is fully integrated within the MCH services (Rajapaksa et al., 2014).

The link developed at the national level extends to the district level through district STD clinics and the district team responsible for MCH services (Fig. 2.7). At the district level, the district team comprising district authorities, MCH services and STD services complement the services in addressing the reproductive health needs of the population. At the grassroot level, the MOH provides services to the community through his public health staff. The strong link between the NSACP and FHB has strengthened over the years and the link extends to the district level and through that to the community level. Close coordination of relevant

institutions, keen interest shown by provincial and district authorities as well as involvement of secondary and tertiary care institutions through a multidisciplinary approach are the reasons for the success of the EMTCT of HIV and syphilis programme (Rajapaksa et al., 2014).

Fig. 2.7. Stakeholders in EMTCT of HIV and syphilis programme



Source: A strategy for EMTCT of HIV and syphilis in Sri Lanka, 2018

WHO and UNICEF supported the EMTCT of HIV and syphilis programme by providing technical support as well as funding and logistics. UNICEF was instrumental in improving quality of laboratory services while supporting monitoring of the activities. World Bank and other UN partners supported the programme when necessary. The involvement of KP organizations and PLHIV organizations facilitated to take services to difficult-to-reach areas. PLHIV organizations support pregnant women and children with HIV coming from very low socioeconomic settings by providing accommodation facilities, meals and other basic requirements.

Medical supplies

The forecasting, procurement and distribution of drugs to the country is the responsibility of the MoH through the MSD. The RMSDs are responsible for the distribution of drugs and surgical items to health-care institutions in the districts including district STD clinics. ARV drugs, laboratory test kits and reagents, condoms and lubricants and IEC material are procured and distributed to district STD clinics directly by the NSACP.

Human resources

The total human resource of the MoH is around 121 500. It is distributed as 65 522 in the central ministry and 56 211 in the provinces (MoH, 2017). Recruitment of all categories of staff is carried out by the MoH. Other than the medical officers, training of all other staff categories is carried out by the MoH. In addition, transfers of medical officers and all categories working in the central ministry are carried out by the MoH.

Medical officers are trained in nine state-run universities and the government absorbs all medical graduates in the state sector. All the other categories of staff are recruited based on the results of G.C.E. advanced level examination or through government-conducted competitive examinations. The MoH has training institutes throughout the country such as nurses training schools, PHM training centres and the National Institute of Health Sciences, which provides basic, post-basic and in-service training to all categories of health staff engaged in curative and preventive services. Postgraduate training of specialists in every field of medicine is carried out at the Post Graduate Institute of Medicine, University of Colombo.

In 2017, there were 92.3 medical officers per 100 000 population and 1118 population per medical officer (MoH, 2017). The distribution of medical officers is not uniform throughout the country with Colombo district reporting the highest number and Nuwara Eliya the lowest. There are 212.1 nurses per 100 000 population and 26.8 PHMs per 100 000 population (MoH, 2017).

The provincial primary health-care system is affected in geographically difficult areas due to inadequate human resources and uneven distribution. The international migration of health human resources, especially medical officers to developed countries is a challenge to the provision of health services in the country.

Health Financing

The government of Sri Lanka provides free health services to all citizens ensuring non-discriminatory access. Public sector health care is universally accessible to the entire population of Sri Lanka and is free of charge.

The total current health expenditure (CHE) in Sri Lanka for the year 2017 amounted to Sri Lankan rupees 347 billion. Per capita CHE was SLR 9615 (\$111) for the same year (MoH, 2017).

More than 90% of government spending on health is financed by the treasury and the rest is funded by multilateral agencies, international organizations and bilateral aid (Policy, 2018).

Financing for EMTCT programme

Since 1950, screening services for syphilis among pregnant women were funded by the government. In 2002, PMTCT of HIV was commenced and in 2013, it was further strengthened as the EMTCT programme, with funding from the government. Since 2013, UNICEF supported training and quality improvements for EMTCT while WHO provided technical support. According to the costed NSP 2018–2022, the total expenditure for EMTCT component is US\$ 3 292 006.

Health services for inbound migrants

According to the General Circular No. 01-37/2019 of the MoH on implementation of “Health Protection Plan” (HPP) all resident VISA applicants are being assessed for malaria, TB, HIV and filariasis. Those who are screened positive are referred to the respective national disease control programmes for confirmation, treatment and follow-up. The applicants with a valid HPP are eligible to avail the above health services free of charge at the point of delivery (Annexure 18)

Sri Lanka national migration policy 2013 covers the health of inbound migrants.

2.4. Health-care needs and access for marginalized populations

The MoH in collaboration with International organization of migration (IOM) provides STI and HIV services for inbound migrants free of charge through government STD clinics. This includes returnee refugees and international refugees referred by the International Organization for Migration (IOM).

The National AIDS Committee (NAC) was established in 1988 with its subcommittees. The Legal and Ethics Subcommittee of the NAC was established with a view of addressing legal, ethical and human rights issues in the implementation of national response to HIV epidemic. It was able to resolve some legal and ethical issues relating to PLHIV such as the issue of insurance and Employees’ Provident Fund (EPF) for PLHIV. The country coordinating mechanism and KP task force facilitate participation of KPs and PLHIV in national response to HIV.

The NSACP has been able to assure confidentiality of information on people living with HIV or STI and thereby, protect and promote human rights of service-seekers. Based on the guidance given by the chief justice to the ethical and legal sub committee of National AIDS Committee, if a person referred from courts for STI screening is found to be HIV positive, a report to that effect needs to be handed over to the magistrate. Confidentiality is maintained by handing over of the document by the relevant medical officer to the magistrate in the judges’ chambers.

Introduction of the subjects of HIV/AIDS and human rights in the curricula of the undergraduate and postgraduate medical courses (PG Diploma in Venereology, Postgraduate Institute of Medicine) are important measures that have been adopted in the country.

AIDS was added to the list of notifiable diseases by Minister’s orders under the Contagious Diseases Ordinance in the early 1990s. This provision violated the right to health and the right to privacy of the infected person and led to stigmatization. Subsequently, AIDS was removed from the notifiable diseases list due to the continuous representations made by the NAC.

The multisectoral approach in HIV prevention and control is a fundamental principle in Sri Lanka. In this regard ongoing training and advocacy programmes have been conducted among judicial officers, police and prison officers to create an enabling environment.

The National Strategic Plan 2018-2022

The National Strategic Plan (NSP) 2018–2022 guides Sri Lanka's response to HIV/AIDS and STIs for the next five years. There are eight guiding principles of NSP – strategies based on evidence, human rights and stigma reduction, gender-based approach, meaningful involvement of PLHIV, community involvement and engagement, coordinated approach, multisectoral partnerships, quality improvement and quality assurance and broad political commitment (NSACP, 2017d).

The following areas have been addressed by the NSP 2018–2022:

- Addressing issues of human rights, stigma and discrimination through training
- Provision to issue specific guidelines to the education sector for protection of human rights of children affected by and infected with HIV
- Enhancing awareness of laws and policies that promote human rights of all people including KPs and PLHIV
- Conducting advocacy programmes for an enabling environment for KPs and PLHIV in order to reduce stigma and discrimination and address violence against KPs
- Developing a policy for ethical reporting on HIV/AIDS/STI by the media and advocate with the media on responsible reporting
- Training of law enforcement officers to sensitize them on human rights and freedom for all, which is essential to build a supportive environment

Targeted interventions for key populations

The NSACP, being the principal stakeholder of the HIV response, works together with the PLHIV, KPs, community-based organizations (CBOs) and NGOs in planning, implementing, monitoring and evaluation of the programmes conducted throughout the country for prevention and control of HIV.

The first objective of the NSP is to prevent new infections of HIV/STIs among KPs such as commercial sex workers (CSWs), MSM, transgenders TG, beach boys, people who use drugs and prisoners. KPs are being provided with a package of sexual health services by peers since 2012 through the FPA, an NGO under the technical guidance of the NSACP, and funded by the Global Fund for AIDS, TB and Malaria (GFATM). In 2018, nearly 30 000 KPs were reached through this programme.

Currently, programmes are carried out in several districts by the FPA and NSACP as shown in Fig. 2.8. Since GFATM is gradually reducing its commitment for funding, the KP programmes will be handed over to GoSL in a phased manner from 2019 onwards.

Fig. 2.8. Transition Plan of KP interventions from GFATM to GoSL

NSACP
 FPA

District	KP Component														
	MSM			FSW			TGW			BB			PWID		
	2019	2020	2021	2019	2020	2021	2019	2020	2021	2019	2020	2021	2019	2020	2021
Colombo															
Gampaha															
Kalutara															
Kandy															
Matale															
N'Eliya															
Galle															
Matara															
Hambantota															
Ratnapura															
Kegalle															
Badulla															
Monaragala															
Anuradhapura															
Polonnaruwa															
Kurunegala															
Puttalam															
Jaffna															

Source: NSACP, 2019

Enhancing the capacity of CBOs, forming and strengthening the networks of KPs including PLHIV contributed to minimize the discrimination and stigmatization. Stigma and discrimination at service delivery sites have been further minimized by staff training, which focused on developing desirable attitudes towards those seeking services. According to stigma assessment of PLHIV report of 2017, 98.7% of PLHIV were able to have a constructive discussion with health-care worker about sexual and reproductive health (NSACP, 2017g). Raising awareness and sensitivity regarding KPs among law enforcement authorities has continued for the past 10 years through the multisectoral unit of the NSACP with the objective of creating an enabling environment (NSACP, 2017e). PLHIV or KPs are encouraged to submit their grievances to the legal and ethics subcommittee. In addition, the country coordinating mechanism and KP task force meetings can be used to take their issues to the highest level of the MoH.

Key population members including PLHIV, FSWs, MSM, CBO and NGO representatives are well represented in country coordinating mechanism (CCM). KP task force which meets once in two months is represented by all KP organizations and chaired by a community member. In addition, KP organizations are represented in NAC and IEC, advocacy and condom promotion, legal and ethical, strategic information management, multisectoral and HIV care sub committees. NAC meets once in six months while sub committees meet once in 3 months.

Key population members have been regular participants of National validation committee of EMTCT of HIV and syphilis programme.

Prison health is under the MoH. Prison health staff belongs to MoH directorate on prison services. HIV and STI prevention programmes through peer educators have been conducted in all 30 prisons in the country for the last 15 years. Advocacy and training programmes have been conducted for prison officials. Prison officials have a tolerant attitude towards condoms. STD clinics visit prisons regularly for HIV and syphilis

screening programmes and in the year 2018 16,453 prison inmates have undergone HIV testing. Through this testing nine prisoners were identified as having HIV infection and linked to HIV care services. (NSACP, 2017e.)

In addition to the GFATM HIV project, Family Health International 360 Linkages programme also supports some prevention activities in the community. This includes providing services through general practitioners in high prevalence districts Colombo and Gampaha, developing mobile application “Know4sure” for young key population, developing a feed back system by clients on STD clinic services, strengthening capacity of KP organizations, developing KP specific IEC material and pilot project of KP programme by internet peer educators.

2.5. Laboratory services

In the state sector, laboratory services are available in both the curative and preventive sectors. The curative care service of the government sector with tiered hospital system island-wide is complemented by laboratory services in hospitals. These laboratories are supported either by the central government or the provincial councils depending on their location. Public health laboratories in the preventive health-care sector provide essential services for specific control programmes. The services of these laboratories include disease detection and surveillance. Public health laboratories function as a network and serve the national system. The NSACP being a public health programme is supporting the NRL for HIV and STIs and the network laboratories at STD clinics in the peripheries. The NRL is under the administrative control of the central government and the district STD clinic laboratories are governed by the provincial councils. All these laboratories have capacities for serological testing of HIV and syphilis. The NRL serves as the reference laboratory and offers reference services and confirmatory test services, which are unavailable at the peripheral setting (Fig. 2.9).

Sri Lanka has a national laboratory policy (MoH, 2016c). The policy covers all medical laboratories in both the public and private sectors. It directs to have a sound legislative and administrative support to monitor and regulate the activities pertaining to laboratory services and to encourage achievement and maintenance of laboratory standards accepted nationally and internationally, and thereby to obtain accreditation.

The NRL is continuously working for improving the standards as per ISO 15189 and has applied for certification in 2019. Few assessments of the NRL as per the requirement of the Sri Lanka Accreditation Board were carried out before application to identify and improve the required standards. An internal audit was carried out by three laboratory auditors (one external and two local) in 2019.

Laboratory services are available in the private sector as well, mainly in association with private sector hospitals. Certain private sector laboratories are chain laboratories with a network of collection services with clustered testing services. All these laboratories liaise with the NRL of the NSACP for confirmation of HIV. All screening-positive samples of the private sector are sent to the NRL for confirmatory testing; hence, the data of all HIV-positive individuals are available at the NSACP. The private sector laboratories are linked to the MoH through the private health regulatory council.

2.5.1. Organization and scope of laboratory services related to EMTCT

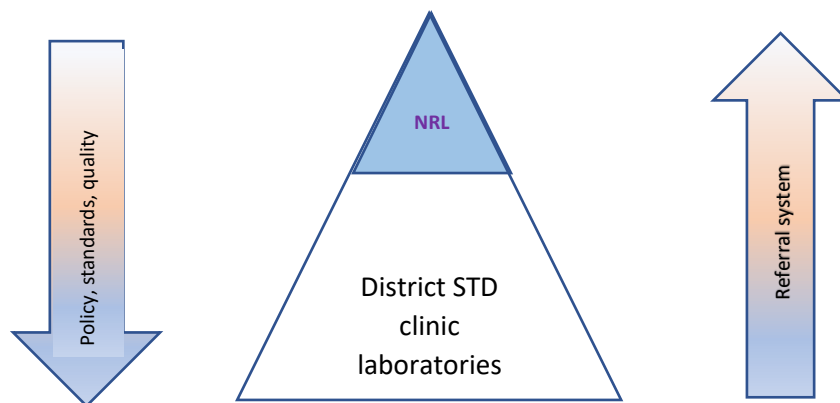
Testing for HIV and syphilis

The laboratory services for the diagnosis of HIV and syphilis are provided by the government sector through a network of 24 district STD clinic laboratories with the technical support of the NRL (Fig. 2.10). These laboratories are dedicated laboratories in the national laboratory system for diagnosis and monitoring of STDs and HIV. The NRL is primarily responsible for planning, coordinating and providing technical guidance to the STD clinic laboratory services across the country. The district STD clinic laboratories are responsible for providing STD and HIV laboratory services to their respective districts.

The NRL is housed within the NSACP headquarters in Colombo and the peripheral laboratories are housed in district STD clinics. Each district has one or more STD clinics with laboratories. The STD clinics without laboratories have identified designated neighbouring laboratories within the network, to perform testing of samples and are linked to the NRL for referral services. This system allows efficient and effective coverage of the entire country, with efficient use of limited resources.

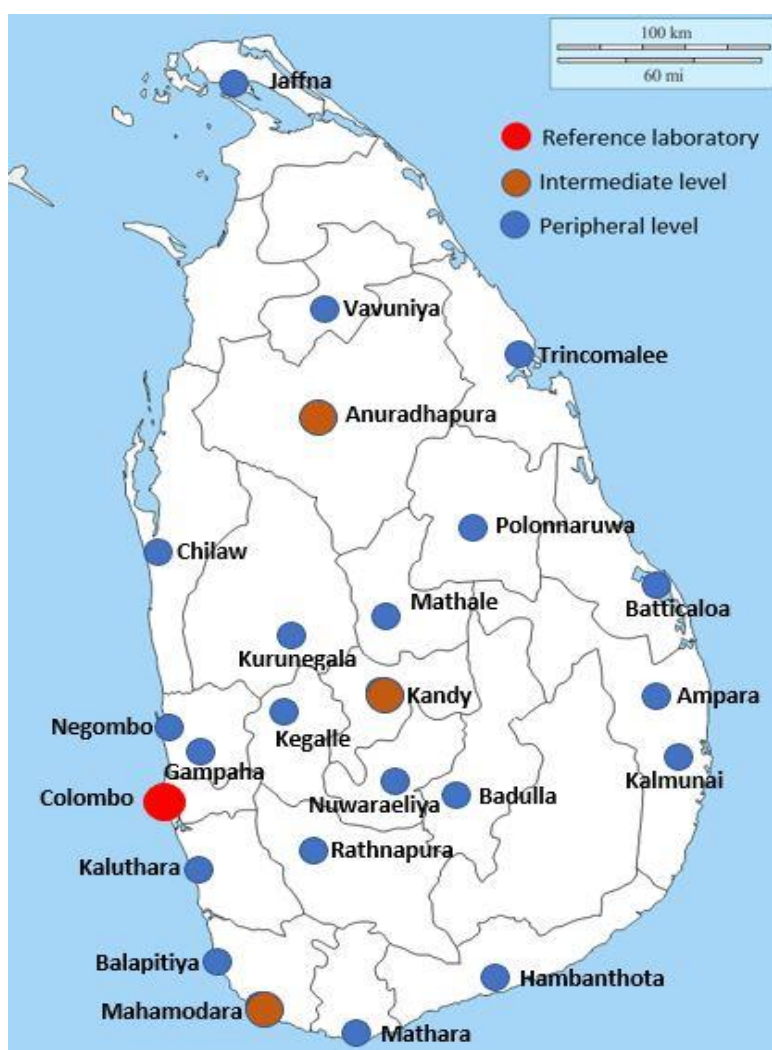
The NRL is staffed with a microbiologist, medical officers, medical laboratory technologists (MLTs) and public health laboratory technicians (PHLTs) and supportive staff. The district laboratories are manned by MLTs and PHLTs.

Fig. 2.9. Organizational structure of laboratory system for HIV & Syphilis



Source: NRL, 2019

Fig. 2.10. Distribution of the network of laboratories for HIV & Syphilis



Source: NRL, 2019

Each laboratory identified for the EMTCT programme receives blood samples for HIV and VDRL testing from designated MOH areas in the district. The regional team has developed a system to transport the antenatal samples to the identified respective STD clinic laboratory.

All laboratories adhere to national algorithms for testing for HIV and syphilis. District STD laboratories carry out screening for HIV and syphilis as well as the confirmatory test for syphilis. All specimens are sent to the NRL for confirmation of HIV.

Early infant diagnosis and monitoring of PLHIV with viral load testing is also performed at the NRL. Few district STD clinic laboratories (intermediate) were additionally identified by the NSACP in 2018 to perform viral load testing and CD4 testing to increase accessibility to testing services (Table 2.2)

Table 2.2. Availability of diagnostic and monitoring services for EMTCT programme

Test	Facility available in
VDRL, TPPA	NRL, District Laboratories
HIV screening	NRL, District Laboratories
Viral load	NRL, Galle, Anuradhapura
CD4	NRL, Galle

Source: NSACP, 2019

2.5.2. HIV and syphilis testing in pregnant women

HIV screening and confirmation

The national testing algorithm for HIV diagnosis in adults is used for EMTCT testing of HIV. The initial screening test for HIV performed in STD clinic laboratories is a fourth generation ELISA test (Genscreen Ultra). All samples, which are reactive for HIV, are referred to the NRL for confirmation by immune and molecular assays (Fig. 2.11). All the private sector laboratories also send the screening reactive specimens to the NRL for confirmation. This has been the practice in the country since the first case of HIV was identified in 1986. This collaboration with the private sector facilitates linking PLHIV with services and helps to assess the disease burden.

HIV rapid tests (Ag-Ab COMBO test – Alere Determine) are widely used in community programmes conducted for testing of KP. This happens through peer led targeted interventions organized by KP organizations and outreach programmes conducted by STD clinics for KP. Further, rapid tests are used in drop-in-centres where tests are being carried out by the community members. When the first rapid test is positive two more types of rapid tests are used to diagnose and to link to services. (Figure 2.12) This algorithm reduces the turn around time to less than one hour. Rapid tests are available in all major hospitals up to base hospital A category and have been made available to few MOH offices with difficult geographical accessibility to be used when necessary.

Pregnant women presenting in late pregnancy and at delivery without HIV screening test results are subjected to rapid HIV test and all test positives are started on ART without waiting for confirmation. Emergency ART packs (Zidovudine + Lamivudine + Raltegravir and single dose Nevirapine) have been made available to hospitals with the guidance documents to obstetricians. (Annexure 20)

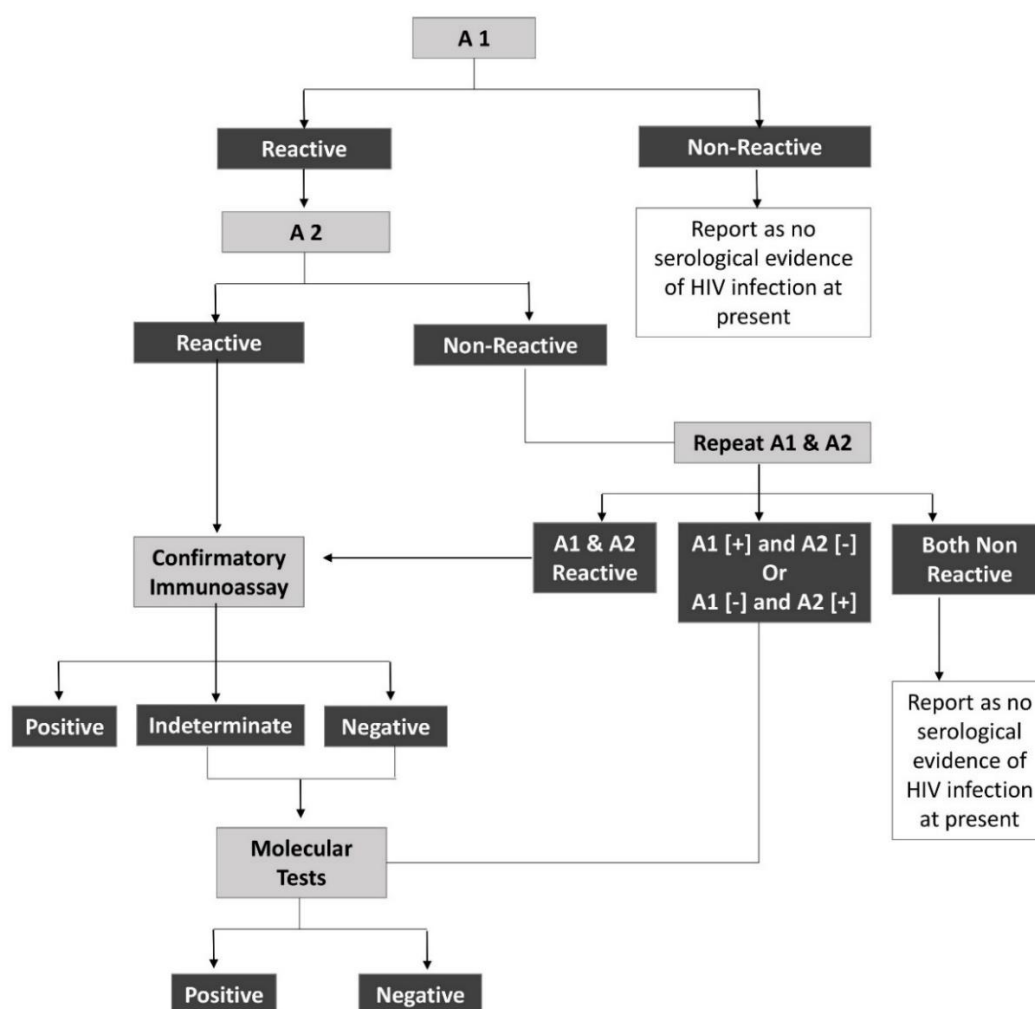
Disease monitoring of HIV

In addition to the tests for opportunistic infections and biochemical tests, viral load and CD4 tests are provided as part of free laboratory service in the country to facilitate PLHIV management (NSACP, 2016a). All pregnant women identified with HIV are provided with testing services according to the guidelines.

HIV genotyping/drug resistance

As HIV genotyping/drug resistance are still not established in Sri Lanka, blood samples are sent to the National AIDS Research Institute (NARI) for testing. The specimens from suspected drug-resistant PLHIV are transported as dried blood spots to reach the NARI within a week of collection. The reports are communicated electronically to the NRL. (Table 2.3)

Fig. 2.11. Testing strategy for HIV diagnosis in adults.



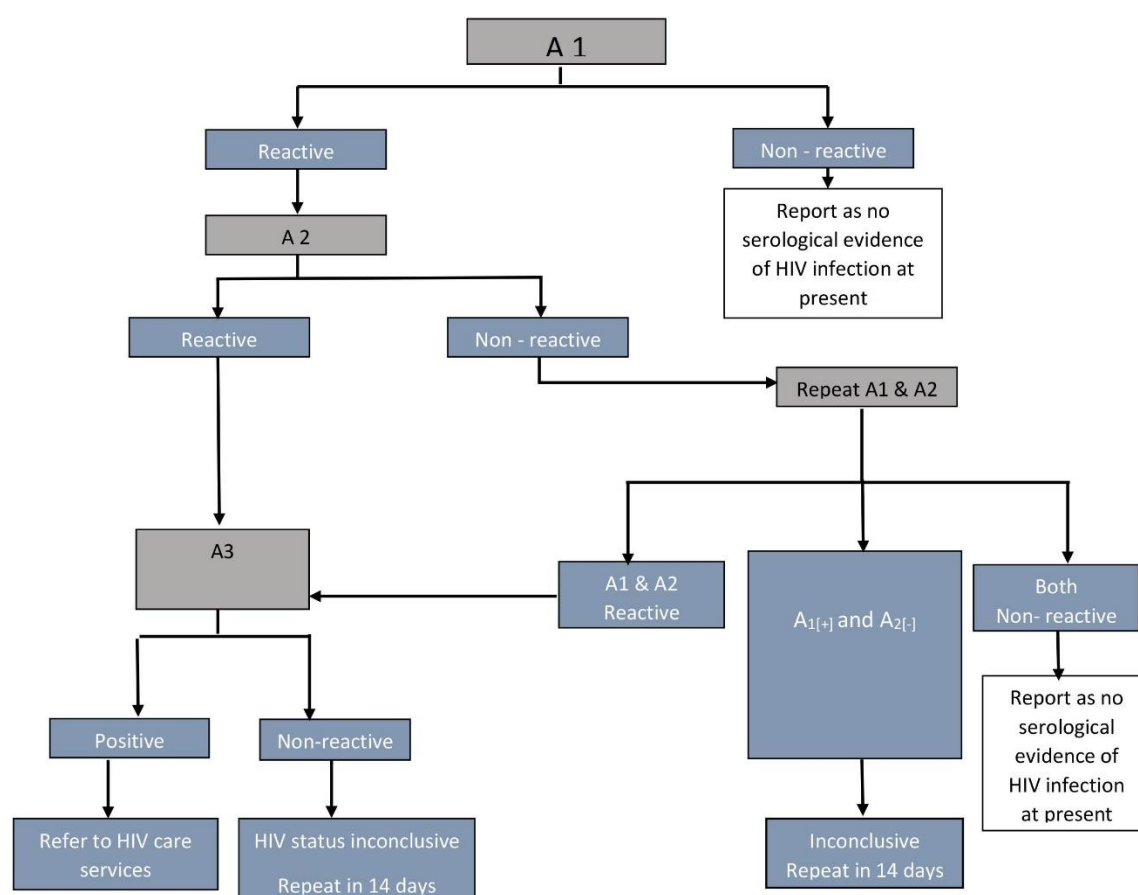
A1 - A 4th Generation Immunoassay in laboratory settings
A2 – A 2nd Immunoassay Test with different method

Source: A strategy for EMTCT of HIV and syphilis in Sri Lanka, 2018

Table 2.3. Laboratory Turnaround time for HIV & Syphilis Testing

Test	Turnaround time			
	NSACP		District STD clinic laboratories	
	Urgent Request	Routine Request	Urgent Request	Routine Request
Syphilis Diagnosis				
VDRL	2 hrs	2-3 days	1 day	4 days
TPPA	1 day	3 days	1 day	5 days
HIV Diagnosis & Management				
ELISA-HIV	0-1 day	2-3 days	1 day	4 days
Confirmatory immunoassay	-	1 week	-	1 week
CD4	0-1 days	1-2 days	0-1 day	1-2 days
Viral RNA	-	7 days	1 day	7 days
Early Infant Diagnosis	1 day	1 day		1 day
HIV genotyping/ drug resistance testing		1 month		1 month

Source: NRL, 2019

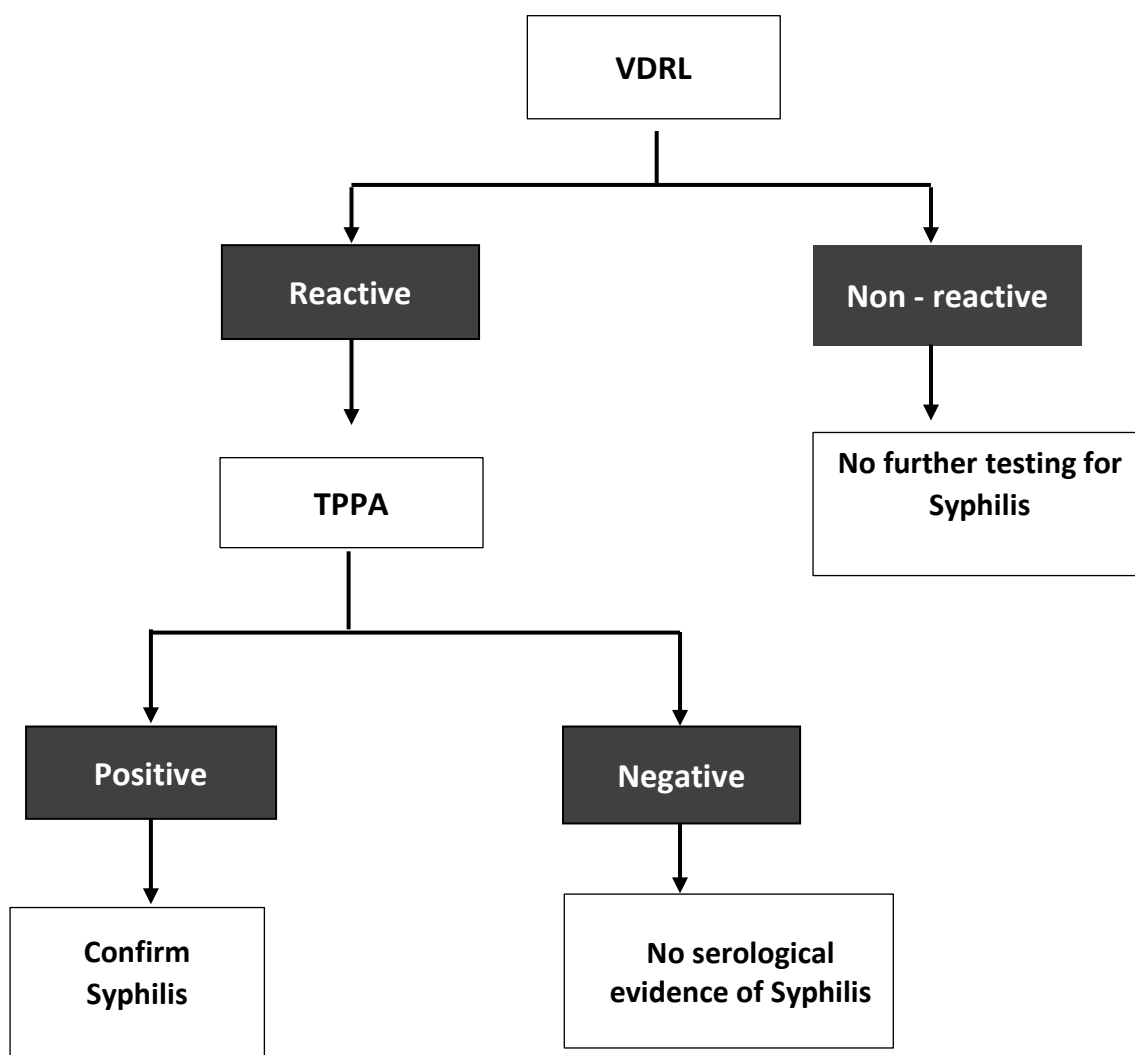
Fig. 2.12. Testing strategy for HIV diagnosis for outreach Programmes in Sri LankaA₁ – 4th Generation RDT assayA₂ – Ab RDT assayA₃ – Ab RDT assay different from A₂

Ref: WHO testing strategy in low prevalence countries

Syphilis Screening

The NRL and 24 peripheral district STD laboratories are equipped to perform screening and confirmation for syphilis. All laboratories use the VDRL test as the screening test for syphilis. However, many private laboratories conduct syphilis screening using the non-treponemal rapid plasma reagin (RPR) test. All STD laboratories use treponema pallidum particle agglutination (TPPA) for the confirmation of syphilis. The testing algorithm for syphilis is shown in Fig. 2.13 (WHO, 2017)

Fig. 2.13. Testing strategy of syphilis for pregnant women

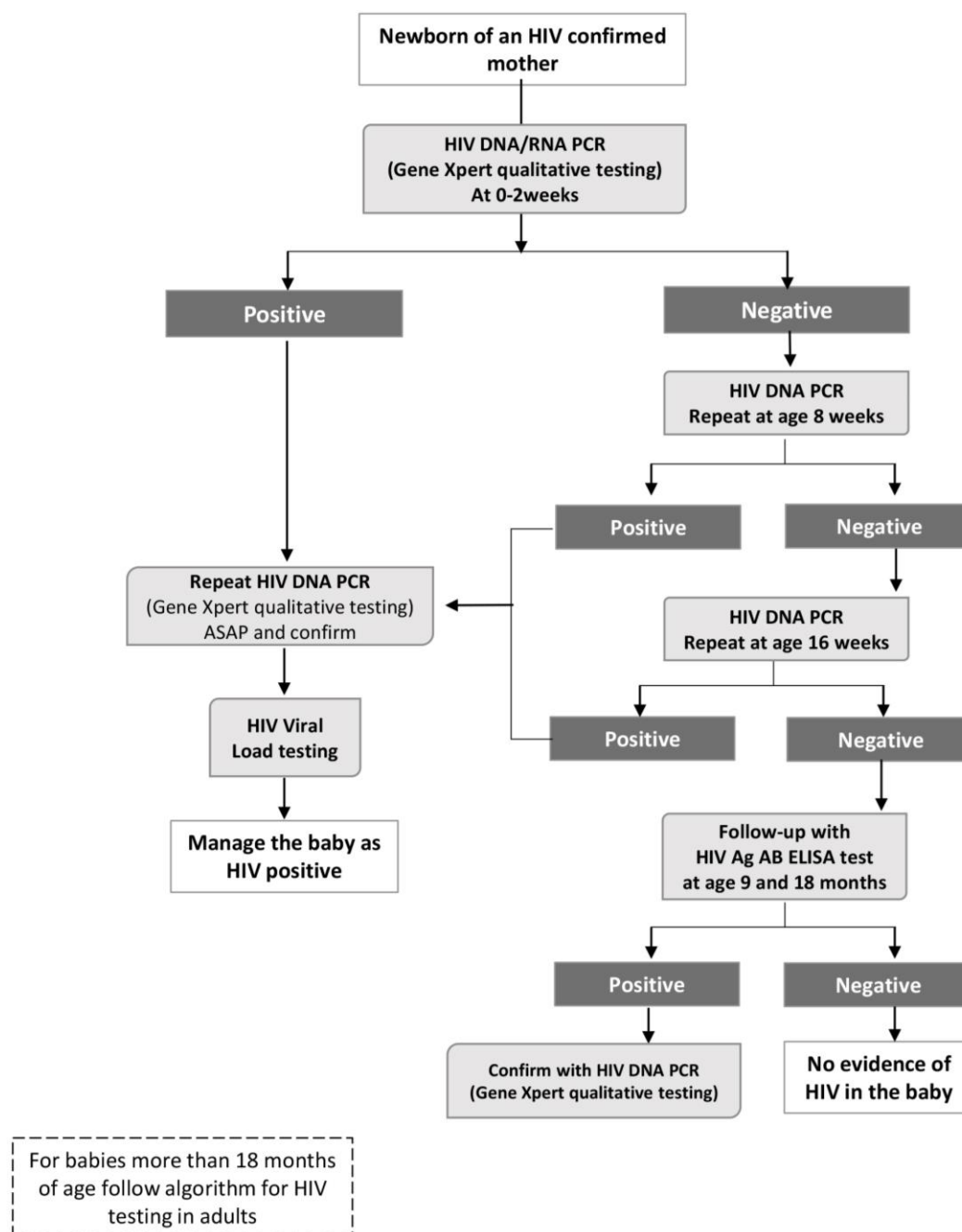


Source: A strategy for elimination of mother-to-child transmission of HIV and syphilis in Sri Lanka, 2018_(NSACP, 2018c)

2.5.3. Early Infant Diagnosis of HIV (EID)

HIV DNA polymerase chain reaction (PCR) testing to diagnose HIV infection in infants younger than 18 months with prenatal HIV exposure was started at the NRL in 2018 with Gene Xpert system, an automated real-time PCR platform (Fig. 2.14) Until then, samples from HIV-exposed infants were sent to the NARI, India for testing. At present, the specimen tested is whole blood and it is planned to develop the laboratory system to have EID with dried blood spots in the future.

Fig. 2.14. Infant testing algorithm



Source: Adopted from Antiretroviral therapy for HIV infection in infants and children: towards universal access. Recommendations for a public health approach. 2010 revision. Geneva, WHO 2010

Source: A strategy for elimination of mother-to-child transmission of HIV and syphilis in Sri Lanka, 2018 (NSACP, 2018c)

2.6. Case definitions of HIV and syphilis

Case definition for congenital syphilis (NSACP, 2018c)

1. A live birth or fetal death at >20 weeks of gestation or >500 g (including stillbirth) born to a woman with positive syphilis serology and without adequate syphilis treatment*
or
2. a live birth, stillbirth or child aged <2 years born to a woman with positive syphilis serology or with unknown serostatus, and with laboratory and/or radiographic and/or clinical evidence of syphilis infection (regardless of the timing or adequacy of maternal treatment).

The following laboratory and radiographic evidence will be used to diagnose syphilis in infants:

- a. Demonstration by dark-field microscopy of *Treponema pallidum* in the umbilical cord, placenta, nasal discharge or skin lesion material or autopsy material of neonate or stillborn infant
- b. Analysis of the cerebrospinal fluid (CSF) reactive for venereal disease research laboratory test (VDRL) or elevated CSF cell count or protein
- c. Long bone radiographic evidence suggestive of congenital syphilis
- d. Infant with a reactive non-treponemal serology titre four-fold or more than that of the mother
- e. Infant with a reactive non-treponemal serology titre less than four-fold than that of the mother's titre but remains reactive more than 6 months after delivery
- f. Infant with a reactive non-treponemal serology test of any titre and any of the clinical signs suggestive of congenital syphilis born to a mother with positive or unknown serology independent of treatment
- g. Stillborn infants with a reactive maternal syphilis test are considered as having congenital syphilis

Case definition used for diagnosing syphilis in adults

Any adult with a positive treponemal test (TPPA) without documented evidence of adequate treatment is considered as having syphilis (Fig. 2.13).

Case definition for HIV diagnosis in adults (Persons Aged ≥18 Months)

A positive HIV ELISA test followed by a positive confirmatory test according to the national algorithm (Fig. 2.11).

Case definition for HIV diagnosis in children aged <18 Months (NSACP, 2016b)

HIV diagnosis in a child <18 months of age is based on HIV NAT tests (DNA PCR). The diagnosis is confirmed with two or more positive NAT tests (Fig. 2.14). The following three tests are available for HIV-exposed children <18 months:

- HIV NAT at birth
- HIV NAT at 8 weeks
- HIV NAT at 4–6 months

If any of these tests become positive, HIV NAT is repeated as soon as possible to confirm the diagnosis.

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3. Methodology and use of tools and checklists to evaluate key areas

3.1. Brief description of the National Validation Process

The National Validation Team (NVT), which is chaired by the Director General of Health Services (DGHS) of the MoH, was constituted in January 2019; it has met monthly since then.

The members consist of the Deputy Director Generals of Public Health Services (DDG PHS), Laboratory Services (DDG LS), presidents of professional colleges, directors and consultants of the FHB and NSACP, representative from the Private Hospitals Association, PLHIV (Positive Womens Network) and the UN agencies including WHO, UNICEF, UNFPA and World Bank (Annexure 1).

The terms of reference (ToR) of the NVT include providing support for the validation process, submission of the report and the request for validation to WHO Regional Office for South-East Asia by July 2019. The ToR also include to support the visit of the regional validation team and clarify issues raised by the Regional Validation Team (RVT) and the Global Validation Advisory Committee (GVAC) (Annexure 2).

Before the constitution of the NVT, the National Validation Committee (NVC) was formed in 2017. NVC is chaired by the DDG PHS¹. The members of the NVC consist of DDG PHS, administrators, consultants of FHB, NSACP, academic colleges of obstetricians and paediatricians, provincial consultants, representatives from NGOs, KPs and PLHIV (Annexure 4).

Since January 2017, the NVC has met regularly once in 3 months and monthly in 2019 to facilitate the validation process by identifying issues which can affect the validation process and to take remedial action (Annexure 3).

In 2017, a decision was taken by the NVC to establish district committees on EMTCT of HIV and syphilis to support and monitor activities at the district level (Annexures 7 and 8).

In May 2017, two external consultants visited the country to assess the readiness of the programme for validation. They recommended to request for validation of the EMTCT of syphilis programme in 2017. However, the NVC decided to apply for validation of EMTCT of both HIV and syphilis programmes by 2018.

In mid-2017, a local consultant was appointed by WHO to facilitate validation of two domains – laboratory services, and programmes and services. The visit by another external consultant in March 2018 facilitated the validation process further by identifying country readiness for validation of the EMTCT of HIV and syphilis programme by end-2018 (Annexure 9).

Four working groups were formed under the NVC in March 2017 to work in four main domains of the EMTCT programme, i.e. programmes and services, data management, laboratory services and human rights. The working groups were headed by two coordinators each from the NSACP and FHB (Annexures 5 and 6).

They conducted desk reviews, consultative meetings and workshops and surveys when required. The existing standard operating procedures and guidelines were reviewed and updated. In addition, focus group discussions were held with PLHIV groups as well as FSWs to assess the accessibility of reproductive health services. A survey was also conducted among women in postnatal units in 10 major private hospitals in Colombo (NSACP, 2018c).

In November 2017, a two-day residential workshop was held to compile all relevant documents and to assess the progress. Each working group had four meetings in 2018 followed by another two-day residential meeting in November 2018 to review the programme and to collect documents for the country report. In addition to these, district reviews, provincial reviews and national reviews were conducted. The NVC met quarterly to review the current status of the validation process.

The following decisions were taken by the NVC:

- To use the global minimum indicators for validation of the EMTCT of HIV and syphilis programme.
- Under the impact indicators, it was decided to base fetal loss due to syphilis on gestational age >20 weeks rather than weight >500 g. It is important to record POA at the time of miscarriage in case records of pregnant women with syphilis.
- To conclude that if a miscarriage was due to congenital syphilis, the pregnant woman should be confirmed as having syphilis and would not have received treatment.
- Check VDRL results in women presenting with miscarriages or stillbirths. General Circular No. 01-59-2016 was issued by the DGHS (Annexure 10).
- Nuwara Eliya and Vavuniya districts were chosen as the lowest performing districts for validation of the EMTCT of HIV and syphilis programme based on the geographical terrain, poor accessibility to services and issues of human resource.
- The importance of having the data on coverage of private sector HIV and VDRL testing was also discussed. According to the DHS survey in 2016, only 5.4% of deliveries took place in the private sector. Certain districts such as Colombo, Gampaha and Kalutara had >10% of deliveries in the private sector but these deliveries were in 10 private hospitals based in Colombo. Therefore, it was decided to conduct a rapid survey among these hospitals to assess the coverage of service in relation to HIV and syphilis in pregnancy (DHS, 2016).
- The issue of laboratory-based serological tests versus rapid tests for screening for HIV and syphilis was discussed at length. Sri Lanka had a well-organized STD laboratory network with trained staff to perform VDRL tests for over four decades. The HIV antibody test was integrated seamlessly into this established system for over 30 years. The laboratory system has maintained internal and external quality assurance as well. The decision-making flow chart for maintaining or introducing new syphilis screening strategies given in the WHO guidelines was followed (WHO, 2017b).
- Within the MOH services, blood was drawn from pregnant women since 1952 for VDRL tests and it was only a matter of increasing the amount of blood drawn that was required to test for HIV. Considering the above factors, a collective decision was taken by relevant stakeholders to continue laboratory-based serological testing for HIV and syphilis.
- The current VDRL and HIV testing algorithm requires sample transport and reconciling information across laboratories. It was recommended that each district should develop its own mechanism for collection and transport of blood samples to the STD clinic as per the MoH circular issued in 2016 (Annexure 10).
- Rapid HIV tests are used in the testing services of community-based KP programmes, at general practitioners settings, in hospitals up to base hospital A category level and in PEP management.
- Pregnant women with HIV are counselled on infant feeding options: exclusive breast feeding under ART cover or formula feeding. However, in the recent past all pregnant women with HIV have opted for formula feeding. Therefore, an MTCT rate of <2% was considered for validation.

3.2. Data verification and impact assessment

This report summarizes a range of methods used to assess different aspects of the EMTCT programme. The main components of the EMTCT programme were reviewed using WHO validation tools, both quantitative and qualitative methods, drawing on primary and secondary data sources. Routine programme monitoring data, from both the NSACP and FHB were the primary sources of data for impact and process indicators. Denominator values were obtained from the FHB (ANC1) and the Registrar General's Department (registered live births). The estimated number of pregnant women were calculated by adding 10% to registered live births to compensate for the fetal losses during pregnancy. The national HIV monitoring and evaluation plan 2017–2022 was used for guidance (NSACP, 2017d).

The documents used are given below:

:

- **Quarterly returns of STD clinics (STD/ART return)** – indicate the number of pregnant women and children diagnosed, number treated adequately, and laboratory data on antenatal HIV and syphilis tests.
- **e-RHMIS (electronic reproductive health information management system) of the FHB** – gives antenatal care coverage, delivery data, HIV syphilis/testing coverage at the time of delivery, outcome of delivery (e.g. stillbirth, live birth, abortion).
- **Case investigation forms for pregnant women with HIV and syphilis** – give information on pregnant women with HIV and syphilis including details of partners and children. An Excel database was prepared according to the year of delivery for extracting information from these forms.
- **Case records** – information on pregnant women with HIV and syphilis, their partners and exposed babies as well as children diagnosed with HIV and syphilis are available.
- **Registers maintained at STD and HIV clinics** – the antenatal syphilis register is available at all STD clinics. The paediatric HIV case register and the PMTCT services register are maintained at the EMTCT unit, NSACP.
- **Laboratory and pharmacy records** – HIV and syphilis testing data and stock situations
- **Registrar general department statistics** – number of live births registered in a given year

3.2.1. Data verification

Data were verified in several ways. Meetings were held with district teams, which include the RDHS, consultant community physician, MO MCH, venereologist, obstetrician, paediatrician and the MOH. Supervision of MCH services (field and hospital) was carried out by expert teams of the FHB to assess data quality. During these meetings, district (subunit) coverage was analysed based on the defined numerators and denominators.

During monitoring and supervision visits to district STD clinics, ANCs, STD clinic laboratories, registers were reviewed and compared with the data reported to the FHB and the NSACP. Data discrepancies and outliers were investigated and corrected.

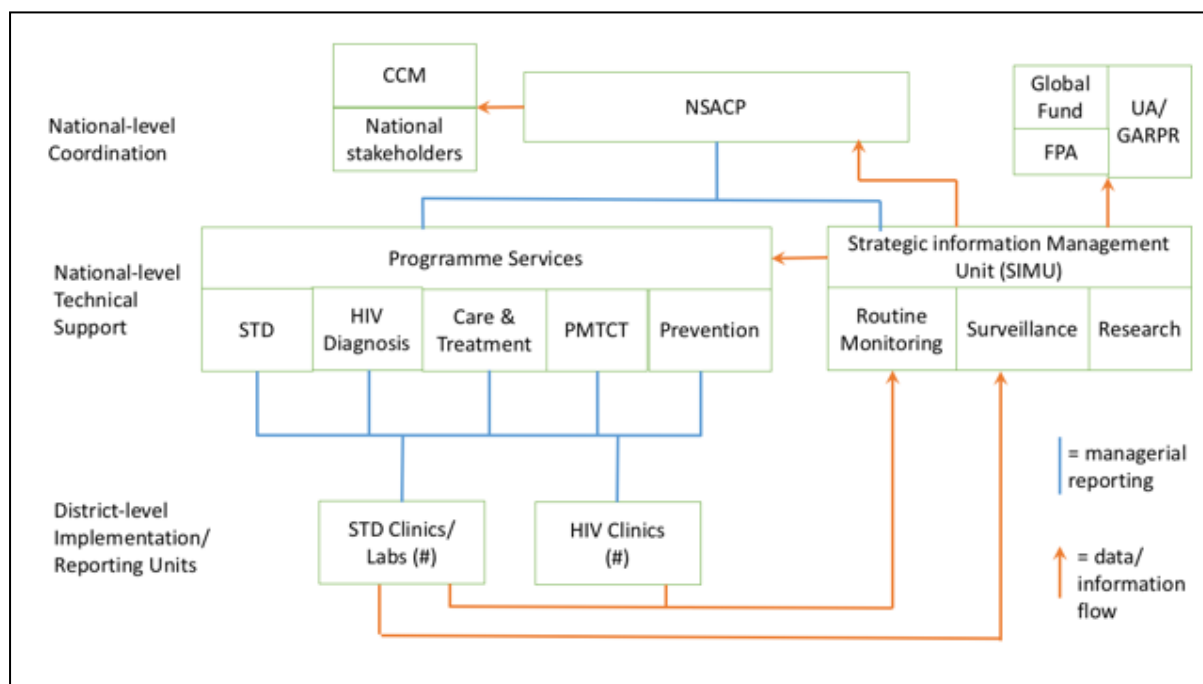
For estimates related to women receiving antenatal care and/or delivering in the private sector, the DHS data from 2016 were supplemented by a more recent 2018 survey of private hospitals in Colombo, where the majority of private providers practice (NSACP, 2018c).

3.2.2. Data triangulation

For the triangulation purposes, multiple data sources were compared for consistency and plausibility. For example, ANC registration (often completed by the midwife at the woman's home) was compared to ANC1 (first ANC visit). These numbers were examined in relation to data on deliveries and live births, as well as to derived estimates of the number of pregnancies. As expected, the ANC registration is consistently higher than ANC1 visits, which in turn is higher than the number of deliveries or live births. This drop-out, due to expected early pregnancy loss, is particularly sharp in Sri Lanka because of very early registration (nearly 80% before 8 weeks' gestation). This early attention to antenatal care services may explain some high indicator values (FHB, 2018).

The data validation working group had several meetings to assess the status of data. MCH services introduced the e-RHIMS system in 2017, which covers nationwide MCH data. The NSACP is currently working on an electronic information management system (EIMS), which was initiated in 2017. As of end-2018, it is functioning in three STD clinics and will be scaled up to cover all STD clinics during the next two years.

The Strategic Information Management (SIM) unit of the NSACP has a system for regular collection of data from district STD clinics on a quarterly basis. Similarly, the M&E unit of the FHB collects data from MOH units directly on MCH services (Fig. 3.1, Fig. 3.2).

Fig. 3.1. Monitoring and evaluation data flow of STD and HIV clinics to the NSACP

Source: SIM unit, NSACP, 2018

At the Central level the SIM unit of the NSACP is responsible for the following:

Coordination role

1. Develop and ensure the implementation of the national M&E plan
2. Provide data for planning and budgeting
3. Share data with the relevant national stakeholders (e.g. CCM, MoH Epidemiology unit) and development partners
4. Repository and nodal unit for disseminating strategic information about the HIV and STD epidemic and response in the country, including programme monitoring, surveillance and operations research. Prepare reports for reporting international requirements such as Global AIDS Monitoring (GAM) and Sustainable Development Goals (SDG).
5. Prepare periodic reports for national and global stakeholders

Implementation role

1. Coordinate with the STD and HIV clinic reporting units to get quality data and carry out data quality audits
2. Provide feedback to the reporting units to improve quality of data
3. Provide feedback to the implementing units on performance
4. Build capacity and guide the reporting units in the field on collection, validation and analysis of data of their own
5. Prepare reports for the Global Fund for activities implemented by the NSACP

Technical role

1. Develop and implement operations research with other institutions/ consultants such as on client satisfaction, quality of service, etc.
2. Triangulate data for tracking of epidemics and overall performance at the national level
3. Design and carry out biological and behavioural surveillance
4. Design and carry out or commission specific evaluation studies and programme assessments

M&E efforts of the NSACP are led by the SIM unit and epidemiology unit. The SIM unit is headed by the coordinator-strategic information. The staff consists of a full-time medical officer, three data management officers whose specific job titles are Public Health Nursing Officer, ICT officer and Development Officer. The epidemiology unit of the NSACP consists of an epidemiologist and medical officer. In addition to these dedicated positions, M&E is integrated into the work of other programme coordinators and their supporting staff.

At the reporting unit level, the NSACP, STD and HIV/ART clinics are responsible for collecting and sending reports on the activities of their units. The responsibilities of the reporting units are to:

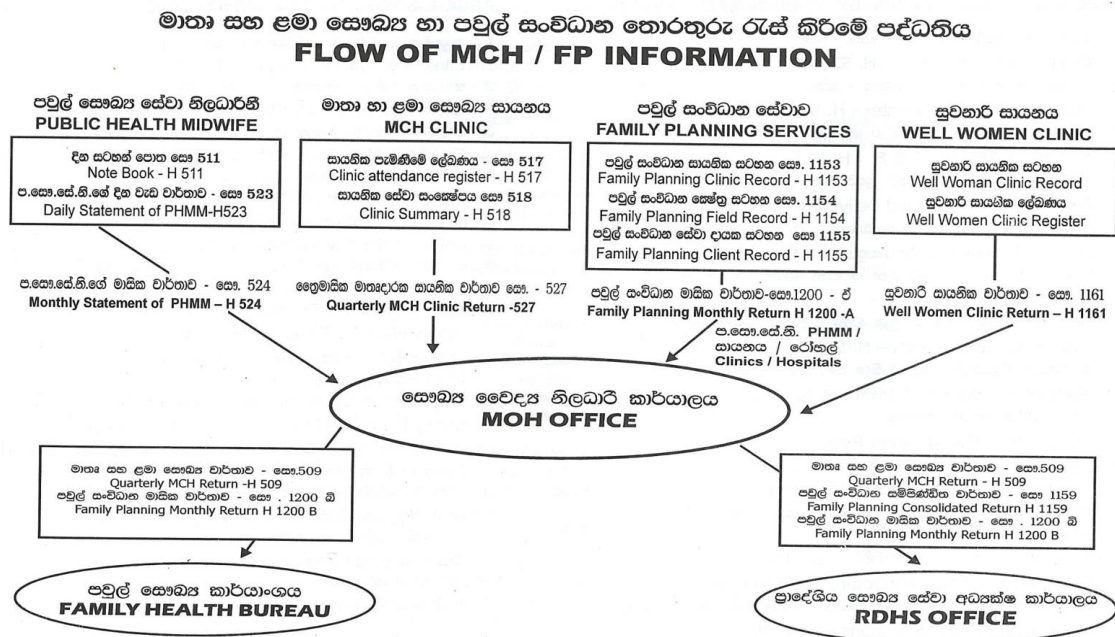
1. Record the details of the patients/clients/services offered in the specified registers in specified formats
2. Verify and validate the data, including making registers available for periodic quality assessment
3. Periodic (weekly) backup of data from the computers, if the records are computerized.
4. Prepare and send reports to the SIM unit of the NSACP in specified time frame.
5. Analyse the data from the reporting unit (NGO) and submit to area MO/STD.

At service provision units of the NSACP (STD and HIV clinics), M&E activities are shared between the clinical staff and the public health staff. Medical officer-in-charge of the clinic (venereologist or a senior medical officer) is responsible to oversee data management functions of PHIs, PHNS, nursing officers and MLTs.

Data Management in MCH services

A quarterly MCH return (H509) provides a comprehensive set of data on the performance of the RMNCAYH programme at the MOH level. Several registers, records and returns maintained in field and clinic settings are used to compile H509 (Fig. 3.2). Each MOH compiles the H509 in three copies and sends one copy to the FHB and one to the RDHS office before the 25th of the following month of each quarter. The third copy is to be retained at the MOH office (FHB, 2018).

Fig. 3.2. Flow of MCH and FP information



Source: M&E unit, FHB, 2018

Due attention was paid to the quality of data when calculating process and impact indicators. Several documents and systems were reviewed during the data verification assessment.

These included annual reports of the NSACP and FHB, returns from STD and MCH services, case definitions and reporting systems, sentinel surveillance and IBBS reports, DHS reports, electronic information systems and M&E plans.

Measures were taken to avoid double counting and possibility of over- or under-estimation. The SIM unit of the NSACP worked on spectrum estimates to interpret the estimates of PLHIV in the country including estimated numbers of pregnant women. Estimates of syphilis infections and possibilities of MTCT were also calculated using the new syphilis estimation tool developed by WHO.

Impact and process indicators were calculated using the following data:

1. Routinely available programme data and survey data were used as data inputs in most instances.
2. Estimates had to be considered for identifying some denominators.
3. Data were triangulated comparing routine data, population-based surveys and estimates.

Indicators were calculated using relevant data from 2015 to 2018.

ANC Coverage

Attention was paid to identify the number of pregnant women who attended the ANC at least once (ANC1). The first visit was taken as one ANC visit. In addition, the FHB collects data on pregnant women who had a minimum of four visits.

The expected number of pregnancies in a year was calculated by adding 10% to the number of live births registered by the Registrar General's Department. According to the DHS survey in 2016, the reporting of live births was close to 100% in Sri Lanka (DHS, 2016). The figure of 10% was added considering adverse pregnancy outcomes.

According to DHS 2016, 5.4% of pregnant mothers had delivered in private sector facilities. At present, there is no formal mechanism of reporting data from the private sector to the MoH. However, private sector hospitals work closely in the EMTCT programme as members of the NVT and NVC. The survey conducted among private hospitals in Colombo in 2018 showed >80% coverage of HIV and VDRL testing among pregnant women. (NSACP, 2018c)

All HIV screening positive samples from private or public sector in the country are sent to NRL, NSACP for confirmation. All confirmed HIV positives are reported to the epidemiology unit of NSACP and measures are taken to link HIV positive persons with ART services.

From mid 2019 June a web based system has been introduced by FHB to collect data on maternal and new born services from major private sector hospitals in Colombo. The system covers antenatal HIV and syphilis screening services as well. This practice will be scaled up to other districts gradually. (Annexure 22)

Testing coverage among pregnant women

Quarterly returns of STD clinics give the number of tests done during the quarter. Repeated testing of the same pregnant woman may result in overestimation of the numerator of the above indicator. However, retesting is done only for pregnant women with positive TPPA or HIV results. As these numbers are small, this may not cause significant overestimation of the numerator. Duplication is avoided by doing retests under the clinic master number as a registered patient for services.

Data are collected from the routine data collection system and representative of actual service delivery practices

Treatment coverage among pregnant women with HIV and syphilis

HIV screening tests are done at STD clinics and when HIV screening test is positive, the sample is sent to the NRL for confirmatory test, and each new case is informed to the venereologist of the STD clinic, epidemiologist of the NSACP and EMTCT coordinator by the microbiologist for epidemiological purposes as well as for linking to care services. The number of pregnant women with HIV or syphilis infection is few and their case reports are maintained including all necessary details at the STD clinic. Important information regarding all pregnant women with HIV is collected from STD clinics through case investigation forms by the EMTCT unit of the NSACP. A PMTCT register is maintained to record this information.

VDRL tests are done at STD clinic laboratories and when the VDRL test is positive, the same sample is tested with TPPA. All TPPA-positive reports are immediately informed to the relevant MOH or hospital director/visiting obstetrics and gynaecology doctor (VOG) and are requested to refer the pregnant woman to the STD clinic for services.

All necessary information including treatment regimens, retention and adherence, counselling for family planning, mode of delivery, infant feeding, etc. are entered in the case reports. One pregnant woman with HIV received services from the private sector in 2018. In this instance, the STD clinic staff collaborated with the obstetrician in the management of HIV in a private hospital.

All pregnant women with HIV infection are regularly followed up at STD clinics as they are on ART for life. Their partners are also managed at STD clinics. In case of default of services by any member of the family, action is taken to trace them based on the preferred method of contact. If necessary, home visits are made by the PHNS or PHI of the STD clinic to assess any issues that they may face.

Pregnant women diagnosed with HIV infection before becoming pregnant are added to the ANC numbers for the numerator and denominator. Confirmed HIV-positive results among ANC attendees are cross-checked with data from the HIV case reporting system.

HIV impact indicators

Case reporting data are complete, and representative of pregnant women diagnosed with HIV. The baby is followed up for 18 months and mother is encouraged to continue lifelong ART. All these services for the mother, baby, partner and other children living with HIV, are provided by the STD clinic.

WHO case definitions for paediatric HIV and congenital syphilis are followed in making the diagnosis, thereby avoiding under- or overestimation. As mother and baby pairs are being followed up at STD clinics, information on the exposed infants is routinely reported to the NSACP. All babies are routinely tested according to the national algorithm for EID.

In the recent past all pregnant women with HIV have opted for formula feeding. Therefore, an MTCT rate of <2% was considered for validation.

When a child is tested as HIV-positive in the screening test, according to the testing algorithm, further testing is carried out at the NRL. The NRL provides details of confirmed children to the consultant epidemiologist of the NSACP, thereby ensuring maintenance of complete data at the epidemiology unit. The EMTCT unit of the NSACP maintains the paediatric HIV register.

Triangulation is done based on the district STD clinic data, national data and laboratory data. The spectrum analysis provides the estimates of children living with HIV in a given year.

Programme data on the outcome of HIV exposed infants

All babies born to pregnant women with HIV were given syrup nevirapine for 6 weeks and followed up regularly till HIV infection is excluded. Since 2015, all babies (n=58) born to women who received EMTCT services remained HIV-negative.

Children living with HIV

Data regarding children with HIV born after the year 2000 are available in the paediatric HIV register. An estimated number of 100 children were living with HIV by the end of 2018. The cumulative number of reported cases by the end of 2018 was 85. Of those, details of 78 children are available at the NSACP. Of these 78 cases, 63 are currently alive and 60 have been started on ART. Parents of three children refused to initiate ART.

In a few instances, where there was lack of responsibility by the parents to continue treatment for the children, the support of PLHIV organizations was sought. The legal aspects pertaining to the above situations have been explored by seeking advice from the Attorney General through the MoH. Services were

obtained from the National Child Protection Authority (NCPA) and child probation services when necessary. The NCPA and Legal Draftsman's Department are members of the NAC, HIV care subcommittee, ethics and legal subcommittee and the NVC.

Impact indicators of syphilis

The data were obtained from the outcomes of pregnant women who were diagnosed with syphilis as well as children newly diagnosed with syphilis in a given year according to the WHO definition.

Data are available for all pregnant women with syphilis giving details up to delivery, partner's and baby's details until syphilis is excluded or diagnosis of congenital syphilis is made. STD clinics have individual case reports with details of management for all pregnant women having syphilis. In addition, model estimates were also used to assess the burden of congenital syphilis in the country.

Since pregnant women are tested for syphilis in early pregnancy and all positive cases are managed at the STD clinic, it is possible to assess the outcomes of pregnancy in a given year including stillbirths. Further, the MoH circular issued in 2016, advises to do VDRL testing in all cases with adverse pregnancy outcomes such as stillbirths, abortions, etc., if VDRL has not been done during pregnancy (Annexure 10).

In 2018, there was only one case of symptomatic congenital syphilis. However, all asymptomatic cases which fell into the WHO case definition were considered for diagnosis of congenital syphilis.

Data quality assurance

User-guides provide detailed instructions for completing each format to ensure standardized data collection at the national and district levels. The SIM unit of the NSACP reviews quarterly returns and interacts with individual reporting units (STD clinics) to obtain the necessary clarifications or missing data elements.

Measures are taken to review data at the district and national levels. Relevant STD staff have been trained in data management process and tools. Regular training takes place including pre-service and in-service training. An information dissemination system is given in the national HIV M&E plan. This includes publication of annual reports and quarterly dissemination of STD and HIV data via the website of NSACP (NSACP, 2017b).

3.3. Assessment of programmes and services

The programmes and services working group met four times during 2018. Attention was paid to the service coverage, turnaround time for testing, adequacy of treatment of pregnant women, partner and children, contact tracing and defaulter tracing. Management of the baby was assessed up to the exclusion of syphilis or HIV infection in the baby.

The programme and services area was assessed using operational guidance given by WHO on how to assess the programmes and services required to achieve and sustain EMTCT (WHO, 2017a). It outlines a methodology for assessment and provides tools to assist with systematic implementation to make sure that the assessment is done using a common methodology and set of standards.

The checklist and the validation tools given were used for validation. The assessment included qualitative and quantitative approaches.

The following components of services were assessed:

- Primary prevention of HIV and syphilis
- Antenatal care services
- Diagnosis of HIV and syphilis
- HIV treatment and care
- Syphilis treatment and care
- Postnatal care
- Infant and child health

The assessment included central-level programmes and service delivery level, both primary- and secondary-level care provided by public and private providers. Key informants were selected to represent central-level and provincial-level programme managers, service providers in MCH and STD services, civil society representatives, KPs and PLHIV. Interviews were held with national and regional programme managers, service providers, civil society representatives and women living with HIV and syphilis.

The DGHS is the chairperson of the NVT which met monthly in 2019 to review the country status with regard to validation. As a member of the NVT and as the chairperson of the NVC, the DDG PHS works closely with the FHB and NSACP to maintain satisfactory indicators. The College of Obstetricians and the College of Paediatricians are members of the NVT and NVC and have always supported the programme. The Health Sector Development Council meeting and Directors' meetings included validation of the EMTCT programme as an agenda item to regularly review the country status.

The EMTCT programme is implemented at the provincial level. The PDHS, RDHS, consultant community physician, MO MCH, MOH and the consultant venereologist are in the district and provincial teams which meet regularly to discuss the EMTCT validation process (Annexures 7 and 8). Quarterly meetings at the RDHS have the EMTCT programme on their agenda.

During assessment, attention was paid to specific areas and it was noted that:

- a. There is an adequate service delivery system to provide the MCH services as well as STD services to achieve and maintain EMTCT of HIV and syphilis.
- b. The service delivery package for pregnant women includes the essential service package, which is provided freely to all including HIV and syphilis testing.
- c. MCH services are universally available and accessible for all, including socially marginalized and vulnerable populations. Services are provided free of charge and there is a service provision centre within the distance of 3–5 km from anywhere in the country.
- d. STI services are provided through the NSACP and district STD clinics while MCH services are provided through the FHB and MOH units and secondary and tertiary care institutions. STD clinics provide services for timely and effective diagnosis, treatment and follow up of pregnant women and exposed infants. MOH units increase awareness, collect blood for testing, collect reports on time and refer pregnant women with HIV and syphilis for services while continuing antenatal care services.
- e. The EMTCT programme is mostly funded by the government with some support from UN agencies such as UNICEF and WHO. Therefore, the sustainability of the services is guaranteed.
- f. Human rights are considered at every level including patient management. Engagement of the community (KP and PLHIV) is evident at the planning, implementation and monitoring levels. Community members are important stakeholders in EMTCT committees. Gender has been mainstreamed into the RMNCAYH programme in Sri Lanka. Sri Lanka has low level of gender discrimination when it comes to education or employment. There are separate programmes in the health and other sectors to promote gender equity.

Leadership and governance

1. Several documents have been printed to support the EMTCT programme including the national EMTCT strategy (2014, 2018); Guideline on management of pregnant women with syphilis (2016); Guideline on management of pregnant women with HIV (2009, 2011, 2016); Guideline on ART including paediatric HIV management (2004, 2013, 2016). An MCH guide has been developed to train health-care workers at the grassroots level (2015).
2. Links have been developed between STD and MCH services since 1952 and these have been further strengthened since 2013 under the EMTCT programme.
3. Circulars have been issued by the DGHS on the EMTCT programme (2014, 2016), ending AIDS (2016) on adolescent reproductive health (2015).
4. There are no legal barriers that restrict access to services and opt out options are available.
5. The national HIV/AIDS policy emphasizes on informed consent and counselling for HIV testing (NSACP, 2011).
6. There are no laws, regulations or policies to force contraception or abortions for pregnant women with HIV or syphilis.
7. There are no laws to criminalize vertical transmission.
8. Civil society including KP and PLHIV are involved in programmes at several levels including planning, implementation and monitoring.

9. Government MCH services and STD services are supervised and assessed regularly. These occur through regular national, provincial and district reviews, in-service training and supervision visits. Private sector MCH services are provided by specialists. However, there is a need to improve private sector services with regard to data management.

Financing

1. Health services in the public sector including MCH services and STI services are provided free of charge. Anyone has the freedom to get health services from anywhere in the country through the private sector or public health services according to their preference. There are no insurance schemes or benefit packages as services are widely available and accessible through the public health sector.
2. As the EMTCT programme was integrated into the existing MCH programme, which has been in existence for the past 60 years, sustainability is guaranteed.
3. The major source of funds for civil society organizations was the GFATM. With the transition from the GFATM to GoSL in 2022, financial assistance to KP organizations and PLHIV organizations received so far may be affected. As they are identified as important stakeholders of the prevention and care service provision, the government needs to identify ways to continue supporting these organizations.
4. As health services are provided free of charge, the out-of-pocket expenses are minimum.

Human resources

1. There are adequate categories of staff to provide EMTCT services at STD clinics and MCH services. However, in few geographically challenged areas availability of human resources may be limited. There are adequate categories of staff to provide EMTCT services at STD clinics and MCH services. However, in a few geographically challenged areas, availability of human resources may be limited. This has not affected the service provision with regard to basic services. With adequate numbers, the quality of services can be improved further.
2. There are regular training programmes for staff members. The FHB, which is responsible for MCH services, conducts regular training to improve quality of MCH services. At the field level, monthly in-service training programmes are conducted with regular reviews at the district and national levels.
3. The STD staff gets regular training at the district and national levels. This includes pre-service and in-service training. Training programmes are conducted for undergraduate and postgraduate doctors, nursing officers and laboratory and supportive staff. District and provincial reviews are coordinated by the consultant venereologists.
4. Service providers in both MCH and STD services are trained on provision of services to adolescents. In the general circular issued in 2015 (General Circular No. 01-25/2015) clearly states that health-care workers can provide sexual and reproductive health services to adolescents <16 years even without consent from the guardian if necessary (Annexure 14).
5. Health-care workers in STD clinics are given regular training by the NSACP, on working with KPs including FSWs, MSM, drug users and PLHIV.

Service delivery

1. MCH and STI services have developed strategies, guidelines and standard operating procedures for EMTCT of HIV and syphilis. These are available at service delivery points.
2. HIV and VDRL testing services are provided in early pregnancy to facilitate timely management. All positive HIV screening test reports of pregnant women are informed immediately to the relevant officers and the pregnant woman is counselled and referred to the STD clinic promptly for further testing.
3. All pregnant women with syphilis are referred to STD clinics and offered treatment with benzathine penicillin. Partners and children are also managed according to the guidelines at the STD clinic.
4. Defaulter tracing is an important component in patient management at the STD clinic. If the pregnant woman is lost to follow up, defaulter tracing is done according to the guideline. Considering the urgency, home visits are made based on the patient's consent.
5. When a pregnant woman arrives in late pregnancy or at delivery and if HIV test results are not available in the ANC record, rapid HIV test and VDRL test are done. Rapid HIV test kits are available in all major hospitals up to the base hospital A category. If the rapid test is positive for HIV, the pregnant woman is managed as HIV-positive till confirmatory result is available. Emergency packs with AZT/3TC/RAL have been made available to all STD clinics to be used in these situations.
6. Under strategic direction 01 of the NSP 2018–2022, prevention of HIV and STI among KPs, vulnerable populations, youth and general population is identified as an important strategy. KPs are FSWs, MSM, drug users, beach boys and prisoners. As there are very few injecting drug users in the country, both injectable and inhalation drug users have been identified under the drug user category.

The NSP of Sri Lanka clearly identifies strategies to reach these KPs. Since 2011, KPs are provided services in the community through a peer-led approach. The services were implemented for FSWs in 10 districts, for MSM in six districts, for beach boys in seven districts and for drug users in 10 districts. Currently, the peer-led prevention programme service package includes: providing information on HIV and STIs, promotion of care-seeking behaviour including testing services, condom promotion, escorting KPs for STD clinic services and linking KPs with STD clinics for STI and HIV care services. In 2018, close to 30 000 KPs were reached and 8791 have been escorted to STD clinics. KP interventions are carried out by the FPA with support of the NSACP and funded by GFATM. Testing services are provided in the community through mobile clinics, in addition to STD clinic services. These services are available for adolescent KPs as well.

Regular training programmes are carried out for service providers to reduce stigma and discrimination. Programmes are also conducted for police officers to create an enabling environment for KPs. The stigma assessment among PLHIV 2017 report shows improvements in relation to stigma. However, internal stigma needs to be addressed.

Vulnerable populations identified in the NSP include migrant returnees, workers in the tourism sector and armed forces. The multisectoral unit of the NSACP works closely with the Ministry of Defense, Sri Lanka Foreign Employment Bureau, Ministry of Tourism and National Youth Services Council. Youth are approached through the Ministry of Education and Higher Education Schools. In addition, the NSACP has been working with the National Youth Council (NYC) in training out-of-school youth groups.

7. Sri Lanka is planning to implement a comprehensive national communication strategy to increase coverage of HIV testing to reach 90-90-90 targets by 2020. The strategy has been developed and budgeted. The Cabinet approval has been granted in June 2019 and the NSACP hopes to launch the implementation of the communication strategy by the end of 2019. The strategy has an important component of social marketing of STD/HIV clinic services (NSACP, 2017e).
8. The strategy for elimination of new paediatric HIV infections and congenital syphilis published in 2014 was updated in 2018 and is widely available (NSACP, 2014; NSACP, 2018d).
9. Primary prevention including promotion and distribution of condoms is extensively addressed in the NSP 2018–2022 (NSACP, 2017b).

The NSACP has been promoting condoms as a means of prevention, and condoms are provided free to people attending the STD/ HIV clinics. KPs are provided condoms through peer leaders in the community. During 2018, a total of 3 654 030 condoms were distributed among KPs by peer leaders under the GFATM project (NSACP, 2018b). In addition, MCH services promote condoms as a family planning method and are provided free to the general population by the field health staff.

10. The FHB is responsible for providing family planning services. STD medical officers have been given training to provide family planning services for women attending STD/HIV care services including FSWs and women with HIV. STD clinics do have family planning commodities including OCP, DMPA and IUCD. If needed, women are referred to the closest family planning centre for hormonal implants and tubal ligation procedures.
11. The MCH policy encourage early registration for antenatal care services before 8 weeks of POA (GoSL, 2012). The registration for antenatal care services is done during home visits and during visits to the ANC.
12. General Circular No. 01-59/2016, clearly states that pregnant mothers are to be screened before 12 weeks of POA for HIV and syphilis (preferably at first visit) (Annexure 10).
13. The guidelines for management of pregnant women with HIV infection clearly indicate the treatment plan including management of the partners and children exposed. Pregnant women with HIV are managed at STD clinics according to the guidelines. Partners and children are also managed at the same centre and if infected, services are continued lifelong. Case records are maintained at STD clinics for the pregnant woman, partner and children (NSACP, 2016b). In addition, case investigation forms pertaining to each case is maintained at the EMTCT unit, NSACP.
14. Infant feeding guideline has been developed for babies exposed to HIV (NSACP, 2016b; FHB, 2015). All pregnant women with HIV are counselled on the options available for infant feeding. Services are provided according to the choice of the pregnant women. If the woman decides on formula feeding, formula milk is provided free for one year through the National AIDS Foundation, which is an NGO.
15. The guidelines give detailed instructions on follow up and diagnosis of infants and children exposed to HIV (NSACP, 2016b). Infants are followed up till HIV antibody test becomes negative.
16. Routine syphilis testing (VDRL) is offered in early pregnancy. The guideline for management of pregnant women with syphilis gives details on treatment for pregnant women with benzathine penicillin. If the woman is sensitive to penicillin, the treatment option is erythromycin. In addition, testing of partners and children and appropriate management are included. Partners having syphilis are treated with benzathine penicillin. (NSACP, 2016c). Case records are maintained at STD clinics for the pregnant woman, partners and children. Exposed infants are followed up for 6 months till VDRL test becomes non-reactive.

17. All pregnant women with syphilis are followed up at the STD clinic. STD clinic has data regarding the outcome of all pregnant women with syphilis including adverse pregnancy outcomes. government circular in 2016, as well as the guideline on syphilis indicates the importance of HIV, VDRL testing in women who experience abortions, still births and other adverse pregnancy outcomes if the tests have not been offered during pregnancy (NSACP, 2016c) (Annexure 10).
18. A guide to ART (NSACP, 2016a) includes management of paediatric HIV. All children with HIV are managed at STD clinics according to these guidelines.
19. The FHB has a special unit on gender and women's health which works on gender equity and prevention of gender-based violence (GBV). Several activities have been carried out over the years to train health-care workers to identify GBV and refer for services. Special service centres have been established in 68 hospitals (Mithuru Piyasa) to address GBV issues. These units are headed by a trained medical officer. The MOHs and medical officers of the respective hospitals are trained on GBV and for referral if necessary

Medical products

1. Laboratory services for diagnosis of HIV and syphilis of pregnant women are available at district STD clinic laboratories. Blood samples from pregnant women are transported to STD clinic laboratories from field ANCs.
2. Diagnostic services for exposed infants (DNA/RNA PCR testing) is available at the NRL. Blood samples of exposed infants are transported to the NRL for testing. Due to availability of transport and accessibility within 12 hours from any part of the country to the NRL and as the sample are few in numbers, there are no serious logistic issues.
3. No stock-outs of HIV or VDRL test kits were reported in the recent past. Only the test kits which are registered by the NMRA are procured. Kit verifications are performed on receipt of new stocks and thereafter periodically.
4. HIV and syphilis testing services are available freely for partners and children of infected women.
5. Sri Lanka took a policy decision in 2016 to start ART for all persons diagnosed with HIV infection irrespective of their CD4 levels.

No stock-outs of ART were reported for pregnant mothers. Syrup AZT or 3TC is not available for infants and dispersible tablets of AZT+3TC are used instead. However, correct dosing is a challenge. Understanding the importance of the EMTCT programme, the MoH has taken necessary measures to provide timely ART. Benzathine penicillin is available at STD clinics and hospitals for management of syphilis and stockouts have not been reported.

6. Condoms and contraceptives are available and accessible through government units such as STD clinics or MOH clinics and are also widely available in the private sector. Sri Lanka has adequate stocks of condoms and lubricants, which are mainly funded by GFATM and stock-outs are not reported.

Strategic information management

1. From 2013, Sri Lanka adopted global minimum indicators for validation of the EMTCT programme (NSACP, 2018c). At NSACP, the data originates from the district STD clinics. Quarterly returns are sent to the SIM unit of the NSACP. There are several guidelines to facilitate uniformity in data collection and reporting. Patient records, registers and reporting formats are developed in a standardized manner. Necessary instructions are given in English and national languages as necessary.
2. Data on MCH services originate at the PHM level. These data are collected and compiled at the MOH office. From the MOH office the return H509 is sent to the M&E unit of the FHB with a copy to MO MCH at the district level. Since 2017, the FHB has developed a DHIS2-based e-RHIMS to facilitate timely data collection.
3. Quarterly returns of STD clinics provide laboratory data in relation to the number of pregnant women tested, the number diagnosed, and the number appropriately managed for HIV and syphilis. Data on EMTCT services for HIV are available through quarterly ART returns. The number of live births per year are available from the Registrar General's Department. The estimated number of pregnant women in a given year is calculated by adding 10% to the registered live births (estimated pregnancies = live births x 1.1).
4. The NSACP has been collecting quarterly returns from peripheral STD clinics for several decades and these reporting mechanisms and forms have been improved over time. Based on the data available from countrywide STD clinics, the SIM unit publishes the annual report of the NSACP, which is disseminated through the website as well as hard copies. With quarterly data, the SIM unit regularly updates the website giving latest information.
5. Quarterly ART returns sent from STD clinics to the SIM unit give information on PLHIV including pregnant women with HIV. EMTCT case investigation forms have been developed to collect details on pregnant women with HIV and syphilis and children diagnosed with congenital syphilis and HIV. District STD clinics submit these forms quarterly to the EMTCT unit of the NSACP. These forms are initiated when a pregnant woman or a child is diagnosed with HIV or syphilis. The information in the case investigation forms is updated quarterly. The two registers maintained at the EMTCT unit, i.e. the PMTCT register and the register of paediatric HIV/AIDS cases, are updated accordingly.
6. The SIM unit expects quarterly returns to be submitted by the 20th of following month at the end of each quarter. If a site does not report or if there are errors or discrepancies, the respective STD clinic is contacted and measures are taken to verify data.

3.4. Laboratory assessment

The laboratory working group met several times during the year 2018. The group has been preparing for the accreditation of the NRL and to improve the quality of peripheral laboratories. The laboratory committee covered four areas including laboratory quality management, quality of tests, quality of testing, and data management.

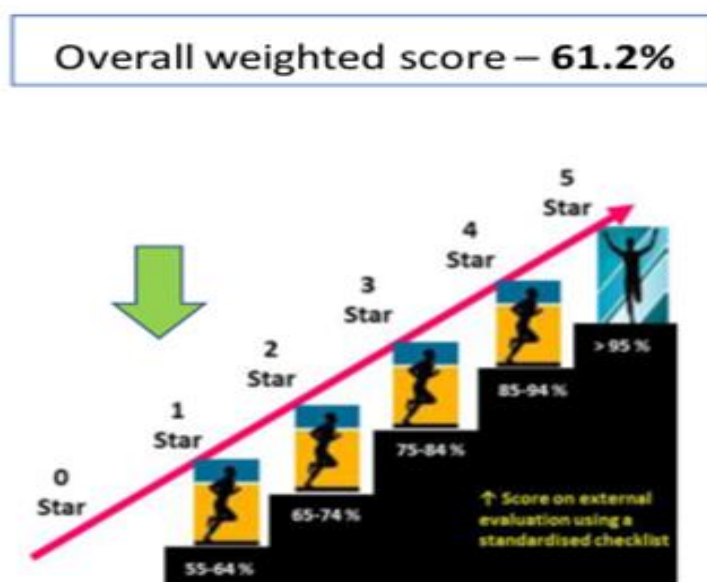
Laboratory quality management

The NRL is continuously working for improving the standards as per ISO 15189 and has applied for certification in 2019. Few assessments of the NRL as per the requirement of the Sri Lanka Accreditation Board were carried out before application to identify and improve the required standards. An internal audit was carried out by three laboratory auditors (one external and two local) in 2019.

The NSACP is striving to improve the quality of the laboratory network and much effort has been put in with the support of CDC/Christian Medical Association of India (CMAI), India to improve the quality of network laboratories. It underwent few assessments in the recent past including WHO SLIPTA assessment in 2017 with two external assessors from the support of CDC/CMAI India. A sample of district laboratories were also assessed together with the NRL in 2017.

Some technical gaps were identified following a situation analysis. The quality management system, equipment management and documentation issues were the major gap areas identified (CDC, 2017)

Fig. 3.3. Rapid situational analysis of the laboratory network under NSACP August 2017



Source: NRL 2019 (CDC, 2017)

A repeat assessment was done in January 2019 to assess the impact of quality improvement activities. There was an overall improvement with higher marking in the stepwise laboratory improvement process towards accreditation (SLIPTA) scale, but certain gaps were still found and are being addressed.

Fig. 3.4. Rapid situational analysis of the laboratory network under NSACP, January 2019

Source: NRL 2019

Situational analysis of the STD clinic laboratories

The NRL provides technical guidance and reference testing to district clinic laboratories, and the laboratories work in a network fashion. The national norms and standards as well as supervision for district STD clinic laboratories are provided by the NRL.

These laboratories have been guided to improve their quality management system. Continuous quality improvement is achieved by promoting to adhere to the guidelines issued, providing training and by on-site evaluation during supervisory visits. Supervisory visits were coordinated by the NRL and the supervisory team members included the microbiologist, a medical officer, senior medical laboratory technologist and a senior public health laboratory technician. In addition, supervisions were carried out by the consultant (specialist) venereologists who are acting as primary laboratory coordinators. A checklist based on ISO 15189 elements consisting of management, personnel, equipment, pre-examination, examination, safety and post-examination was used to evaluate and make recommendations for improvements. During the visits, measures were taken to ensure that policies and procedures are in place for pre-analytical, analytical and post-analytical aspects of testing. Specimen reception and storage, reagent handling, stock management, equipment maintenance, reporting and recording were assessed during the visits.

Staff training and competency

Capacity building of technical staff in STD clinic laboratories is carried out regularly by the NRL. Medical laboratory technologists are recruited to the government sector following a two-year training period and are registered in the Sri Lanka Medical Council (SLMC).

There are regular pre-service and in-service training programmes for the central and peripheral STD clinic laboratory staff. During the past few years, special attention was given on training on quality management and quality improvement with the support of CDC/CMAI, India. The senior technical staff has been trained at Christian Medical College, Vellore, India on quality assurance and on ELISA. The senior technical staff of the NRL have also been trained in ISO 17043 for proficiency testing as well with a view to improve the national external quality assurance (NEQA) of the NRL/NSACP. The district-level staff are given training on ELISA technique and quality assurance at Christian Medical College, Vellore. The NRL supported quality improvement in testing for HIV and syphilis in private sector laboratories as well. Consultant venereologists were guided to liaise with private sector laboratories in respective districts for quality improvement of the service.

Quality of HIV and Syphilis tests

There is a national plan for procurement and distribution of HIV, VDRL and TPPA test kits. A document describing the procedure is available and known to all STD laboratories (GoSL, 2018; NSACP, 2018a).

Procurement and distribution of testing materials are centralized and it is through the MoH. All the clinics receive the same testing material to maintain uniformity of testing. This task is carried out by the NRL as per the national procurement guidelines. The procurement is done through the MSD of the MoH and the State Pharmaceutical Corporation (SPC), which is the government's central procurement arm for medical items. Only the test kits which are registered by the National Medicinal Regulatory Authority (NMRA) are considered in the procurement process. Registration of test kits is done by the national committee of the NMRA based on laboratory evaluations carried out locally in relevant expert laboratories selected by the NMRA. Products/items registered by the NMRA usually have a high specificity and sensitivity. During evaluation for the procurement process, the sensitivity and specificity of the test kit and the WHO pre-qualification or the approval status by the Food and Drug Administration (FDA) are considered to assure the quality.

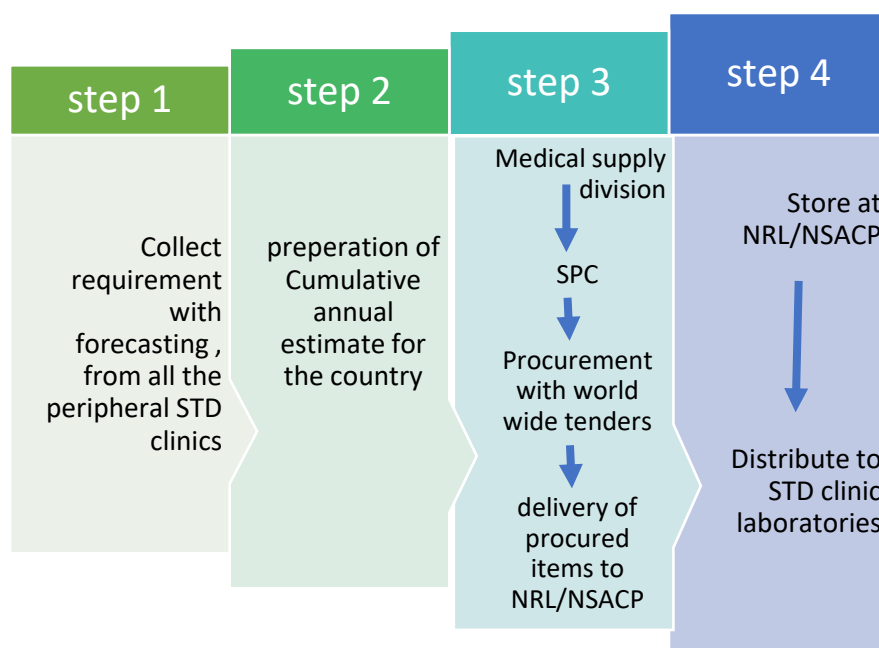
The national requirement of test kits is estimated by the NRL based on the cumulative estimates for the country. Forecasting for estimates is done at an annual meeting with all relevant district staff, considering the routine requirements and community testing programmes planned for the year.

When the procurement is carried out, the bulk stock is delivered to the NRL. On receipt of the test kits, kit verifications are performed. When a new lot arrives, from each lot randomly selected test kits are subjected to kit verification by using known positive and negative samples.

The policy for batch testing upon receiving diagnostic assays and the frequency of validation of these assays at 6 monthly intervals have been established. Storage and disposal of tests are well defined (NSACP, 2018a).

Test kits are distributed per the requests made by STD clinics and well documented. Distribution of reagents and supplies reach all testing sites within the appropriate time frame and STD clinics are located so that they can be reached within 12 hours' drive. After receiving the kits, each laboratory needs to perform the acceptance test to ensure the quality of the kit.

If an unexpected need arises, the NRL takes necessary measures such as local purchase of items. The system of central procurement is explained in Fig. 3.5.

Fig. 3.5. Steps in procurement of test kits and distribution to district STD clinics

Source: NRL, NSACP

The quantity of test kits is frequently monitored to prevent stock-outs. The stock balances are closely monitored and regular meetings with the MSD and SPC are carried out to ensure stock availability. An electronic system is available to monitor the stocks received from MSD and stocks dispatched to district STD clinics.

Due attention is paid to the shelf-life of test kits with the “first expired, first out” (FEFO) approach. Proper storage and periodical checking of test kits is done to monitor the potency of reagents. The laboratories have been advised to practise periodical physical stock-taking. The test kits are stored as per the manufacturer’s instructions in the Central Stores and in district laboratories. The disposal of expired test kits is well documented and all district clinics are informed regarding the steps to be taken with test kits close to expiry.

Internal quality control and external quality assurance for testing

Quality assurance and quality control procedures are implemented in all STD laboratories across the country to ensure the quality of testing. The NRL participates in the external quality assessment programme in HIV and syphilis on a regular basis and results in the past years have been satisfactory (Table 3.1).

Table 3.1. Participation of External Quality Assessment Schemes by NRL

EQA Scheme	Frequency per year	Responsible Institute
External Quality Assessment Scheme for HIV Serology	2	National Serology Reference Laboratory for HIV, Australia
External Quality Assessment Scheme for CD4 Count	6	Siriraj Hospital, Thailand, WHO collaborating Centre
External Quality Assessment Scheme for Syphilis serology	3	Centres for Disease Control Atlanta, USA
External Quality Assessment Scheme for HIV viral load testing	2	National Serology Reference Laboratory for HIV, Australia

Source: NRL, 2019

The NRL conducts an NEQA programmes on HIV serology and syphilis serology for all STD clinic laboratories (Tables 3.2 and 3.3). (Annexure 23)

Table 3.2. Participation in HIV EQA by STD laboratories performing EMTCT testing

Institution	2016	2017	2018
No of laboratories	22/22	23/23	23/23
Average Performance data	100%	100%	98.3%

Source: NRL 2019

Table 3.3. Participation in Syphilis EQA by STD laboratories performing EMTCT testing

Institution	2016	2017	2018
No of laboratories	22/22	23/23	23/23
Average Performance data	96%	98.5%	96.8%

Source: NRL 2019

For a non-conforming EQA, the STD laboratories are advised to determine the reason for the discordant result. The consultant/medical officer in-charge of the laboratory is expected to attend to poor results with the technical person of the laboratory to find out the root cause. If recurrent discordant results are obtained, the laboratory is advised to discuss the issue with the NRL. In the root cause analysis, the NRL considers the degree of operator dependency and other independent causes for the non-conformity. For the errors, corrective and prevention actions are taken.

Quality assurance of private laboratories

The five large laboratories which provide islandwide laboratory services through a network (Chain Laboratories) are accredited with the ISO15189 standard. EQA participation is mandatory in obtaining accreditation. Therefore, these laboratories are under an EQA scheme conducted by EQA-conducting institutions. (SLAB,2019)

Laboratory data management

The data management system of the laboratory is currently in a transitional state from paper-based to electronic system. A paperless electronic information management system (EIMS) for maintenance of medical records is being developed and implemented in the NSACP and peripheral district STD Clinics. A laboratory module is included in this electronic system. The existing paper-based system will be converted to this electronic system, which will be implemented in STD clinics across the island by end of 2019.

All antenatal samples are accompanied by a request form that is uniform throughout the country and is especially formatted to send antenatal samples. This form is generated in triplicate in the ANC. The first copy is kept at the ANC. The second and third copies are sent to the laboratories with samples. The second copy is kept at the laboratory for record purposes as the request form and the third copy is used for reporting and sent back to the ANC as the report.

When samples are received at the laboratory, they are entered into a sample receiving register. When the samples are subjected to testing, the test results are entered into a separate register as well as into the report format. The report prepared by the MLT is verified by a senior MLT and it is validated by a designee medical officer before it is released. The testing statistics are manually prepared by the MLT on a monthly basis.

The reactive results of antenatal samples are informed to the MOH immediately. In NRL, the consultant microbiologist informs the EMTCT unit about the reactive results to be informed to the MOH. In peripheral units, the venereologist informs the results to the MOH for further action. The reports are collected by the staff of MOH and distributed to the ANCs to ensure the traceability of the persons involved.

All the documented evidence of testing is kept in the laboratories in an orderly manner for easy retrieval of information. Measures have been taken to avoid unauthorized access to laboratory information.

3.5. Assessment of human rights, gender equality and civil society engagement

The EMTCT of HIV and syphilis programme is based on strategies and activities consistent with international and national human rights standards.

The human rights component was assessed in three areas, namely human rights, gender equality, and civil society and community engagement. The human rights working group met several times in 2018. A legal expert was identified to do the desk review on legal aspects. All relevant documents on policies and laws were collected and compiled. This report is based on the information gathered.

Desk review

A desk review was done to review the national programme and policies. The national constitution and laws for protection of human rights were reviewed. Judgments given also were considered in the desk review.

Being a member of the United Nations, Sri Lanka has made a firm commitment towards protection, promotion and implementation of Human Rights. In this regard, Sri Lanka has acceded or ratified many international conventions and fulfilled many of its obligations in respect of such instruments by taking legislative and administrative measures. The measures taken by the government towards protection and promotion of human rights and maintaining gender equality have paved the way to prevent the spread of HIV/AIDS including that of MTCT to a great extent and has helped in maintaining low prevalence of HIV/STIs in the country.

The relevant provisions of the Constitution of the Democratic Socialist Republic of Sri Lanka

In line with the Universal Declaration of Human Rights (UDHR) and other international instruments, Sri Lanka incorporated human rights principles into the Constitution of the Democratic Socialist Republic of Sri Lanka. The Constitution which is the fundamental law of the country has enshrined many of the rights concerning non-discrimination and gender equality. The Constitution contains provisions related to the protection of rights of people.

Right to life – Though there are no explicit provisions in the Constitution relating to the right to life, the Supreme Court of Sri Lanka has held that it is inferred in Article 13(4) of the Constitution.

Though there are no specific provisions in the Constitution relating to the rights of people living with HIV/AIDS, the above said Articles protect their rights without any discrimination.

Right to health – Sri Lanka has ratified the International Covenant on Economic Social and Cultural Rights. Article 12 of the said Convention, which states that every person has the right to enjoyment of the highest attainable standard of physical and mental health, has been given due importance in health-related legislations and policies. The Supreme Court of Sri Lanka, in a Fundamental Right case, recognized the petitioner's right to health and granted relief.

Right to education – Article 27 (2)(h) of the Constitution recognizes the right to Universal and Equal access to education at all levels. It is noteworthy to refer to the judgment of the Supreme Court of Sri Lanka in this regard.

A student was denied access to education on the ground that the parents were HIV-positive. The mother made an application to the Supreme Court (SC. FR. No.77/2016) against the violation of the fundamental right on access to education to be admitted to a school, and the court granted relief. The court referring to Article 27 (2)(h), stated that "the court also wishes to place on record that the state should ensure that the human rights of the people living with HIV/AIDS are promoted, protected and respected and measures to be taken to eliminate discrimination against them".

Right to employment – The right to employment is guaranteed by the Constitution irrespective of whether a person is HIV-positive or not. A worker was dismissed from employment because he was HIV-positive. He went to the Labour Tribunal against the employer regarding the dismissal. The tribunal stated that he cannot be dismissed on the ground of being HIV-positive and that he should be reinstated with wages.

Prevention of Domestic Violence Act No. 34 of 2005 – The introduction of this Act enabled more women to speak openly about domestic violence and also to report the incidents to the police and seek relief in courts.

Penal Code

Several provisions were included in the Penal Code to include new offences for the protection of women and children from sexual harassment and similar acts. Sexual harassment and grave sexual abuse have been identified as criminal offences. Procurement for illicit intercourse, rape, gang rape, marital rape, incest, statutory rape, human trafficking have also been made offences.

Voluntary carnal intercourse between men-men, women-men, with animal and acts of gross indecency between persons are offences punishable with fine and imprisonment (Sections 365 and 365A).

Vagrants Ordinance – The Vagrants Ordinance was enacted in 1841 and it is one of the oldest ordinances that were introduced by the colonial rulers. The long title of the ordinance states "an Ordinance to amend and consolidate the law relating to vagrancy"

In terms of the provisions of the Vagrants Ordinance, there are certain sections pertinent to FSWs and connected offences. However, if a sex worker is arrested, it should not be on mere suspicion or belief and also the arresting officer should have evidence to prove that the woman is a sex worker.

As early as 2008 the ethical and legal sub committee of NAC, made representations to the parliamentary select committee requesting amendments to the vagrants ordinance.

Advocacy and awareness programmes have been conducted for the department of police to create an enabling environment for implementation of targeted interventions for FSW. As a result of representations made by the legal and ethical subcommittee of NAC against producing condoms as evidence of sex work, the Department of Police has issued a circular to all police officers to consider condoms as a medical device. (Annexure 19)

Brothels Ordinance – The Brothels Ordinance was introduced in 1889, again during the colonial rule. According to the Brothels Ordinance, any person who keeps or manages or acts or assists in the management of a brothel or facilitate running a brothel shall be guilty of an offence. However, according to Sri Lankan Law, sex in private is not an offence.

Drug use – It is a known fact that there are around 90,000 heroin users in the country with around 1000 injecting drug users. There are different organizations with defined mandates to deal with drug use in Sri Lanka. While the National Dangerous Drugs Control Board (NDDCB) is mandated for prevention, treatment, rehabilitation and research activities aimed at reducing harm from dangerous drugs, law enforcing authorities are active in nabbing drug dealers. However, the health needs of drug users are met by health services of the country without any discrimination. Trade of dangerous drugs as well as their possession are punishable offences according to the law of the land.

While these laws are there in the legal system, the NSACP and partners have been working hard to promote sexual health of FSWs, drug users and MSM. As described elsewhere in this report, since 2012 peer-led targeted interventions have been carried out successfully, providing sexual health services and HIV tests for thousands of members of KPs including FSWs, MSM and drug users. The NSACP has conducted several advocacy programmes for law enforcing authorities including judiciary to secure their support for peer-led targeted intervention programmes for KPs.

National Child Protection Authority Act No. 50 of 1998 – The National Child Protection Authority established under this Act has been empowered to take all measures as are necessary for the purpose of preventing child abuse and for protecting and safeguarding the interests of the victims of such abuse.

Education Ordinance – Chapter 185 – This Ordinance protects the right to education of a child and makes education compulsory for a child from 6 years to 14 years. It provides that no applicant shall be refused admission into any public or assisted school on account of religion, nationality, race, caste, social status or language of such applicant or either of his parents.

Maternity Benefits – The Maternity Benefits Ordinance (applicable to workers in the Estate sector), the Shop and Office Employees (Regulation of Employees and Remuneration) Ordinance (applicable to workers in the private sector) and the Establishment Code (applicable to the officers of the government sector) contain provisions enabling female workers to obtain maternity leave (paid leave) for specified periods of time. The respective provisions prevent employers from employing female workers during the said periods.

Legal Aid Law No. 27 of 1978 – The Legal Aid Commission has been established to provide legal assistance, advise and appear in courts to deserving persons throughout Sri Lanka. The objective of the Commission is to establish centres across the island to give legal aid for litigation and render assistance in other related matters to the needy, the deserving and the downtrodden.

Enforceability of the Human rights:

Judiciary – The Supreme Court of Sri Lanka has jurisdiction to hear matters relating to the infringement or imminent infringement of the Fundamental right of any person by an executive or administrative action by a state authority and grant relief.

Human Rights Commission of Sri Lanka Act No. 21 of 1996 – The Human Rights Commission is empowered to inquire and investigate into complaints regarding compliance with the provisions of the Constitution relating to the fundamental rights and to promoting respect for and observance of fundamental rights.

Parliamentary Commissioner for Administration Act No 17 of 1981 – This Act enables a person whose fundamental rights have been infringed to obtain redress.

Other measures:

National Plan of Action for Women – This was adopted in 1996 consequent to the World Conference on Women in Beijing and based on the Global Platform for Action on Women. Violence against women, women and human rights, women and armed conflict, health, decision-making are some of the areas covered in the Action Plan.

A National Committee on Women was established to monitor the implementation of rights under the Women's Charter. A Women and Children's desk has also been established in police stations to assist affected women and children.

Related policies:

The National HIV/AIDS Policy – The National HIV/AIDS Policy was developed by the MoH in 2011 and was approved by the Cabinet of Ministers. The objectives of the policy were to prevent HIV and other STIs in Sri Lanka through effective strategies aimed at reducing sexual transmission, transmission through blood and blood products, and MTCT, and to improve the quality of life of people infected and/or affected by HIV/AIDS.

These strategies emphasize the importance of protecting and promoting human rights of people living with HIV/AIDS. These include non-discrimination and non-stigmatization, having enabling environment to seek relevant services, equality before law, the right to work and education, the right to sexual and reproductive health services and the right to knowledge about HIV/STIs-related issues (NSACP, 2011).

National Health Policy (MoH, 2016b) – The present health policy was available for the public with a vision of a healthier nation that contributes to its economic, social, mental and spiritual development and with guiding principles for a people-centred health system in Sri Lanka. The policy was approved by the Cabinet of Ministers in 2017. Among other things, it addresses the following broad strategic directions which guarantee equal rights as well as equitable access for health services:

- Appropriate and accessible high-quality curative care for all Sri Lankan citizens
- Strengthening service delivery to achieve preventive health goals

National Policy on Maternal and Child Health – It is directed at women during pregnancy, delivery and postpartum period, and at newborns, infants and children up to 18 years (GoSL, 2012). The policy consists of the following:

1. Promotion of health of women and their partners to enter pregnancy in optimal health, and to maintain it throughout their life.
2. Ensure a safe outcome for both mother and newborn through provision of quality care during pregnancy, delivery and the postpartum period.
3. Reduction of perinatal and neonatal morbidity and mortality through provision of quality care.
4. Enable all children up to 9 years to survive and reach their full potential to growth by providing optimal nutritional status, immunization and psychosocial development.
5. Ensure that national, provincial, district and divisional level health managers are responsive and accountable for provision of high quality MCH services.
6. Ensure effective M&E of maternal and child care programmes that would generate quality information to support decision-making.
7. Promote policy research on best practices in MCH.
8. Ensure sustainable conducive behaviours among individuals, families and communities to promote MCH.

National Action Plan for the Protection and Promotion of Human Rights, 2017– 2021

One of the objectives of this national plan is to guarantee the human rights of people living with HIV and AIDS.

This includes protecting the right to life explicitly, protecting personable liberty, the right to privacy and security and freedom from arbitrary arrest; guaranteeing equality and non-discrimination; provide equal rights with access to ownership, access to sexual and reproductive health and rights (GoSL, 2017).

National Policy on HIV and AIDS in the World of Work in Sri Lanka (ILO, 2010)

The National Policy on HIV and AIDS in the World of Work in Sri Lanka has been developed by the Ministry of Labour and Labour Relations, with the help of the ILO in June 2010, for the safety of the workforce in Sri Lanka from HIV and AIDS, access to treatment and care, prevention of stigma and discrimination of PLHIV and protection of human rights of PLHIV who are in the workforce. Sri Lanka has a workforce of nearly 7.6 million men and women in the formal and informal sectors.

Prison HIV Prevention, Treatment and Care Policy 2017 (NSACP, 2017f)

The NSACP, together with the Department of Prisons and other stakeholders, developed the Policy on Prison HIV Prevention, Treatment and Care.

The main objectives are:

1. Prevent HIV among all prisoners in prison settings
2. Enable prisoners to know their HIV status
3. Provide access to treatment for HIV and STI
4. Preserve and protect the rights of people living with and affected by HIV
5. Ensure that the prison environment is conducive to promote and preserve the health of prisoners and prison staff

The document was approved by the Cabinet in 2019.

Circulars

1. **Circular No. 01-51/2016** – Programme for ending AIDS by 2025 in Sri Lanka (Annexure 12)

It states the importance of maintaining confidentiality of details of patients and requires to respect the human right of those living with HIV.

2. **Circular No. 01-59/2016** – Programme for EMTCT of HIV and syphilis in Sri Lanka (Annexure 10).

This circular states the measures to be taken to scale up services for pregnant women for EMTCT of HIV and syphilis. It highlights the importance of screening antenatal mothers before 12 weeks of gestation for HIV and syphilis and providing services without stigma and discrimination

3. **Circular No. 01-31/2017** – Guideline for education and demonstration of condoms (Annexure 13)

This circular instructs the directors of central and provincial institutions and campaigns to create awareness about condoms.

4. **Circular No. 01-25/2015** – Sexual and reproductive service for adolescents (Annexure 14)

This circular ensures sexual and reproductive health services for all adolescents including pre-pregnancy care, pregnancy care, contraceptive/ family planning service, prevention, care and management of STI and HIV/AIDS and prevention of GBV.

5. **Circular No. 01-34/2016** – Gender Recognition Certification (Annexure 15)

This circular allows the consultant psychiatrist to issue a Gender Recognition Certificate (GRC) to assist with the process of changing the sex on a birth certificate.

6. **Circular No. 01-19/2017** – Management of health-care worker following occupational exposure to blood and other body fluids and post-exposure prophylaxis for HIV (Annexure 16)

This circular suggests the management of health-care workers who experience occupational exposure to blood and body fluid that might contains HIV.

National Health Strategic Master plan (2016–2025) (MoH, 2016b)

It is a comprehensive health plan with monitoring tools from 2016 to 2025, which is people-centred and includes Equity, Accessibility, Quality and Financial security.

Population and Reproductive Health Policy 1998 (MoH, 2016c)

This policy addresses reproductive health aspects such as safe motherhood, subfertility, induced abortion, STI and HIV.

Sri Lanka National Migration Health Policy 2012

The policy ensures access to reproductive health information and services to all internal, in-bound and out-bound migrants.

Validation tools and check lists

Interviews were conducted with relevant stakeholders, such as consultants from the legal draftsman's department, officers from the Attorney General's Department, consultants of GBV unit of the MoH and officials of the Ministry of Law and Order.

Semi-structured interviews were conducted with women living with HIV, Positive Women's Network, Positive Hopes Alliance and Lanka plus (organizations of PLHIV), regarding their views on human rights related to HIV and women's right, as well as EMTCT programmes and services. Focus group discussions were conducted with FSWs to understand issues related to GBV as well as stigma and discrimination.

Interviews were conducted with national HIV and EMTCT programme managers, provincial and regional authorities and health service providers such as consultants, medical officers, nurses and midwives regarding their views on human rights related to HIV. The validation tool checklists were used.

During these discussions the following points were highlighted;

1. There are no laws to criminalize exposure to HIV or syphilis or non-disclosure of status on HIV/syphilis to sexual partners.
2. According to the national HIV/AIDS policy, the GoSL promotes voluntary confidential counselling and testing. There is no mandatory testing or treatment for HIV or syphilis. Pregnant women are informed that they have a right to refuse testing or treatment. There are no documented reports of mandatory testing or treatment. Informed consent is an essential component in testing for HIV.
3. According to the General Circular issued by the MoH (Circular No. 01-25/2015) a medical officer could consider providing adolescent reproductive health services to a minor (below the age of 18 years) considering the best interest of the child. It is likely that such minors would engage in sexual intercourse, which is detrimental to the physical and mental health, if such services are not provided. These services include pre-pregnancy care, antenatal care, intranatal care, postnatal care, family planning services, prevention care and management of STI/HIV as well as GBV (Annexure 14).

Further information is given in the guidelines to health staff on providing adolescents sexual and reproductive health services. The country has experience in adequately managing few adolescents with HIV including a pregnant teenager (17 years) with relevant stakeholders.

4. There are no reports of forced or coerced contraception or abortion.
5. Confidentiality and privacy are important components in the management of PLHIV and patients with STIs. Circular No. 01-59/2016 on the EMTCT programme and Circular No. 01-51/2016 on

ending AIDS by 2025 both emphasize the importance of providing services without stigma/discrimination and the importance of confidentiality (Circular No. 02/125/98) (Annexure 17).

6. The national HIV/AIDS policy states that the GoSL accepts the rights of those living with HIV to have access to treatment without stigma and discrimination. The national policy further states that the GoSL will ensure that the human rights of PLHIV are promoted, protected, respected and measures taken to eliminate discrimination and combat stigma.
7. Laws currently applicable for KPs include the Brothels ordinance, Vagrants ordinance and 365A ordinance which deals with unnatural sex indicating anal sex as an offence. However, these laws have not affected prevention programmes in the community for KPs. Regular programmes are conducted for law enforcement officers on the importance of HIV prevention among KPs to create an enabling environment.

Community engagement

KP communities and PLHIV support groups regularly attend meetings of the NAC and subcommittees and they are also members of the EMTCT steering committee and the NVC. There are three PLHIV support groups. All of them regularly engage in planning, implementation and monitoring of EMTCT programmes. KP organizations are well represented in CCM. Further, the KP task force includes all KP organizations. KP organizations are members of the NAC and legal and ethical and HIV care sub committees.

The inputs given by the members are taken into consideration in revising the operational plan.

Gender-based violence

There are several policies which address GBV. The population and reproduction policy of Sri Lanka of 1998 identifies achieving gender equality as an important issue that needs to be addressed.

The formation of the National Committee for Violence of the MoH shows the commitment of the state. It addresses GBV as well. The FHB has a separate directorate responsible for women's health inclusive of GBV issues. The MCH policy recognizes the role of the health sector in addressing GBV. Goal 8 of the MCH policy states: "to promote reproductive health of men and women assuring gender equity and equality". Based on the recommendations, 68 service centres have been established in major hospitals. In 2016, there have been 7577 new survivors of GBV attending these centres and the total consultations for 2016 was 17 028. A multi-sectoral action plan on GBV (2016–2120) has been developed under the leadership of the Ministry of Women's Affairs. The national HIV/AIDS strategic plan 2012–2017 says: "all planning service delivery and research should be done with gender equality in mind" (NSACP, 2012).

8. As services are free of charge, these are accessible to all including FSWs.

MCH services, sexual and reproductive health services and family planning services are available freely from the public health sector to all women in need.

Health-care workers who provide EMTCT services including staff attached to MCH services in the field and hospital and STD clinics are given regular training on the following:

- Sexual and reproductive rights of people including PLHIV
- informed consent
- maintenance of patients' confidentiality
- importance of identifying GBV and referrals

- provision of quality maternal health-care services.
9. The legal and ethics subcommittee of the NAC is responsible for monitoring human rights violations of KPs and PLHIV. PLHIV are encouraged to report any stigma or discriminatory practices to the subcommittee. There are reported cases of PLHIV taking their issues to courts and the Human Rights Commission.

The judgment given on SC.FR.No. 77/2016 on 14 March 2016 states: “The court also wishes to place on record that the state should ensure that the human rights of the people living with HIV/AIDS are promoted, protected and respected and measures to be taken to eliminate discrimination against them” (page 4).

There is a reported incident of stigma and discrimination experienced by a pregnant woman with HIV. The woman had undergone emergency lower segment caesarean section (ELSCS) at a major hospital and later attended the closest primary level hospital for removal of sutures. She reported that she was discriminated against while providing services. The matter was taken seriously and the area consultant venereologist visited the hospital and had a discussion with hospital authorities followed by a training programme for health-care workers to improve attitude towards PLHIV.

Much work has been carried out in Sri Lanka to fight stigma and discrimination against people living with and affected by HIV. The actions show a positive trend.

Reporting of the stigma index is one way to measure the existence of such stigma experienced by PLHIV. The first survey on stigma was done in Sri Lanka in 2010. The survey was repeated in 2017 and the results of the stigma index were still high: feeling of shame 42.7%, self-blame 46.7% and feeling of guilt 31.3%. Thus, measures need to be taken to improve the situation (NSACP, 2017d).

According to the study conducted in 2015 among women infected with HIV, self-stigma plays an important role in a person's ability to adjust to life with HIV. Fewer women experienced discriminatory practices by neighbours or in the workplace as they had not disclosed their HIV status (NSACP, 2015b)

Involvement of PLHIV organizations in national response for HIV

Currently, there are three PLHIV organizations working with NSACP closely to facilitate HIV care services in the country. They actively participate as members of the HIV care subcommittee, NAC and NVC of the EMTCT programme. Representatives are members of working groups of NVC.

A PLHIV centre managed by Positive Women's Network has supported pregnant women who have social or financial issues. The organization is headed by Ms Princy Mangalika, a strong advocate of women's rights. She has received the Red Ribbon award for the tireless work to improve standard of PLHIV organizations. The centre provides accommodation facilities and meals for PLHIV who experience temporary difficulties.

Lanka Plus is another organization which provides accommodation facilities and meals for PLHIV. Positive Hopes Alliance, a PLHIV organization, conducts mainly prevention-related activities in the community.

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4. Limitations of evaluation methods

The EMTCT indicators were calculated using data reported from several sources including FHB (ANC data) and NSACP (STD clinic and national reference laboratory data). In addition, private health facilities were surveyed to estimate coverage of antenatal care and screening for HIV and syphilis (NSACP, 2018)

Limitations of existing data systems

There is limited data on the small proportion of pregnancies managed entirely in the private sector by private providers (5.4%). The country's policy is to provide free health services for all, and health services are accessible to all sectors of the community. However, with the development of the economy, a proportion of pregnant women seek services from private sector hospitals. All these hospitals provide specialist obstetric and paediatric services. The overall percentage of pregnant women who delivered in private sector facilities was 5.4% across the country (DHS, 2016) and higher in urban areas. Certain districts such as Colombo, Gampaha and Kalutara reported having >10% of deliveries in private hospitals, but these deliveries took place in 10 major private hospitals in Colombo. A survey (NSACP, 2018) conducted among pregnant women in 10 private hospitals in Colombo found that >80% of women had documented evidence for screening of HIV and syphilis at the time of delivery.

District (Subunit) coverage data

Customarily, some women go to their parent's place for their confinement. Further, the specialized hospital in a major city is identified for delivery services. Therefore, a woman gets registered for antenatal care services in one district but may end up in a different district for antenatal care services in late pregnancy, delivery and postnatal services. This may affect the coverage data of districts due to the denominator issues, which may be <95% in some areas, while some districts may have >100% coverage. However, continuity of services is not affected as the pregnant woman carries her antenatal case record with her (H512).

Problems related to estimations. Process indicators (antenatal care and HIV testing coverages) are measured against the estimated number of pregnancies, which is estimated from live births registered at the Registrar General's Department using a fixed formula (estimated pregnancies = live births registered at RGD x 1.1). According to the DHS, 99.9% of deliveries took place in health-care institutions. Data from FHB showed that nearly 100% of institutional deliveries occur in institutions with specialist services (FHB, 2018). Therefore, the number of live births registered in major cities are much higher than that in other places, giving a higher estimate for these districts. As the denominator (estimate of pregnancies) gets higher, the coverage of services automatically gives a lower value. However, it should be noted that the national-level indicators are not affected by this practice.

Numerator for HIV and syphilis testing coverage. Currently, antenatal HIV and syphilis testing data are not reported through MCH services. Numerator for number of HIV and syphilis tests in pregnancy was obtained from the SIM unit, NSACP. All blood samples from ANCs are sent to the area STD clinic for VDRL and HIV tests. Quarterly STD clinics report the number of ANC HIV and VDRL tests done to the SIM unit of the NSACP. The FHB collects data on VDRL and HIV tests related only to the first visit in pregnancy and at the time of delivery.

Other numerator and denominator discrepancies and artefacts arise from programmatic factors such as the laboratory testing schedules. All HIV and syphilis tests are run from one sample, yet reported

numbers may vary when testing is done at different times. However, these differences are noted to be converging in recent quarters.

e-RHMIS was introduced in the MCH services in 2017. The NSACP started the EIMS in 2018. Some difficulties were observed during this transition period as health-care workers are getting adjusted to the new systems.

Limitations in laboratory services validation

The laboratory system has many in-built strengths which facilitated country-wide EMTCT testing. Nevertheless, the laboratory system has some drawbacks, which make it difficult to move fast to achieve global quality standards.

Documentation

Poor documentation that existed in the laboratory system was a challenge for the quality management system, which needed much effort to implement the critical changes. The documentation was limited to a few registers and reports. This had to be improved with addition of records for environmental monitoring, equipment identification and monitoring, introducing logs and inventories for equipment, and many documents in supply chain management, reporting and recording.

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5. Key findings: achievements and indicators

5.1. Country context for assessing the EMTCT programme

The EMTCT of HIV and syphilis programme in Sri Lanka builds on strong foundations of public health services that have facilitated declining transmission of STIs over several decades. With recent improvements in detection and management of HIV and syphilis in pregnant women, rates of MTCT for both diseases have fallen well below the global elimination targets – consistently <5 per 100 000 live births. The performance of the EMTCT programme currently meets or exceeds 95% targets for ANC attendance, early screening for both HIV and syphilis, and syphilis treatment. All pregnant women with HIV have started lifelong ART with excellent adherence and retention.

This success is due primarily to strong prong 1 and prong 3 interventions and services that maintained low transmission among adults while detecting increasingly rare maternal infections early in pregnancy. These critical pathways are highlighted in Fig. 5.1.

Fig. 5.1. EMTCT Critical Pathway in Sri Lanka

Prong objective	Current status	Programmatic Progress	Evidence
1. Transmission low / declining among adults	Very low HIV prevalence (0.03%*)	Appropriate prevention focus on key population	Very good: through STD clinic reports
➔ Very low transmission among adults means few maternal infections			
3. Detection of maternal infection	>95% ANC >95% HIV Screening >95% Syphilis screening	Scale-up since 2013 with close monitoring	Excellent FHB and NSACP monitoring
➔ Universal ANC attendance with complete HIV and syphilis screening means no missed cases			
<div style="text-align: center;">↓</div> Systems in place for individual case management of any pregnant woman found with HIV or syphilis Extremely small numbers of cases permit complete care and follow-up of infected mothers and infants		Prong objective	Current status
		Prevention of Unwanted pregnancies	Available for positives
		4. Management of maternal infection	100% of positives
		4. Follow-up and management of newborn	100% of exposures

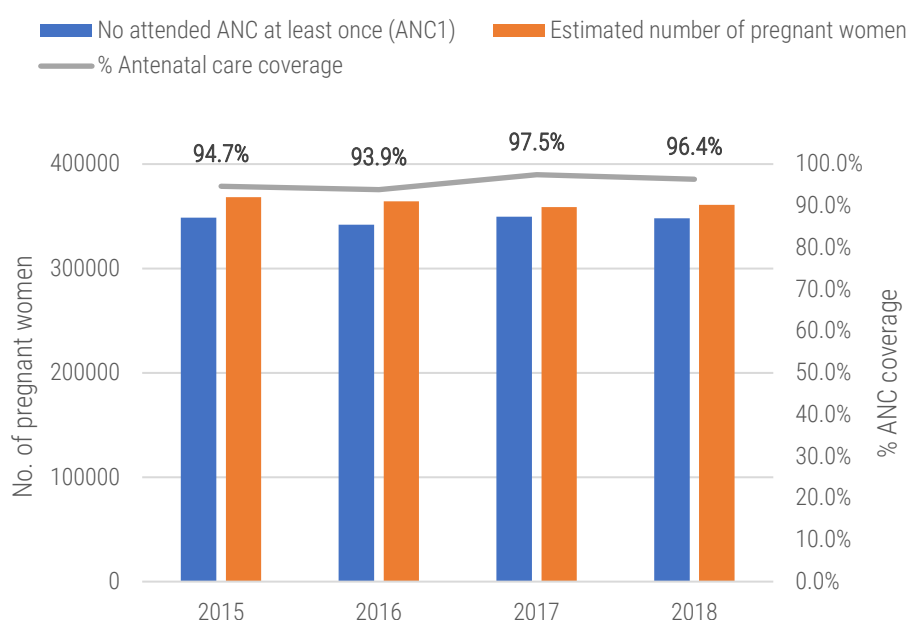
*Spectrum data, SIM Unit, NSACP, 2018

High-level commitment is evident throughout the implementation of the EMTCT programme. The country assigns high priority to EMTCT of HIV and syphilis, allocating resources, assigning an EMTCT coordinator,

engaging key stakeholders and meeting frequently to review progress and data. The MoH has issued circulars for both the public and private sectors for promoting attendance at ANC, early screening for HIV and syphilis, and monitoring of key indicators.

Impact indicators well surpass minimum EMTCT criteria, with no MTCT of HIV and very few congenital syphilis cases occurring during the past two years. Even maternal rates of infection (0.008% for syphilis and 0.003% for HIV among pregnant women in 2018) are well below the EMTCT impact indicator cut-off levels. There were 16 deliveries in 2018 among women living with HIV, while 36 pregnant women who had syphilis delivered in the same year. All women received treatment following national protocols, and the newborns remain free of infection. Process indicators have progressively improved, exceeding 95% coverage for attendance at ANC, screening and treatment coverage for HIV and syphilis since 2017 (Figs 5.2, 1.10, 1.13, 5.3, 5.5).

Fig. 5.2. Coverage of ANC services, 2015 - 2018



Source: SIM Unit, NSACP, 2018

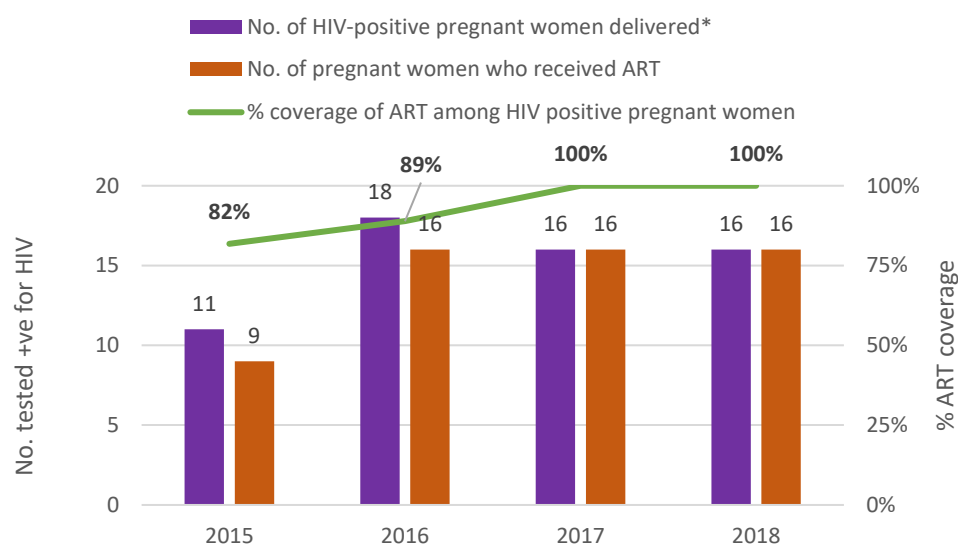
5.2. Achievement of EMTCT of HIV

In 2018, the prevalence of HIV among pregnant women was 0.003%, based on NSACP data that covers 33 STD clinics across the island (Fig. 1.12). In 2018, government STD clinics offered HIV testing services for 95.9% of pregnant women (Fig. 1.10). Sixteen HIV-positive pregnant women delivered in 2018. All were provided ART from early pregnancy and exposed infants were given syrup nevirapine for six weeks (Fig. 5.3).

The MTCT of HIV rate has decreased significantly since the use of triple ART from 14 weeks of period of amenorrhoea (POA) according to the rapid advice recommendations of WHO in 2009. This has been practised since 2010 and included in the national guidelines for all HIV-positive pregnant women (option B) in 2011. In 2013, it was decided to continue treatment for pregnant women for their lifetime. Since 2011, none of the babies born to pregnant women who received EMTCT services for HIV were infected.

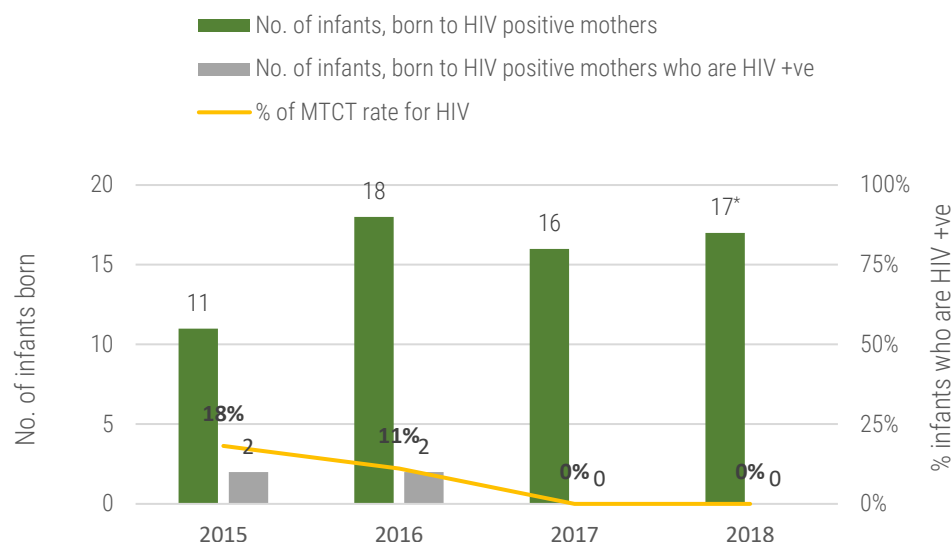
Two infants each were diagnosed with HIV in 2015 and 2016. They were born to women not detected of HIV during pregnancy and therefore had not received EMTCT services. HIV testing services for pregnant women were scaled up to cover the entire country by end-2016 (Fig. 5.4).

Fig. 5.3. HIV care services for pregnant women diagnosed with HIV, 2015-2018



Source NSACP Annual report 2018

Fig. 5.4. MTCT rate of HIV among infants born to pregnant women diagnosed with HIV, 2015 – 2018



*One twin delivery reported in 2018.

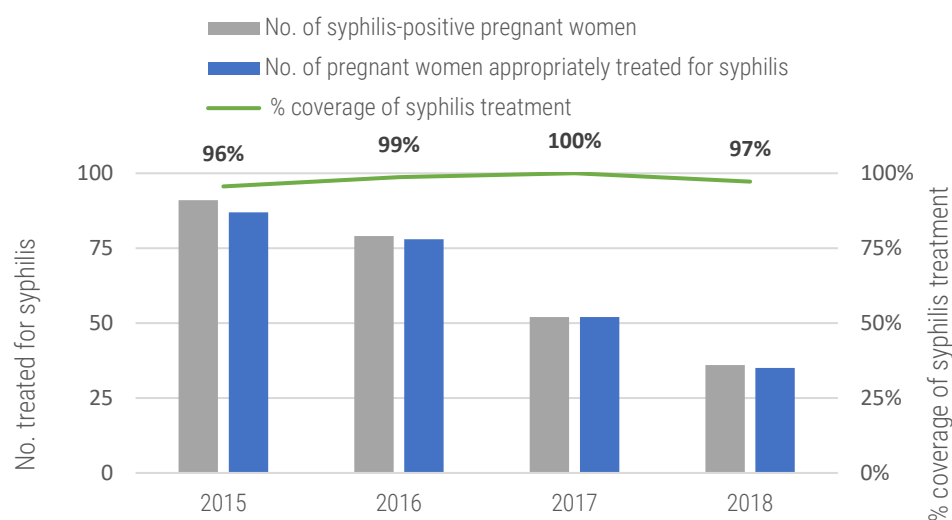
** Two infants were diagnosed in each year 2015 and 2016

Source: SIM Unit, NSACP, 2018

5.3. Achievement of EMTCT of syphilis

Sri Lanka initiated screening for syphilis during pregnancy in 1952. In 2018, 99.3% of pregnant women received syphilis testing and the prevalence of syphilis during pregnancy was 0.008%. Almost all pregnant women with syphilis are treated and followed up at STD clinics until delivery (Fig. 5.5). Five cases of congenital syphilis (1.5 cases per 100 000 live births) were reported to the NSACP in 2018, and five cases (1.5 cases per 100 000 live births) in 2017 (Table 5.1).

Fig. 5.5. Coverage of syphilis treatment among pregnant women, 2015 – 2018



Source: SIM Unit, NSACP, 2018

Table 5.1. Congenital syphilis cases and rate, 2015- 2018

Year	Global surveillance case definition	Rate/100 000 Live births
2015	13	3.9
2016	9	2.7
2017	5	1.5
2018	5	1.5

Source: SIM Unit, NSACP, 2018

5.4. Key elimination indicators

Tables 5.2 to 5.8 summarize EMTCT achievements by impact and process indicators for Sri Lanka.

Table 5.2. EMTCT of HIV and syphilis impact and process indicators

	Target	2018 numerator/ denominator	2017 numerator/ denominator	Data sources	Comments
Impact indicators					
Annual number of live births	NA	328,112	326,052	RGD	Live births registered
HIV mother-to-child transmission (MTCT) rate by birth cohort	<2%	0/17* 0%	0/16 0%	NSACP	*One twin delivery in 2018
Annual rate of new paediatric HIV infections per 100 000 live births	≤50	0/328,112 0	0/326,052 0	NSACP / RGD	Two infants were diagnosed in each year 2015 and 2016. HIV testing services covered the whole country in late 2016.
Annual rate of congenital syphilis cases (including syphilis-associated stillbirths) per 100 000 live births	≤50	5/328,112 1.5	5/326,052 1.5	NSACP / RGD	Global surveillance case definition used.
Process indicators					
ANC1 coverage (government sector)	>95%	347,954/360,923 96.4%	349,524/358,657 97.5%	FHB/RGD LB*1.1	Estimated pregnant women = live births registered x 1.1
HIV testing coverage of pregnant women	>95%	345,985 /360,923 95.9%	341,318 /358,657 95.2%	NSACP / RGD LB*1.1	Estimated number of pregnant women
Syphilis testing coverage of pregnant women	>95%	345,657 /347,954 99.3%	338,662 /349,524 96.9%	NSACP / FHB	ANC attendance at least one visit
ART coverage of HIV- positive pregnant women	>95%	16/16 100%	16/16 100%	NSACP	HIV-positive pregnant women delivered in the respective year
Adequate treatment coverage of syphilis- positive	>95%	35/36 97%	52/52 100%	NSACP	Syphilis-positive pregnant women delivered in the respective year

Table 5.3. Achievements of lowest-performing District- Vavuniya District

	Target	2018 numerator/ denominator	2017 numerator/ denominator	Data sources
Impact indicators				
HIV mother-to-child transmission (MTCT) rate by birth cohort	<2%	0/0 0%	0/0 0%	NSACP
Annual rate of new paediatric HIV infections per 100 000 live births	≤50	0/ 4153 0	0/ 3836 0	NSACP/RGD LB
Annual rate of congenital syphilis cases per 100 000 live births	≤50	0/ 4153 0	0/ 3836 0	NSACP/FHB
Process indicators				
ANC1 coverage	≥95%	2950/ 4568 64.6%	2818/4220 66.8%	FHB/RGD LB*1.1
HIV testing coverage of pregnant women	≥95%	2961/4568 64.8%	2762/4220 65.5%	NSACP/ RGD LB*1.1
Syphilis testing coverage of pregnant women	≥95%	2961/2950 100%	2762/2818 98.0%	NSACP/ FHB
ART coverage of HIV-positive pregnant women	≥95%	0	0	NSACP
Treatment coverage of syphilis-positive women	≥95%	0	2	NSACP

Source: SIM Unit, NSACP, 2018

District of Vavuniya was identified as the lowest performing subnational units (districts) based on the services, geographical difficulties in accessibility and human resource issues. Vavuniya is in the Northern province which experienced a civil war for thirty years before 2009. Services have been improved during recent years with improvements in infrastructure with increased donor funding in addition to the contribution of MoH. Poor geographical accessibility and lack of human resources are concerns to improve the quality of health services. However, the basic health services are available to all and coverage levels are satisfactory. (Table 5.3)

ANC1 coverage was 64.6% and HIV screening coverage was 64.8% due to the issues in the denominator. The denominator used for these two indicators was the estimated number of pregnant women. The estimated number of pregnant women was calculated by multiplying number of live births registered in the year by 1.1. The addition of 10% is the correction factor to cover pregnancies ending with foetal wastage.

As Vavuniya is a major hospital in the area many pregnant women in other districts seek services in the DGH Vavuniya. Live births are registered based on the place of birth. Therefore, when the number of live births in the hospital increases estimated number of pregnancies in the district also increase. Due to this issue there is an artificial increase of the estimated pregnancies (denominator) which leads to reduction in the coverage levels. However, if the number of mothers who had one ANC visit was used as the denominator the HIV testing coverage would have increased to 100%. It was clear the services were satisfactory in Vavuniya. Therefore, the district was selected not based on the coverage but due to the challenges of civil conflict, human resource issues and the poor geographical accessibility.

Table 5.3. Summary of HIV-exposed and -infected infants, 2018

No of HIV-exposed infants	No of HIV-exposed infants with final infection status	No HIV infected	No HIV-uninfected	No with missing or unknown HIV status
17*	17	0	17	0
Estimated HIV MTCT rate			1.95 in 2018 **	

*There was one twin delivery in 2018.

** Spectrum estimate done in 2019 for 2018

Source: SIM Unit, NSACP, 2018

In 2018 there were 16 deliveries and one was a twin pregnancy. Except one, all pregnant women had suppressed viral load by 36 weeks. All babies born in 2018 had negative DNA PCR at birth, 8 weeks and 16 weeks.

Table 5.4. For HIV-exposed and infected infants, 2017

No with 1 polymerase chain reaction (PCR) (+)	No Antibody (Ab)+ at 18 months	Comments
0	0	
No with >1 PCR (+)	No Antibody (Ab)+ at 18 months	Comments
0	0	

Table 5.5. Data for HIV-exposed and -uninfected infants, 2015–2018

	No with 1 PCR (+) and subsequent negative testing	No with 1 PCR (-)	No with >2 PCR (-)	No with 1 PCR (-) and antibody (Ab) (-) at 18 months	Overall percentage with Ab (-) at 18 months (of all those considered uninfected)
2015				9	100%
2016				16	100%
2017				16	100%
2018			17		

All babies born to pregnant women with HIV from 2015 -2017 have completed 18 months by June 2018. Their DNA PCR at birth, 8 weeks, 16 weeks and HIV ELISA test at 18 months gave negative results.

Table 5.6. Syphilis data table

	2018	2017
Prevalence of syphilis in pregnant women	0.01%	0.01%
(Number of syphilis cases in pregnant women/number of pregnant women tested)	29/345,657	43/338,662
Number of congenital syphilis (CS) cases	5	5
Number of CS stillbirths	1	0
Number of CS live births	4	5
Number of CS cases in untreated mothers	1	0
Number of CS cases in mothers treated late in pregnancy (less than 30 days before delivery)	1	0

Source: NSACP, 2018

In 2017 5 cases were identified under the global surveillance definition for congenital syphilis and all were asymptomatic. These included three babies whose mothers were treated with erythromycin in pregnancy. One baby's mother was treated adequate for syphilis in pregnancy but partner did not receive treatment. Baby's TPPA test result remained positive after 18 months. Therefore baby was treated as CS. Other pregnant woman had negative VDRL in early pregnancy. As she had high risk behaviours, VDRL, TPPA and HIV tests were repeated in the third trimester and she had VDRL – R(8) with positive TPPA. Mother was treated in late pregnancy and baby was also treated for CS.

In 2018 there were five cases of CS of which one case was symptomatic. This pregnant woman was screened for syphilis in 25 weeks and VDRL was NR. She started living together with a new partner in late pregnancy and may have contracted syphilis later. Two cases were included CS category as pregnant women were treated with erythromycin. One pregnant woman was diagnosed as having syphilis at 32 weeks and treated. She ended up with IUD at 36 weeks. It is not clear whether IUD was due to uncontrolled diabetes mellitus or syphilis. Both mother and partner were adequately treated.

Table 5.7. Review of issues around human rights, gender equality and civil society engagement

Issue	Yes /No	If yes, does this affect the decision to validate for elimination? Why? What are the suggested recommendations for the country?
Is there criminalization of vertical transmission?	No	
Is there mandatory or coerced testing and/or treatment for HIV and syphilis?	No	
Is there lack of informed consent?	No	
Is there forced and coerced abortion, contraception and/or sterilization?	No	
Is there a lack of confidentiality and privacy?	No	
Is there lack of equality and non-discrimination?	No	
Is there lack of availability, accessibility, acceptability and quality of sexual and reproductive health and ANC services?	No	
Is there a lack of accountability and absence of participation and community engagement?	No	
Are there laws to protect women from gender-based violence?	Yes	
Is there a lack of access to justice, remedies and redress?	No	

5.5. Assessment of strengths for sustaining EMTCT and potential risks

The MoH Sri Lanka is confident of sustaining the success of the EMTCT of HIV and syphilis programmes. The EMTCT of HIV and syphilis programmes were developed and incorporated into the existing PMTCT of syphilis programme in 1952 and PMTCT of HIV programme in 2002. MCH services were established in the 1920s and the infrastructure, human resources and facilities have been developed over the years to provide quality services for pregnant women and children (GoSL, 2012).

High quality STI and HIV services

The NSACP has evolved over the years scaling up services through the STD clinic network in the country. Laboratory services for STI including HIV have improved in both quantity and quality under the NRL, NSACP. According to the Report on Global Sexually Transmitted Infection Surveillance 2013 by WHO, "Countries such as Cuba and Sri Lanka offer a basic set of quality STI services that are widely accessible and include outreach to high-risk settings. In Sri Lanka, STIs have been in decline over decades and were already low in the 1980s when HIV emerged globally. Continued strengthening of STI control and further declines helped to avert emergence of an HIV epidemic despite multiple factors, including an uncircumcised male population and a protracted civil war, that have facilitated growth of HIV epidemics in other countries" (WHO, 2013b).

Strong MCH services

MCH services in Sri Lanka have a long history since 1920. With scaled-up services to cover the entire country under the RMNCAYH programme, Sri Lanka has recorded marked improvement of health-related indicators in the past six decades.

Leadership and commitment of the government

Sri Lanka adopted the Free Health Policy after gaining independence and has been consistent in its progress ever since. As the national policy is to provide free health services for the entire population, accessibility to services for MCH or STI is ensured.

The active involvement of authorities at all levels of the MoH in various committees at the national, provincial and regional levels indicates their commitment to achieve the EMTCT targets and to maintain the same.

Sound financial support

The EMTCT programme is funded entirely by the MoH. The assistance given by UN agencies such as UNICEF and WHO facilitated activities on training, advocacy and reviews. GFATM provides support for implementation of targeted interventions for KPs and for establishing EIMS. More than 90% of government spending on health is financed by the treasury and the rest is funded by multilateral agencies, international organizations and bilateral aid.

Strong links between MCH and STI services

The EMTCT programme is fully integrated into the MCH system as well as into the STD services. The coordinator for the EMTCT programme works in collaboration with the coordinators responsible for four main domains of the NSACP and FHB. Strong links developed between MCH services and the NSACP since 1952 have strengthened through the EMTCT programme. At the district level the district authorities, consultant community physicians and the consultant venereologists/MOs of STD clinics work together to achieve a common objective

Qualified health-care workers

Qualified health-care personnel who get updated with regular training are the main asset of the programme. Increase in coverage of HIV testing among pregnant women from 5.6% in 2012 to 95.9% in 2018 proves their contribution to the programme.

Satisfactory surveillance system in MCH and STI services

Surveillance systems have been in place for STI and MCH services for several decades. With the introduction of e-RIHMS for MCH services and EIMS for STI/HIV services, surveillance will get strengthened further.

Involvement of stakeholders

Involvement of KPs and PLHIV at all levels of the programme has facilitated to increase awareness among these groups. These groups are actively involved in the programme and assure their support to achieve the objective of having a future generation free of HIV and syphilis.

Risks

Use of point-of-care tests. The programme employs laboratory-based tests, which involves collection, transport and testing requiring time and human resources. The possibility of introducing the rapid tests in some areas which experience difficulties due to geographical accessibility issues, etc. will be considered in the future. Discussions will be held regularly at the NVC and relevant decisions will be taken based on the consensus between FHB and NSACP.

GFATM transition. GFATM has been supporting programmes for KPs since 2012. Currently, the GFATM-funded programmes are in the transition phase where the GFATM funding is reduced and GoSL is expected to take over the activities by 2022. This might affect HIV and STI programmes.

Private sector data. The private sector surveillance system has to be improved in parallel with the public sector surveillance systems. A system needs to be developed to regularly collect MCH and STI/HIV data of private hospitals. The M&E unit of the FHB has started work to improve this area.

Migrants

Though inbound health assessment has been introduced for documented migrants, undocumented migrant population may have an impact on the disease burden of HIV and STI in the country. This will be taken into account when planning for the future.

Risks in relation to laboratory services

Infrastructure and equipment management.

Devolution of the health system since 1987 to provinces has posed many obstacles in developing the infrastructure and management of equipment. The STD clinic and the laboratory are directly under the administration of the provincial health ministries, PDHS and RDHS. In some areas, the support extended by the district authorities to maintain quality of laboratory services is not satisfactory, which needs to be improved to maintain high coverage.

Human resource.

Efforts to improve the quality of services are affected by poor distribution of human resources to the STD clinic settings in the provinces.

Long procurement procedure for equipment and reagents

The routine procurement of laboratory reagents in the public sector is a lengthy procedure of about 18 months. However, the coordination extended by the MSD and SPC is appreciable in preventing stock-outs by supporting local purchase and by streamlining the supply chain management.

Importance of the attitudes and behaviour

The proactive nature of the technical staff is the key requirement in fast-tracking the journey towards quality. In any programme, implementing changes in attitudes and behaviour can be challenging. Though poor attitudes towards quality improvements to meet modern standards affected the progress in the initial phase, the situation improved later.

Challenges in relation to Legal system

There are laws such as 365A, Vagrants and Brothels Ordinance and drug-related laws which are directly or indirectly related to the KPs identified as most at risk for HIV. These laws have been introduced more than a century ago and have created issues in interpretation in the current settings. Several organizations have made representations to responsible authorities to modify or repeal these laws to suit current needs of the country.

Sri Lankan youth are seriously affected by drug use and several measures have been taken in the recent past under the directives of the current government to improve this situation. Some hard decisions have been taken to tackle issues concerning drug abuse among youth.

A decision was taken recently to implement the death sentence to drug dealers who operate the drug-dealing network in the country. However, many religious, political and community organizations have opposed this move. Several petitions have been filed in the Supreme Court by civil society organizations, religious leaders and concerned citizens against the proposed death sentence for drug dealers and the Supreme Court has suspended the proposal.

The NSACP has been working with the legal fraternity and law-enforcing authorities for several years to assess the effect of these laws to the HIV prevention programmes for KPs. The Legal and Ethics Subcommittee and Multisectoral Subcommittee of the NAC have been working on these aspects to mitigate. Several awareness programmes have been conducted for law-enforcing authorities and the legal fraternity to create an enabling environment for prevention of HIV transmission among KPs. Advocacy programmes have been conducted for parliamentarians to address these issues and will be continued in the future as well.

The support extended by the Department of Police in implementation of the targeted interventions for KPs has been encouraging. Prisoners have been identified as a KP group and provided opportunities within prisons countrywide to learn prevention of HIV and STI and to get services. Some incidents of resistance from the community have been reported during implementation of prevention activities, which was mainly due to poor advocacy in the pre-implementation period. The high degree of confidence that the health system enjoys among community, political and religious leaders has helped to resolve many issues in relation to implementation of HIV prevention programmes among FSWs, MSM, beach boys, drug users and prisoners. The NSACP has practised an inclusive and participatory approach while giving leadership to the national response to HIV since 1980s and working with NGOs, CBOs, KPs and PLHIV organizations.

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6. Elimination of MTCT of HIV and syphilis programme in Sri Lanka

Introduction

The MoH had clearly identified the importance of antenatal screening for syphilis as a major component of antenatal services provided by the public sector as far back as the 1950s. The programme for elimination of congenital syphilis was officially launched in 2009.

6.1. National EMTCT of HIV policies and programme

The four-pronged model of WHO is considered in the implementation of PMTCT of HIV programme. The first prong is primary prevention of HIV among women of reproductive age. The second prong is on coverage of family planning services, which indicates that higher family planning usage will reduce unplanned pregnancies among women living with HIV. An HIV-positive woman who wishes to become pregnant is supported to have a planned pregnancy with appropriate EMTCT services. The third prong covers EMTCT services during pregnancy starting with early diagnosis and early initiation of ART. This includes appropriate obstetric services as well as infant management. Early infant diagnosis, prophylaxis with syrup nevirapine and AFASS infant feeding are important components in infant management. The final prong involves management of HIV-positive women and infected and affected children including continuum of care after delivery (NSACP, 2018b).

PMTCT of HIV was initiated in early 2002 with the introduction of ART for HIV-positive pregnant mothers. Guidelines for management of pregnant women with HIV infection have been developed and updated regularly in 2008, 2011 and 2016 (NSACP, 2016a).

Based on the clinical trial ACTG 076, treatment with zidovudine (AZT) became the standard of care for PMTCT of HIV in the developed world. In 1995, a trial of short-course AZT for pregnant women was launched in Bangkok (Shaffer et al., 1999). Based on the Bangkok study, Sri Lanka introduced a short-course AZT regimen for PMTCT of HIV in 2002. The ART regimen in pregnancy has been changed periodically based on WHO's and other relevant guidelines. In 2002, the PMTCT regimen for pregnant women consisted of a single dose of AZT starting at 28 weeks of gestation for the HIV-positive mother and for her infant starting at birth for a period of six weeks. The PMTCT regimen was changed to AZT + single-dose NVP (WHO option A) in 2004. Triple ARV therapy (WHO option B) was introduced globally in 2009 and initiated in Sri Lanka during the same period. Lifelong triple ARV therapy was initiated in 2013 (NSACP, 2016b).

However, these services were limited to a few sites. It was necessary to scale up the PMTCT services to cover all pregnant women in the country. In 2012, 99.8% of pregnant women who registered for ANC services were screened for syphilis, of which 60% of testing was carried out at government STD clinics. However, in the same year, the HIV testing coverage of pregnant women was only 5.6%. Therefore, screening for HIV among pregnant women had to be scaled up immediately, starting from areas with a high caseload to reach those in need. WHO consolidated guidelines on the use of ART released in August 2013 recommended HIV testing for all pregnant women through provider-initiated testing and counselling (PITC) in low-prevalence settings such as Sri Lanka (WHO, 2013).

Elimination of MTCT of HIV and syphilis programme

In 2013, the decision was taken to integrate “Prevention of mother-to-child transmission of HIV programme” into the existing elimination of congenital syphilis programme and the new programme was named as “Elimination of mother to child transmission (EMTCT) of HIV and syphilis programme”. The main objectives were to offer HIV and syphilis testing services to all pregnant women, provide information for prevention of infection among women and to provide treatment services to all pregnant women with HIV or syphilis and to the exposed infants.

The EMTCT programme for HIV and syphilis of Sri Lanka was launched in mid-2013, at a gathering of medical authorities of the MoH, MCH services, provincial authorities as well as STD services representing all 25 districts in the country. High-burden districts such as Colombo, Gampaha, Kandy, Matara, Galle and Hambantota were selected for the initial phase. Advocacy meetings were conducted in Colombo, Kandy and Galle districts to introduce the new programme. The MoH issued a general circular emphasizing the importance of screening of pregnant women for HIV and syphilis (Annexure 10). A steering committee was formed to guide the programme through regular reviews.

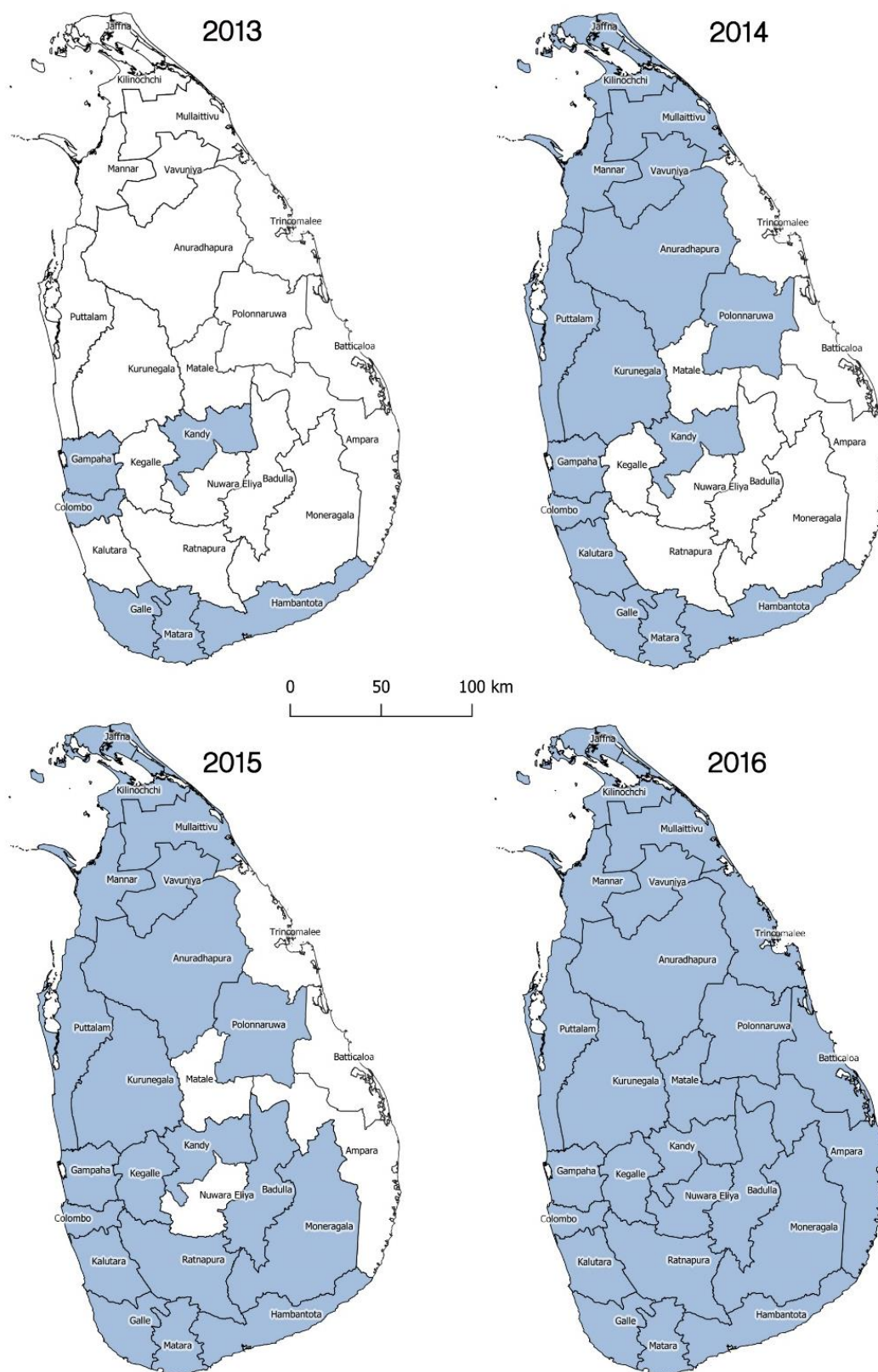
Scaling up testing services

Syphilis serology testing of pregnant women has been carried out at STD clinic laboratories since 1952. Over several decades, links have been developed between STD and MCH services. Blood samples are collected from pregnant women in the field or at hospital ANCs and sent to the closest STD clinic for testing. Till 2012, the practice was to collect 3 cc blood from pregnant women for VDRL testing. With the launch of the EMTCT of HIV and syphilis programme in 2013, health-care workers attached to MCH services were advised to offer HIV test to all pregnant women following pretest information. Leaflets and posters were developed to increase awareness of VDRL and HIV testing services (Annexure 21). Health-care workers were trained on the services emphasizing the voluntary testing approach (NSACP, 2017a). Women who declined the offer for testing were counselled and other services were provided as usual. The amount of blood collected was increased from 3 cc to 5 cc to test for both HIV and syphilis. The EMTCT programme was developed based on the existing elimination of congenital syphilis and PMTCT of HIV programmes. Infrastructure and facilities were in place. Only few improvements had to be added to the existing system.

Laboratory facilities were developed to cope with the increased demand for HIV testing by procuring test kits and laboratory equipment such as ELISA machines. International funding agencies, namely UNICEF, World Bank and WHO supported the programme. In 2014, the services were scaled up to cover Northern, North-Central and North-Western provinces. With further scaling up, EMTCT services covered the whole country by end-2016 (Fig. 6.1). Antenatal HIV testing was integrated into the existing antenatal care service package, which included testing for urine albumin, blood grouping and Rhesus (Rh) factor, blood sugar, haemoglobin and VDRL.

WHO recommendation was to use rapid tests among pregnant women. However, it was not considered practical to change the whole system at that point. System for testing was in place and needed only a few improvements. After several rounds of discussions, the steering committee decided to continue the serology testing with VDRL and HIV ELISA tests.

Fig. 6.1. Scaling up of EMTCT programme from 2013 to 2016



Source: A strategy for EMTCT of HIV and syphilis in Sri Lanka, 2018

National HIV EMTCT policies

In Sri Lanka, measures for PMTCT of HIV were initiated in early 2002 with the introduction of ART. The following strategies and guidelines have been developed and are regularly updated to facilitate implementation of MTCT of HIV and syphilis;

- National strategic plan (NSP)
- National strategy for elimination of paediatric HIV and congenital syphilis
- Guidelines on management of pregnant women with HIV
- Guidelines on management of pregnant women with syphilis
- The guide for MCH staff on EMTCT of HIV and syphilis

The NSP 2013–2017 focused on EMTCT of HIV and congenital syphilis through several strategies. To facilitate the process of EMTCT, the MoH issued Circular No. 02-02/2014 (Annexure 11) and its updated version 01-59/2016 (Annexure 10) on EMTCT of HIV and syphilis to cover all public and private MCH service units. All women in the reproductive age group, including populations at risk and vulnerable to HIV such as FSWs, women who use drugs, etc. can access free MCH services including PMTCT services across the island.

The National HIV/AIDS Policy has identified PMTCT as one of the objectives of the national response to the HIV epidemic. Under section 3.3 PMTCT of HIV, it states “prevention of infection among men and women in the reproductive age and promoting voluntary counselling and testing for HIV in this age group is the primary strategy. Prevention of unplanned pregnancies among HIV-infected women, provision of ART, safer delivery practices and safer feeding practices will also be provided as per standard guidelines” (NSACP, 2011).

The national policy on MCH focuses on women during pregnancy, delivery and the postpartum period, and on newborns, infants and children up to 18 years of age. It includes promotion of health of women and their partners to enter pregnancy in optimal health, and to maintain it throughout the life-course. This goal enables mothers to undergo HIV/syphilis testing during pregnancy and to link STD/HIV care services (GoSL, 2012).

6.1.1. Management of pregnant women with HIV

When the screening test for HIV becomes reactive in a pregnant woman, consultant/medical officer of the STD clinic informs the relevant officers of the ANC (MOH/ hospital director/VOG) requesting to refer the pregnant mother to the STD clinic for further testing (Fig. 6.2). Relevant officers of ANCs trace the woman with the assistance of the staff while maintaining confidentiality. The pregnant woman is appropriately counselled and reassured by the MOH/ obstetrician/hospital director before referring to the STD clinic. MCH staff ensures that the pregnant woman attends the STD clinic without delay.

All screening reactive pregnant women are counselled and confirmatory tests are arranged at the STD clinic. All confirmatory test positive pregnant women undergo post-test counselling and are registered at the STD clinic for HIV care services including EMTCT services.

Pregnant women diagnosed with HIV during pregnancy are offered EMTCT services according to the national guidelines on management of HIV-infected pregnant women updated in 2016 (NSACP, 2016a). Pregnant women are managed in coordination with the area MOH, obstetrician and paediatrician (Fig. 6.1).

6.1.2. Antiretroviral treatment

According to the current guidelines, ART is initiated as early as at 14 weeks of gestation or as soon as possible thereafter during pregnancy and continued for life. CD4, viral load, tests for opportunistic infections and biochemical tests are conducted at base line. The first-line recommended ART regimen is tenofovir + emtricitabine + efavirenz (TDF+FTC+EFV) (NSACP, 2016a). However, alternative regimes are available in case of adverse events. Pregnant women with HIV are counselled on ART and adherence to treatment, choice of infant feeding, partner disclosure/screening, HIV testing of other children and postpartum family planning.

When a pregnant woman is registered for EMTCT services for HIV, a viral load test is done at base line and at 4 weeks after starting ART and at 36 weeks of POA to review the response to treatment. At 36 weeks of pregnancy, a viral load test is done to assess the virological response. If the pregnant woman has >50 copies/ml at 36 weeks of pregnancy or if diagnosed late in pregnancy, treatment regimen is changed to TDF + FTC + raltegravir (RAL). Raltegravir is added to TDF + FTC expecting rapid reduction of viral load to undetectable levels within weeks.

Women presenting at labour/rupture of membranes/requiring delivery without a HIV result are offered a rapid HIV test. A reactive result on the rapid test is acted upon immediately with the initiation of EMTCT services without waiting for further serological confirmation. Pregnant women with a positive HIV screening test close to delivery are presumed to be infected until standard HIV confirmatory tests clarify the HIV status. ART is started immediately for women with positive rapid HIV tests in labour to prevent perinatal transmission of HIV. Rapid test-kits have been made available up to base hospital level A category. The emergency packs of AZT + lamivudine (3TC) + RAL along with NVP single dose are available for immediate commencement of ART. It should be noted that in 2017 or 2018, there were no HIV-positive cases among pregnant women who presented late.

HIV-positive women with CD4 cell counts below 350 cells/mm³ receive *Pneumocystis jirovecii* pneumonia (PCP) prophylaxis with Co-trimoxazole (TMP-SMX 2).

An individualized, regularly updated, plan of care which summarizes the mutually agreed mode of delivery is arranged for all HIV-infected pregnant women. They are counselled on options for mode of delivery. The management plan covers instructions to the VOG and the neonatologist regarding management of the pregnant woman and the baby, respectively.

HIV-positive women receive shared antenatal care at field and institutional ANCs. They receive monitoring of HIV status and ART from STD clinics.

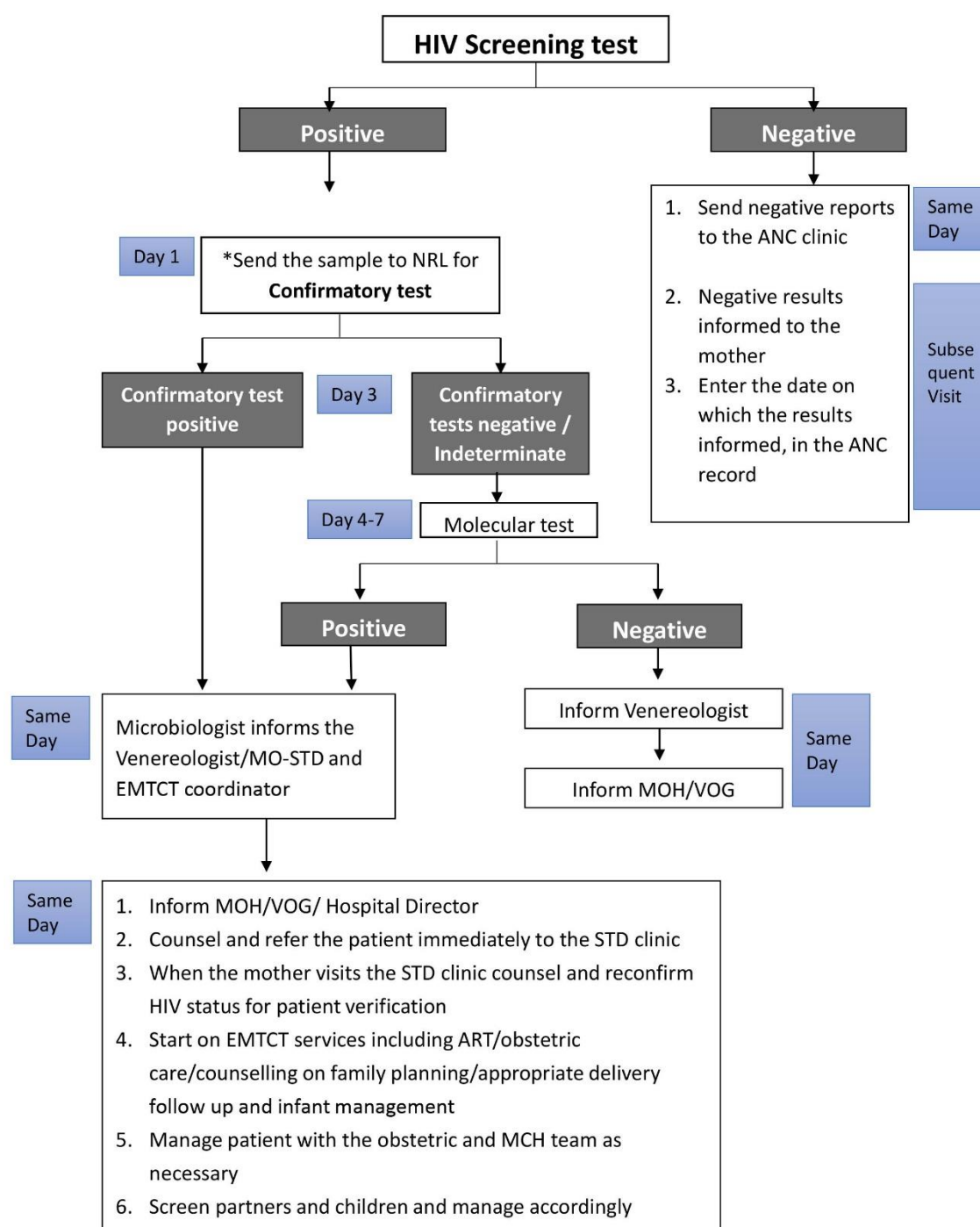
During follow up at clinics, they receive couple counselling on postpartum family planning. Furthermore, couples are encouraged to continue condom use.

Women are counselled on suitable infant feeding practices according to infant feeding guidelines. Following explanation of possible options of infant feeding, if the pregnant woman opts to formula feed, they have been provided with formula milk free of charge for one year by the National AIDS Foundation, an NGO that has been providing this service for the past 10 years. In addition, since 2018, this organization has been providing gas cookers, utensils, feeding bottles and clothing for the mother and baby when needed. Mothers are educated on the preparation of formula milk hygienically during their last trimester clinic visits. If the mother wishes to breastfeed, she is supported according to the guidelines while continuing ART with satisfactory adherence to maintain undetectable viral load levels.

Partners/spouses who are HIV-positive are managed in accordance with the national protocols. All PLHIV receive prevention counselling on protection from acquiring HIV from their partner, whether the couple is

concordant or discordant. HIV-negative male partners are advised to avoid risk behaviour and to get an HIV test done once in 6 months. Condoms are recommended and provided freely from STD clinics for protection.

Fig. 6.2. Protocol to inform HIV test results and management of pregnant women with HIV



*In the event of a positive screening test for a woman in late pregnancy or in an area of difficult accessibility to health-care services the initial sample can be sent to NRL for further HIV testing thereby preventing delay in providing EMTCT services.

Source: A strategy for EMTCT of HIV and syphilis in Sri Lanka, 2018 (NSACP, 2018b)

Pregnant women attending in late pregnancy or labour are offered rapid HIV tests. If rapid HIV test is positive ART emergency pack is started immediately without waiting for serological confirmation. Continuation of ART is based on the HIV ELISA test results.

6.1.3. Diagnosis and management of infants born to mothers with HIV

Before 2013, infant diagnosis was problematic as the only option available was HIV antibody testing at 18 months. In 2013, the NSACP introduced HIV DNA PCR test for HIV diagnosis of infants at 8 weeks and 16 weeks. Testing infants at birth (HIV RNA/DNA PCR) was started in 2016 and samples were sent to the National AIDS Research Institute (NARI) in India up to 2018. In 2018, these facilities were established at the NRL, NSACP to carry out DNA PCR tests.

Neonatal post-exposure prophylaxis is recommended soon after birth within 4 hours. Infants with standard risk receive syrup NVP for six weeks, HIV DNA/RNA PCR at birth followed by HIV DNA PCR at 8 weeks and 16 weeks (NSACP, 2016a)

The 2016 guidelines define high-risk infants as those who are:

- born to women with established HIV infection who have received less than four weeks of ART at the time of delivery; OR
- born to women with established HIV infection with viral load >1000 copies/ml four weeks before delivery;
- born to women with incident HIV infection during pregnancy or breastfeeding (defined as new HIV diagnosis in a pregnant or breastfeeding woman with a prior negative HIV test during pregnancy); OR
- identified for the first time during the postpartum period, with or without a negative HIV test prenatally.

Infants considered to be at high risk for MTCT receive triple ARV therapy. Syrup nevirapine is combined with dispersible oral preparations of AZT + 3TC. This poses a challenge to ensure the exact dose for the infant.

In addition to DNA PCR tests all children born to HIV-positive women receive HIV antibody testing at 9 and 18 months.

HIV exposed infants are followed up regularly at the STD clinic till exclusion of HIV infection. In addition, maternal and newborn postpartum care following discharge is provided by PHM of field MOH clinic. Immunization of the infant is arranged at the paediatric clinic or MOH clinic. BCG vaccination is delayed till HIV status is excluded. OPV is replaced with injectable polio vaccine. Other vaccines are given according to the national immunization schedule.

In instances when the baby is breast fed, additional monthly testing of DNA PCR tests for both mother and infant is recommended.

6.2. National EMTCT of syphilis policies and programme

The MoH of Sri Lanka has clearly identified antenatal screening for syphilis as a major component of antenatal care services. Syphilis screening services for pregnant mothers have been offered since the early 1950s. The national strategic plan 2018–2022 identifies EMTCT of HIV and syphilis under strategic direction 2.4 (NSACP, 2017c).

The national HIV policy under 3.10. prevention and control of STIs states that “Screening for syphilis among all antenatal mothers should be ensured” (NSACP, 2011).

6.2.1. Management of pregnant women with syphilis

When the pregnant woman gets registered for antenatal care services, VDRL test is offered as a routine screening test. Blood samples are collected and transported to the closest STD clinic laboratory. All VDRL-positive samples are subjected to confirmatory testing using treponemal test, TPPA. When treponemal test (TPPA) becomes positive the reports are informed by the consultant/medical officer of the STD clinic to the relevant officers of the ANC, requesting to refer the pregnant woman to the STD clinic as early as possible for further management (Fig. 6.3). When the pregnant woman attends STD clinic repeat testing with VDRL and TPPA is done to verify the infection status.

Pregnant women with syphilis are given appropriate treatment according to the National guideline (NSACP, 2016b). The objective is to complete treatment in early pregnancy. After completion of treatment, mother is followed up regularly till delivery and partner treatment is also completed during this period to prevent re-infection. The obstetrician providing care is informed regarding the plan of management of the mother. In the absence of documented evidence of testing for syphilis in pregnancy, it is recommended to screen for syphilis on admission for delivery and manage accordingly.

Treatment for syphilis in pregnancy

Treatment for early syphilis (*primary, secondary and early latent syphilis) – Benzathine penicillin 2.4 million units intramuscularly as a single dose, after having excluded allergy to penicillin (NSACP, 2016b).

However, when maternal treatment is initiated in the third trimester, a second dose of benzathine penicillin is given 1 week after the first.

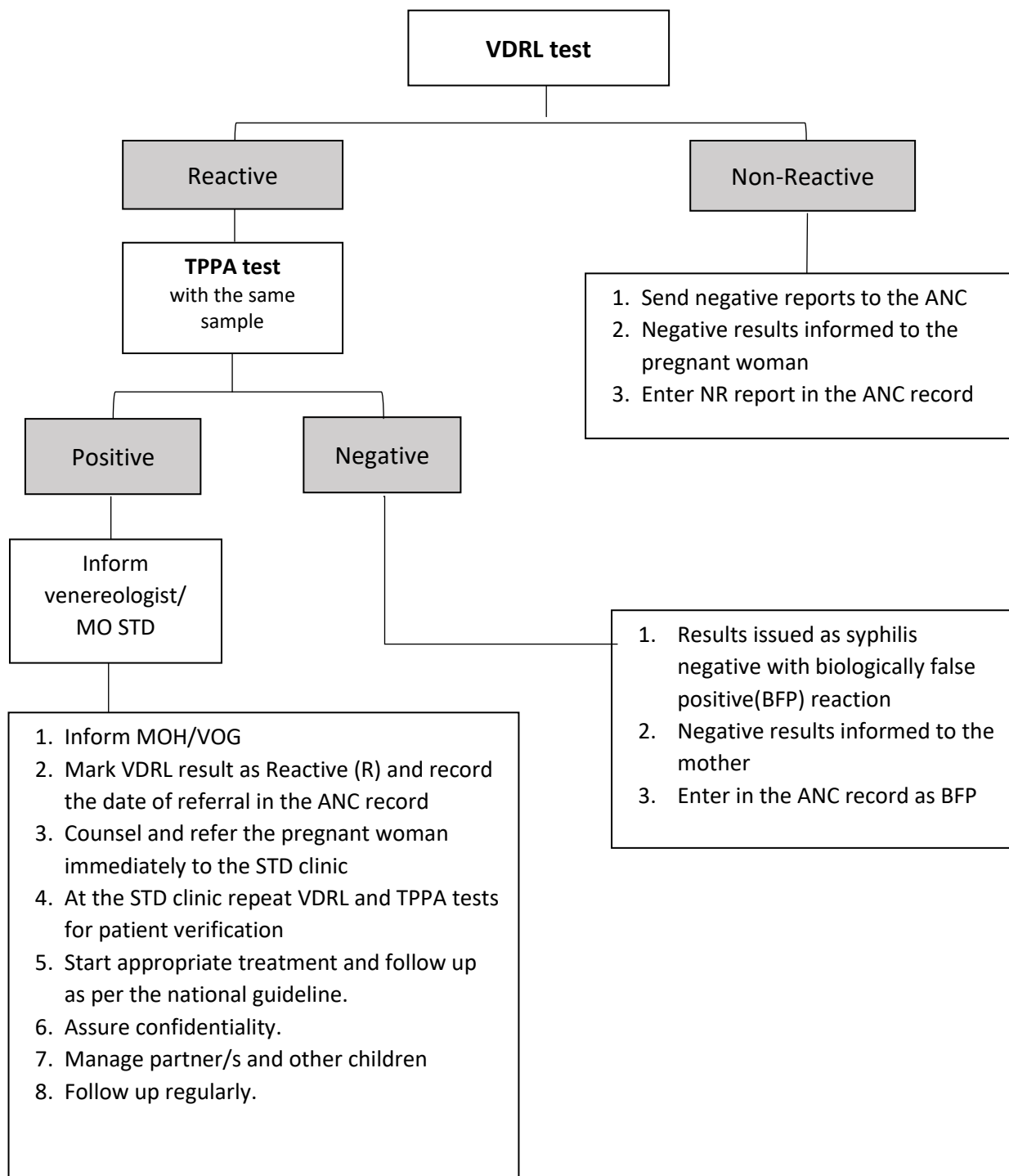
Treatment for late latent syphilis or syphilis of unknown duration in pregnancy – Benzathine penicillin 2.4 MU intramuscularly, weekly 3 doses. Pregnant women who miss any dose must repeat the full course of therapy.

Erythromycin is used when penicillin is contraindicated. Recommended dose is oral erythromycin 500 mg 6 hourly for 14 days in early syphilis and for 28 days in late syphilis.

If the mother was treated with non-penicillin treatment, the baby is treated as having congenital syphilis. For HIV and syphilis coinfecting pregnant women treatment is provided according to the guideline.

Serological (VDRL) follow-up is carried out monthly during pregnancy till delivery and thereafter according to the national guideline. Since specific treponemal tests remain positive for life following effective treatment, proper documentation is maintained to prevent unnecessary retreatment. All pregnant women with syphilis are provided appropriate services including institutional care without stigma or discrimination. Pregnant women are managed in coordination with area MOH, obstetrician and paediatrician.

Babies born to pregnant women with syphilis who were adequately treated with penicillin 30 days before delivery, are given a single dose of benzathine penicillin 50 000 IU/kg (body weight) as prophylaxis. As per national guidelines all other babies are treated with intravenous crystalline penicillin for 10 days.

Fig. 6.3. Protocol to inform VDRL test results of pregnant women

Source: A strategy for EMTCT of HIV and syphilis in Sri Lanka, 2018

6.3. National breastfeeding policy

The National Nutrition policy of Sri Lanka states “Ensure a good foundation for all infants and young children during their early childhood years by providing optimal nutrition through provision of exclusive breastfeeding for 6 months followed by complementary feeding together with continued breastfeeding for 2 years and beyond” (MoH, 2010).

The National Strategy on infant and young child feeding (IYCF) is a guide for action by all relevant stakeholders involved (FHB, 2015). It is based on evidence of the significance of the early years of life in ensuring good physical growth, health and development and evidence-based interventions having a positive impact on nutrition. The IYCF strategy encompasses and upholds the following;

Recommended IYCF practices in Sri Lanka for the general population

- Initiation of breastfeeding in the first hour of birth
- Exclusive breastfeeding for the first 6 months of life (180 days)
- Introducing appropriate locally available complementary food from the time of completion of 6 months of age paying attention to quality, age appropriate frequency, quantity and consistency, responsive feeding practices and safety
- Continued breastfeeding for two years and beyond together with nutritious food
- Growth monitoring according to national recommendations as a means of detection of nutrition problems and identification of impact of IYCF practices

Breast feeding guidelines for HIV infected women

In Sri Lanka, the most appropriate infant feeding option for an HIV-positive mother depends on her individual circumstances, including her health status, the local situation and support she is likely to receive. Counselling by a venereologist and a paediatrician/neonatologist is done in collaboration to assist the mother in arriving at a decision. The counsellor balances the risk of the infant acquiring HIV through breast milk with the higher risk of death from other causes such as diarrhoea among non-breastfed infants.

The following points are considered during counselling:

- Exclusive breastfeeding for 6 months has unlimited benefits to any baby and is the recommendation to all pregnant women in Sri Lanka.
- There is adequate evidence that triple ARV given during prenatal period with safer delivery practices and safer feeding practices has substantially lowered MTCT of HIV.
- Maternal ART reduces but does not eliminate the risk of HIV transmission via breast milk (CDC)
- ART is available for pregnant women free of charge through government health services

The counsellor supports the HIV-positive mother to decide on the best feeding option for her own baby, which is sustainable and safe in her individual socioeconomic and cultural circumstances.

If a mother decides not to breastfeed her HIV-uninfected infant or an infant whose HIV status is unknown, the following are recommended.

- Assure safe water and sanitation at the household level
- Ensure mother is able to prepare formula feeds safely according to guidance
- Ensure avoidance of mixed – feeding in the first 6 months
- Ensure family support

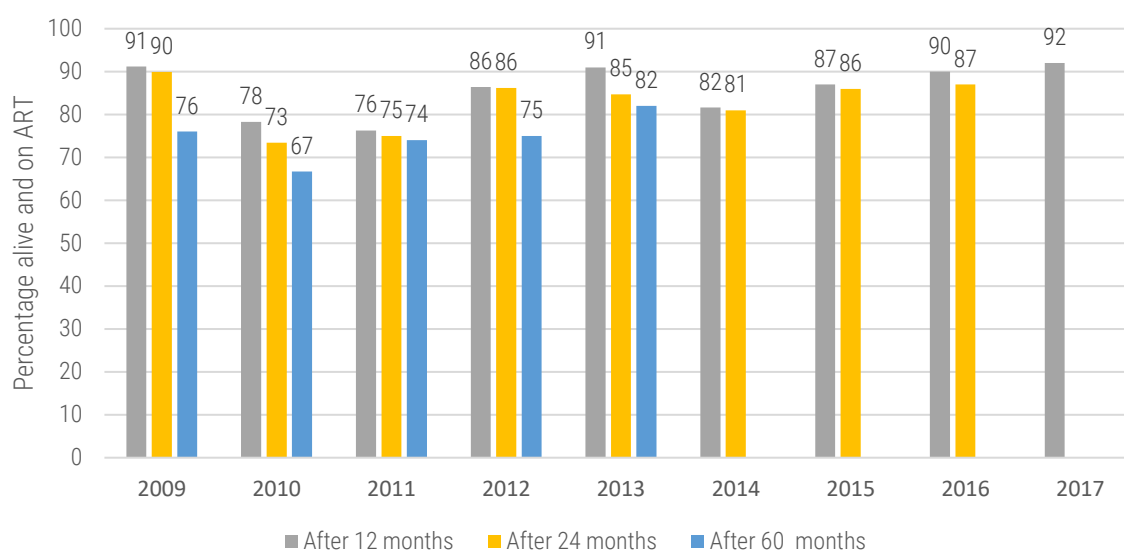
If a pregnant woman decides on formula feeds, formula milk is provided free for the baby for a year.

Where mother and infant are both HIV-positive, breastfeeding is encouraged for at least the first two years of life in line with recommendations for the general population.

6.4. Lifelong ART services for HIV-infected women

All persons including pregnant women living with HIV are registered for HIV care services at the STD clinic. The pregnant women, their partners and children are given services for HIV care and support including universal lifelong ART free of charge through the government STD clinics. As the whole programme is funded by the MoH, sustainability is guaranteed. Cohort analysis of PLHIV on treatment in the year 2018 indicate retention in services 92% at 12 months (Fig. 6.4)

Fig. 6.4. ART Cohort analysis data by 2018



Source: SIM Unit, NSACP, 2018

6.5. MCH services in public and private sector

The national policy is to provide free health services for all, and health services are accessible to all sectors of the community. Any person can access STD and MCH services anywhere in the country according to their liking. A woman of any socioeconomic status can access health services. Further, provision of domiciliary care is an important component of services provided by the PHM for the mother and the baby.

However, with the development of the economy, a certain proportion of pregnant women seek services from private sector hospitals. All these hospitals provide specialist obstetric and paediatric services. The overall percentage of pregnant women receiving only private sector services is 5.4% across the country (DHS, 2016), which is somewhat higher in urban areas. In three districts (Colombo, Gampaha and Kalutara), the percentage was more than 10%. However, most of private sector deliveries in the country happened in 10 major private hospitals based in Colombo.

6.6. Equity of EMTCT services

Women living with HIV are involved in national planning and evaluation of EMTCT services. There are no laws or policies to force HIV and syphilis testing and treatment or to criminalize HIV transmission. Health-care workers at STD clinics are regularly trained on stigma and discrimination. Regular training programmes for other health-care workers including MCH staff are conducted by district venereologists on stigma to reduce negative effects.

There are no reports of human rights abuses such as forced testing, forced birth control/sterilization or forced termination of pregnancy. The ethics and legal subcommittee of the NAC encourages PLHIV to report any adverse incidents and action is taken to address such abuses.

6.7. Model based estimates of EMTCT of HIV and syphilis indicators

Table 6.1. Spectrum* estimates for PMTCT indicators

	2015	2016	2017	2018
Mothers needing PMTCT	17	18	16	16
Mothers receiving PMTCT	11	16	16	16
Single-dose nevirapine	0	0	0	0
Dual ARV therapy	0	0	0	0
Option A: maternal	0	0	0	0
Option B: triple prophylaxis from 14 weeks	0	0	0	0
Option B+: ART started before current pregnancy	4	4	6	7
Option B+: ART started during current pregnancy > 4 weeks before delivery	6	12	10	9
Option B+: ART started during current pregnancy < 4 weeks before delivery	1	0	0	0
% PMTCT coverage	63.92	91.25	97.70	99.86
% PMTCT coverage of more efficacious regimens	63.92	91.25	97.70	99.86
% MTCT rate at 6 weeks	10.87	4.63	2.71	1.95
% Final transmission rate including breastfeeding period	24.77	4.63	2.71	1.95
Number of HIV+ breastfeeding women at 3 months	6	0	0	0
Number of HIV+ breastfeeding women at 12 months	5	0	0	0
Number of new child infections due to MTCT				
Total	4	1	0	0
Male	2	0	0	0
Female	2	0	0	0
% Treatment coverage for HIV+ pregnant women	63.92	91.25	97.7	99.86

Source: SIM Unit, NSACP, 2018

The following parameters were considered for the estimation of burden of syphilis;

(www.who.int/reproductivehealth/topics/rtis/Guidance.pdf).

1. The number of live births (Registrar General's Department),
2. Number of stillbirths (after 28 weeks of gestation) (FHB)
3. Proportion of pregnant women with either test positive (Global Health Observatory data repository, WHO website)
4. Proportion of pregnant women with at least one ANC visit (FHB)
5. Percentage of pregnant women tested for syphilis at first antenatal care visit (FHB)
6. Percentage of seropositive pregnant women adequately treated for syphilis (NSACP).

Using these figures, the estimated burden of syphilis among pregnant women were calculated, depending on the status of the ANC visit. The figures of the consecutive years are given in Table 6.3.

Table 6.2. Outputs from Congenital syphilis tool, 2015-2018

	2015	2016	2017	2018
Syphilis prevalence	0.03%	0.02%	0.02%	0.02%
Demographic estimates				
Total number of live births	368303	364180	358657	360923
Pregnant women who are seropositive before pregnancy	106	88	72	72
Pregnant women who are seronegative before pregnancy	368198	364092	358585	360851
Infant status				
Number of normal births	368,183	364,066	358,550	360,814
	14	9	4	5
Total number of adverse birth outcomes due to congenital syphilis	8	6	3	3
Number of stillbirths	3	2	1	1
Number of neonatal deaths	1	1	1	1
Number of premature/low birth weight	1	1	0	1
Number of infants with clinical congenital syphilis	2	1	1	1
Total number of congenital syphilis cases (clinical and asymptomatic)	15	10	5	6
Clinical congenital syphilis case rate per 100,000 live births for all pregnant women	4	3	1	2

Source: SIM Unit, NSACP, 2018

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Annexures

Annexure 1

National Validation Team

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3. Dr Susie Perera (DDG Public Health Services 2)
4. Dr H.D.B. Herath (Acting DDG Public Health Services)
5. Dr Hemantha Beneragama (DDG Laboratory Services)
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23. Dr Iyanthi Abeywickreme (Former Director, NSACP)
24. Dr Safina Abdulloeva (Manager, Child Survival and Development, UNICEF)

Annexure 2

Terms of reference for the national validation team

14/10/13

Transmission of Syphilis and HIV

1. To support the development and review of national policies, strategies and guidelines, for implementation of EMTCT of HIV services in Sri Lanka.
2. To maintain the provision of EMTCT services for syphilis and HIV services through the services delivery points of the National STD/AIDS Control Programme, Family Health Bureau, Provincial and government health facilities in quality assured manner.
3. To coordinate with and support institutions within and outside the Ministry of Health in the expansion of appropriate, high quality EMTCT of syphilis and HIV services.
4. Training and capacity building of individual/institutions in the public, private, civil society organizations on PMTCT of HIV services, in partnership with relevant programme areas in the NSACP and FHB.
5. To supervise and monitor the quality of EMTCT of Syphilis HIV services in the programme.
6. Advise on provision of technical support, assistance and guidance to provinces, districts and other organizations and agencies in improving quality, supply and access to EMTCT of Syphilis and HIV services.

Annexure 3

National Validation Committee

Dr Paba Palihawadana (Deputy Director General-Public Health Services 1), Dr Rasanjalee Hettiarachchi (Director, NSACP), Dr Chitramalee de Silva (Director, FHB), Dr Iyanthi Abeywickreme (Former Director NSACP), Dr Lilani Rajapaksa (Coordinator EMTCT), Dr G. Weerasinghe (Coordinator Key population programme), Dr K.A.M. Ariyaratne (Coordinator Strategic Information), Dr Jayanthi Elwitigala (Coordinator Laboratory services), Dr Irosha Nilaweera (Consultant community physician, Maternal Care), Kaushalya Kasthuriarachchi (Consultant Community Physician M&E, MCH), Dr Nethmini Thenuwera (Consultant Community Physician, Intranatal and newborn Care) Dr U.D.P. Rathnasiri (Obstetrician and Gynaecologist, CSHW), Professor Hemantha Senanayake (Obstetrician and Gynaecologist, DMH), Dr Nalin Gammathige (Neonatologist, DMH), Dr P.W.P. Chathurangana (Paediatrician, LRH), Dr Sriyakanthi Beneragama (Epidemiologist, NSACP), Dr Himali Perera (Coordinator Training, NSACP), Dr Sathya Herath (Consultant Community Physician, NSACP), Dr Chandrika Jayakody (Coordinator IEC, Advocacy and Condom Promotion, NSACP), Dr Geethani Samaraweera (Venereologist, NSACP), Dr Priyantha Weerasinghe (Venereologist, STD Clinic Gampaha), Dr Ruwan Silva (Obstetrician and Gynaecologist, FHB), Dr Loshan Moonesinghe (Consultant Community Physician, Well Women Programme, FHB), Dr Sanjeeva Godakandage (Consultant Community Physician Family Planning, FHB), Dr Neththanjali Mapitigama (Consultant Community Physician GBV, FHB), Dr Janaka Weragoda (Consultant Community Physician, Western Province), Dr Shanika Jayasena (Venereologist, NSACP), Dr Lasanthi Siriwardena (Venereologist, NSACP), Dr Thilani Rathnayake (Coordinator Multisectoral Unit, NSACP), Dr Dhammika Rowel (UNICEF), Dr Manjula Dhanansuriya (NPO, WHO), Ms Thushara Argus (Executive Director, FPA), Dr Janakan Navaratnasigham (NPO, WHO), Ms Madhu Dissanayake (Assistant Representative, UNFPA), Ms Preethika Sakalasooriya (Legal Officer, National Child Protection Authority), Ms Dharshana Senanayake (Secretary Ministry of Women and Child Affairs), Ms Princy Mangalika (Positive Women's Network), Mr Sarath Peiris (Lanka Plus), Ms Sunanada Jayaratne (Positive Hopes Alliance), Mr Thushara Senanayake (Saviya Development Foundation), Mr H.A. Lakshman (Community Strength Development Foundation), Dr Sunil Rathnapriya (Association of Private Hospitals), Dr Indika Malwatte (SR Venereology, NSACP), Dr Dulari Liyanage (SR Venereology, NSACP), Dr M.P.V.R. Perera (SR Venereology, NSACP), Dr S. Muraliharan (MO, NSACP), Dr Dilanie Peter (MO EMTCT Unit, NSACP) Dr Nilmini Malliyawadu (MO, NRL) and Mrs Yamuna Dabare (Medical Laboratory Technician, NRL), Mr G W Siriwardana (Statistician, Department of Registrar Generals), Ms M.M. Dharshani (Statistician, Medical Statistics Unit, MoH)

Terms of reference for the National validation committee on Elimination of Mother-to-child Transmission of HIV and syphilis

1. To support the process of validation of EMTCT of HIV services in Sri Lanka.
2. Establish necessary working groups.
3. Collect and compile relevant data and documents to facilitate validation
4. Advise on provision of technical support, assistance and guidance to provinces, districts and other organizations and agencies in improving quality, supply and access to EMTCT of HIV and syphilis services

Annexure 4

List of Non-governmental and Civil Society Organization representatives

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Annexure 5

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Ms. Riyaz Ahamed	Dr Randima Wijesekara
Ms. Princy Mangalika	Ms Nadika Fernandopulle
Ms. Thushara Argus	

Annexure 6

Terms of reference for the working groups of four main domains on Elimination of Mother-to-child transmission of HIV and syphilis

14/10/13

Terms of reference for the working groups of four main domains on Elimination of Mother to Child Transmission of HIV and syphilis

1. Facilitate the EMTCT validation process.
2. Collect and compile relevant data and documents reports, guideline etc. relevant to the respective domains
3. Support developing the chapters relevant to the main domains in the report
4. Guide and support the central and peripheral teams to achieve the targets

Annexure 7

Members of the District committee on EMTCT

1. RDHS
2. MO MCH
3. Consultant Venereologist/MO STD clinic
4. One VOG from each hospital
5. One Pediatrician/Neonatologist from each hospital
6. Consultant Community Physician
7. One Medical Officer of Health
8. Hospital Directors/MS
9. RSPHNO
10. Consultant Microbiologist of the area and the relevant MLTs of the laboratories
(Optional - by invitation, when necessary to get assistance)
11. Representatives from private hospitals which provide delivery services in the district
12. VOGs who provide antenatal care and delivery care totally in the private sector

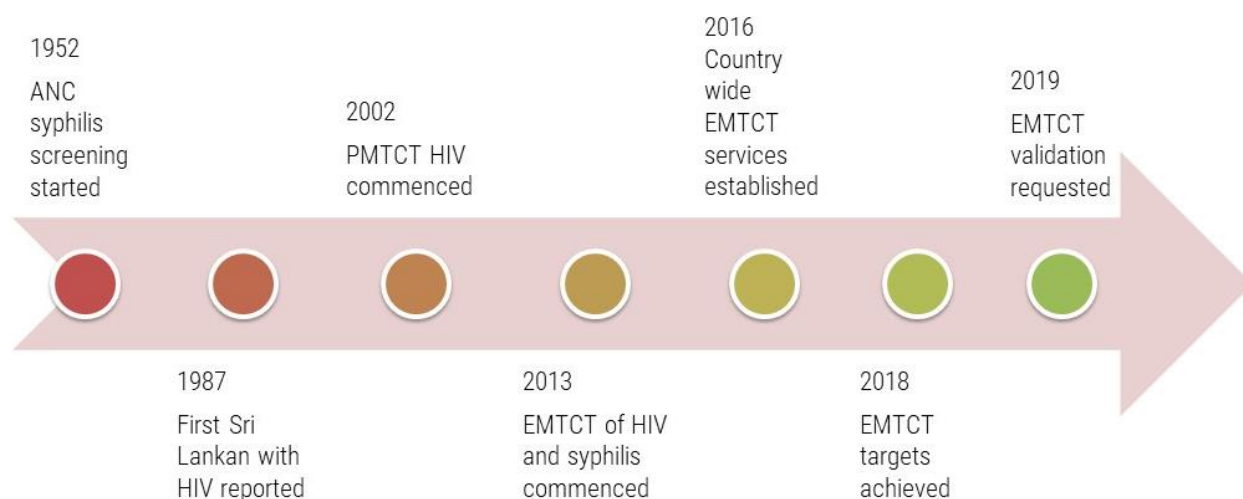
Annexure 8

Terms of reference for the District Committee on Elimination of Mother-to-child Transmission of HIV and syphilis

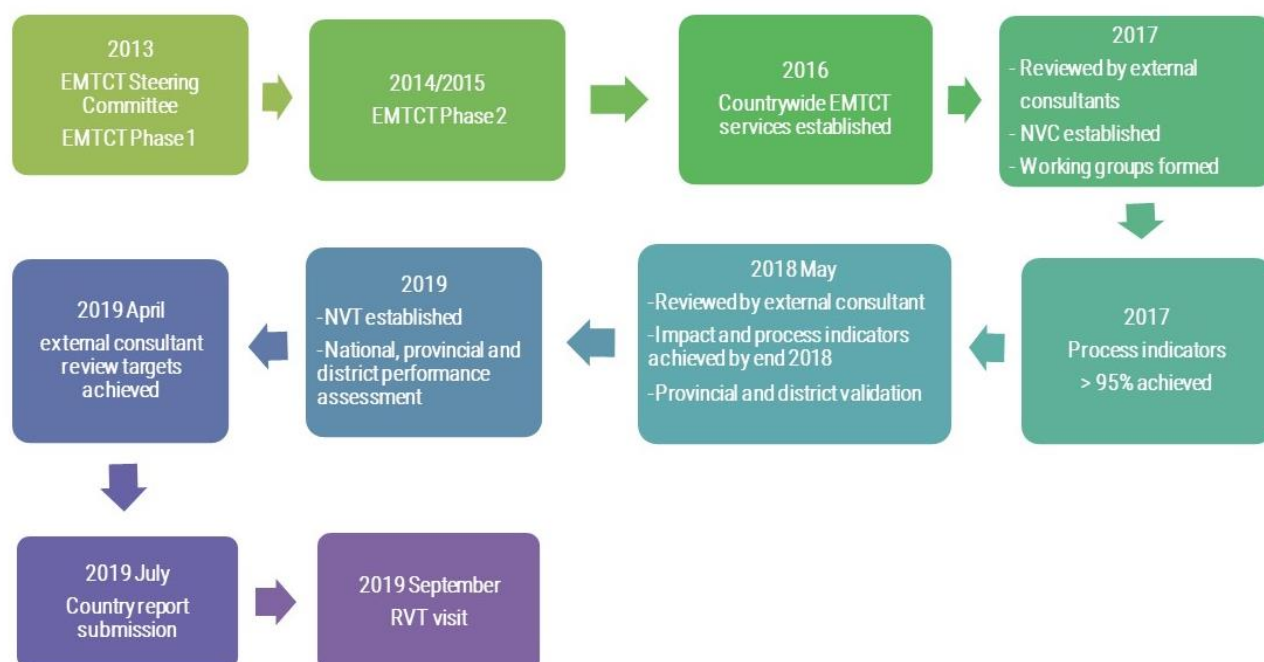
1. To ensure the provision of EMTCT services for syphilis and HIV through the STD clinics, MOH clinics and government and private health facilities in the district in quality assured manner including testing of all ANC mothers at the booking visit for HIV and syphilis and timely referral of positive mothers to the STD clinic for treatment.
2. To coordinate with and support both public and private sector institutions in the expansion of appropriate, high quality EMTCT of syphilis and HIV services including data management in the district.
3. Training and capacity building of individual/institutions in the public and private sector on PMTCT of HIV and syphilis services, in partnership with relevant programme areas in the NSACP and FHB.
4. To supervise and monitor the quality of EMTCT of syphilis HIV services in the district.
5. To ensure the quality management systems in the testing laboratories, collection and transport of specimens from collecting centres to the testing laboratories and participation in EQA programmes by the testing laboratories.
6. Collate data from private sector to understand full MCH service situation in the district, i.e. number of deliveries in private hospitals, VDRL and HIV testing coverage among women who received services mainly from the private sector (informal data through VOG, GPs and formal data by conducting a survey the private sector)
7. Provision of technical support, assistance and guidance to health-care providers in the district in improving quality, supply and access to EMTCT of syphilis and HIV services.
8. To ensure that the positive pregnant mothers, their partners and babies are cared for with zero stigma and discrimination in public and private sector health-care institutions.

Annexure 9

EMTCT of HIV and syphilis Programme- milestones



Scaling up of EMTCT of HIV and syphilis Programme



Annexure 10 - General Circular 01-59/2016

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 My No.) DDG/(PHS-1)/NSACP/201

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 Ministry of Health, Nutrition & Indigenous Medicine

General Circular No : 01-59/2016

All Provincial / Regional Directors of Health services,
 All Directors of Teaching Hospitals,
 All Heads of Specialized Campaigns,
 All Heads of Health Institutions,
 All consultant Obstetricians,

The Programme for Elimination of Mother to child transmission of syphilis and HIV (EMTCT of syphilis and HIV) in Sri Lanka

Sri Lanka has been identified as a country which can achieve the Elimination status of congenital syphilis and mother to child transmission of HIV by end 2017.

2. To achieve the elimination status, effective universal coverage of screening for syphilis and HIV during pregnancy need to be established. In Sri Lanka, by the end of 2015 screening for syphilis during pregnancy has achieved almost universal coverage (98%).

3. The policy decision of screening pregnant women for HIV was taken by the Ministry of Health after a series of consultations and the decision was to couple it with existing syphilis screening. Screening of pregnant mothers for HIV was scaled up from 2013 and HIV screening coverage has increased from 5.6% in 2012 to 71.2% in 2015. To achieve elimination status Sri Lanka needs to reach 95% of HIV screening coverage target by the end of 2016.

4. Ministry of Health seeks the commitment and cooperation of consultant obstetricians in public and private sector to implement the EMTCT of syphilis and HIV programme. It is necessary to take measures to scale up services for antenatal screening of Syphilis and HIV in your institution as per the guidelines given below.

(A) Public sector

- All pregnant mothers are to be screened before 12 weeks of gestation for Syphilis and HIV (preferably at the first visit).

- ii. Antenatal clinic services (MOH clinics and Hospital ANC clinics) have to arrange collection of 5cc of blood in a vacutainer tube and transport to the STD clinic for Syphilis and HIV testing. The method of sample transport need to be locally adopted, after discussions with RDHS, MOMCH, MO/STD and MOHs.
- iii. Review syphilis and HIV test results at subsequent visits. Syphilis and HIV test reports need to be entered in the antenatal record appropriately.
- iv. STD clinics have to carry out Syphilis and HIV screening tests on the blood samples received from ANC clinics and send reports to the relevant officers.
- v. The information on reactive VDRL reports and HIV positive reports need to be informed to the MO, MOH or VOG and measures should be taken to strictly maintain the confidentiality of the information.
- vi. All the pregnant women with positive screening test need to be referred to STD clinic for further management.
- vii. If a pregnant woman was not tested during pregnancy, syphilis and HIV screening should be offered at the time of delivery before being discharged from the ward.
- viii. All pregnant women with Syphilis or HIV should be provided appropriate services including institutional care, without stigma or discrimination.
- ix. EMTCT of syphilis and HIV programme need to be reviewed at the district level every six months with the participation of staff of the STD clinic, MOHs, MOMCH, VOG and RDHS.
- x. Women reporting abortions, still births, adverse pregnancy outcomes may need to undergo VDRL and HIV tests if not done in early pregnancy.

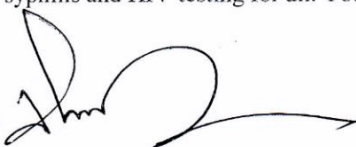
(B) Private sector

- i. All pregnant mothers are to be screened before 12 weeks of gestation for Syphilis and HIV (preferably at the first visit).
- ii. Syphilis and HIV tests need to be done from recognized laboratories maintaining quality standards.
- iii. Syphilis and HIV test details need to be entered in the antenatal record appropriately.
- iv. Women with positive syphilis or HIV test results should be managed according to the national guidelines by referring to venereologist/ STD clinic.
- v. All pregnant women with Syphilis or HIV should be provided appropriate services including institutional care, without stigma or discrimination.
- vi. Data on pregnant women with syphilis or HIV should be informed to the NSACP in relevant formats.

5. National HIV policy of Sri Lanka states that "The government of Sri Lanka accepts the right of those living with HIV/AIDS to have access to treatment without stigma and discrimination. Persons living with HIV/AIDS requiring antiretroviral treatment and management of opportunistic infections will be provided by the state sector in line with the national guidelines and prevailing National Health policy." (3.8 page 22)

6. Further, the judgement given on SC.FR.No.77/2016 on 14.03.2016 states "The court also wishes to place on record that the state should ensure that the human rights of the people living with HIV/AIDS are promoted, protected and respected and measures to be taken to eliminate discrimination against them."(Page 4)

7. I reiterate the policy of the Government of Sri Lanka, is to provide a comprehensive antenatal care package to pregnant women for a successful pregnancy outcome and it includes providing services for syphilis and HIV testing for all. Your cooperation is earnestly requested.



Dr. P.G.Mahipala
Director General of Health Services

Dr. P. G. Mahipala
Director General of Health Services
Ministry of Health, Nutrition & Indigenous Medicine
"Suwasiripaya",
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

Cc

1. Director, Private Health sector, MOH.
2. President, Sri Lanka College of Obstetricians.
3. President, Independent Medical Practitioners Association.
4. President, Ceylon College of General Practitioners.
5. President, Sri Lanka Medical Association.

Annexure 11 - General circular letter No: 02-02/2014

General circular letter No. 02-02/2014

My No. STD/A/
Suwasiripaya
Ministry of Health
Colombo 10
03.01.2014

To All Provincial Directors of Health Services
All Regional Directors of Health Services
All Directors of Teaching Hospitals and District General Hospitals

The Programme for Elimination of Mother to child transmission of syphilis and HIV (EMTCT of syphilis and HIV) in Sri Lanka

Sri Lanka has been identified as a country which can achieve the Elimination status of congenital syphilis and mother to child transmission of HIV.

To achieve the elimination status, effective universal coverage of screening for syphilis and HIV during pregnancy need to be established. In Sri Lanka, screening for syphilis during pregnancy has achieved almost universal coverage (98%).

The policy decision of screening pregnant women for HIV was taken by the Ministry of Health after a series of consultations and the decision was to couple it with existing syphilis screening.


Ministry of Health seeks the commitment and cooperation of provincial health authorities in the identified districts to implement the EMTCT of syphilis and HIV programme.

It is necessary to take measures to scale up services for antenatal screening of Syphilis and HIV in your district/institutions as per the guidelines given below.

- All mothers are to be screened before 12 weeks of gestation for Syphilis and HIV (preferably at the first visit).
- Antenatal clinic services (MOH clinics and Hospital ANC clinics) have to arrange collection of 5cc of blood in a vacutainer tube and transport to the STD clinic for Syphilis and HIV testing. The method of sample transport need to be locally adopted, after discussions with RDHS, MOMCH, MO/STD and MOHs.
- STD clinics have to carry out Syphilis and HIV screening tests on the blood samples received from ANC clinics and send reports to the relevant officers.
- The information on reactive VDRL reports and HIV positive reports need to be informed to the MO, MOH or VOG and measures should be taken to strictly maintain the confidentiality of the information.
- The screening test positive pregnant women need to be referred to the STD clinic for further management.
- All pregnant women with Syphilis or HIV should be provided appropriate services including institutional care, without stigma or discrimination.
- EMTCT of syphilis and HIV programme need to be reviewed at the district level every six months with the participation of staff of the STD clinic, MOHs, MOMCH and RDHS.

The districts identified for the year 2013/2014 are Colombo, Gampaha, Kandy, Galle, Matara and Hambantota.

I reiterate the policy of the Government of Sri Lanka is to provide a comprehensive antenatal care package to pregnant women for a successful pregnancy outcome and it includes providing services for syphilis and HIV testing for all. Your cooperation is earnestly requested.


Dr. Nihal Jayathilaka
Secretary
Ministry of Health

Dr. Y. D. Nihal Jayathilaka
Secretary
Ministry of Health
"Suwasiripaya"
235, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10, Sri Lanka.

- Cc
- | | |
|--|--|
| 1. Director General of Health Services | 4. DDG Laboratory services |
| 2. Representative – World Health Organization | 5. Director, National STD AIDS Control Programme |
| 3. Deputy Director General (Public Health services) 1, 2 | 6. Director, Family Health Bureau |

Annexure 12 - General Circular No 01-51/2016

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 Ministry of Health, Nutrition & Indigenous Medicine

General Circular No : ' 01 - 51 / 2016

All Provincial / Regional Directors of Health services,
 All Directors of Teaching Hospitals,
 All Heads of Specialized Campaigns,
 All Heads of Health Institutions

Programme for Ending AIDS by 2025 in Sri Lanka

Sri Lanka is currently planning to work towards ending AIDS by 2025. The decision to treat all persons living with HIV (PLHIV) with antiretroviral treatment was taken by the Ministry of Health after a series of consultations based on the WHO recommendations. To facilitate this process the Ministry of Health procured ARV drugs using government funds from 2016. With appropriate services majority of PLHIV on antiretroviral treatment will achieve undetectable viral loads within months after starting ART minimizing further transmission risks. With use of ART the quality of life and life expectancy has increased among PLHIV. Most PLHIV who adhere to treatment will be asymptomatic and live for many years eliminating the risk of developing AIDS. They will be able to contribute to the betterment of the country, society and their families.

02. The diagnosis of HIV affects a person physically, psychologically and socially. Care and support provided by the health care workers without stigma or discrimination will help them to adjust to living with HIV. Early identification through testing is important to provide comprehensive care services to all PLHIV. Services for PLHIV including antiretroviral treatment (ART) are available at STD clinics and Infectious Diseases Hospital (IDH).

03. It is necessary to take measures to facilitate comprehensive care services for PLHIV as per the guidelines given below.

- Provider initiated HIV testing should be offered to patients based on symptoms, signs or risky behaviours. Hospital clinic/ward has to arrange collection of 3cc of blood in a vacutainer tube and transport to the local STD clinic for HIV testing.
- STD clinics have to carry out HIV screening tests on the blood samples received from wards and issue reports. The information on HIV positive reports need to be informed immediately to the relevant medical officer or consultant while taking measures to strictly maintain the confidentiality.

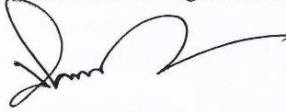
- iii. The screening test positive patient need to be referred to the STD clinic for confirmatory testing. Confirmatory test positive patients will be registered as a person living with HIV (PLHIV) at the STD clinic for further management.
- iv. It is the policy of the ministry of health that all PLHIV requiring institutional care be managed at general wards. Based on this policy decision the following procedures should be adopted. All PLHIV who need inward care facilities should be managed appropriately in the general wards (medical, surgical or any other speciality) in Colombo and in out-stations without stigma and discrimination. (General Circular No. 02/125/98)
- v. All measures need to be taken to maintain confidentiality.
- vi. Patients with infectious complications requiring barrier nursing may be transferred to the National Infectious Disease Hospital, only if the facilities are not available to manage them at respective health institutions.

04. National HIV policy of Sri Lanka states that "The government of Sri Lanka accepts the right of those living with HIV/AIDS to have access to treatment without stigma and discrimination. Persons living with HIV/AIDS requiring antiretroviral treatment and management of opportunistic infections will be provided by the state sector in line with the national guidelines and prevailing National Health policy." (3.8 page 22)

05. Further, the judgement given on SC.FR.No.77/2016 on 14.03.2016 states "The court also wishes to place on record that the state should ensure that the human rights of the people living with HIV/AIDS are promoted, protected and respected and measures to be taken to eliminate discrimination against them.(Page 4)

06. Ministry of Health seeks the commitment and cooperation of all hospital authorities to implement the programme for ending AIDS by 2025.

07. I reiterate the policy of the Government of Sri Lanka is to provide a comprehensive care services for PLHIV without stigma and discrimination. Your cooperation is earnestly requested.



 Dr. P.G.Mahipala
 Director General of Health Services
 Ministry of Health, Nutrition & Indigenous Medicine
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 Colombo 10.

Cc

1. Director, Private Health sector, MOH.
2. President, Sri Lanka College of Physicians.
3. President, Independent Medical Practitioners Association.
4. President, Ceylon College of General Practitioners.
5. President, Sri Lanka Medical Association.

Annexure 13 - General Circular No 01-31/2017

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Ministry of Health, Nutrition & Indigenous Medicine

General Circular No: 01 – 31/ 2017

All Provincial Secretaries of Health,
All Provincial/ Regional Directors of Health Services,
All Directors of Teaching Hospitals,
All Heads of Specialized Campaigns,
All Heads of Health Institutions,

Guideline for Education and Demonstration of Condoms

Among the countries in the South East Asian region, Sri Lanka remains a low prevalent country for HIV infection. This has been achieved through planning and implementation of a number of strategies. Correct and consistent condom use is identified as one such important strategy for HIV prevention.

The Condom is the only method of contraception which prevents both unwanted pregnancies and Sexually Transmitted Infections (STI). Thus it renders dual protection. The use of condoms during sexual intercourse has been recognized as one of the most successful prevention strategies for HIV infection. Therefore, promotion of condoms in Sri Lanka undoubtedly will play a key role in curbing the future HIV epidemic.

The condom is listed under the medical device category in the essential drug list published by the Ministry of Health of Sri Lanka. The National Medicines Regulatory Authority Act No. 5 of 2015 regulates and controls the manufacture, importation, sale and distribution of cosmetics, devices and drugs in Sri Lanka.

Condoms are widely available in Sri Lanka and are being distributed through STD clinics, family planning clinics, public health staff, and retail outlets. The Ministry of Health, Sri Lanka provides condoms free of charge for both family planning purposes and STI & HIV prevention activities, through health care service providers.

The objectives of condom programming in Sri Lanka :

- To prevent STIs and HIV infection through sexual transmission
- To prevent unwanted pregnancies
- To keep spacing in between pregnancies
- To prevent exchanging of different virus stains among HIV positive people when having sex with positive partners, to avoid ART resistance

National STD/AIDS Control Programme (NSACP) is responsible for the distribution of condoms free of charge for the clients attending the STD clinics, in order to achieve the objectives of dual protection and prevention of transmitted Anti Retro Viral Therapy (ART) resistance. STD Clinic clients include people who seek treatment from the island-wide STD clinic network and People Living with HIV (PLHIV). Further, The NSACP provides condoms free of charge for key populations through Principal Recipient-2 (PR-2) under the Global Fund for AIDS, Tuberculosis and Malaria (GFATM).

The NSACP encourages consistent condom use, in conjunction with the additional contraceptive methods among women living with HIV who are in need of family planning services. The objective of giving an additional family planning method is to avoid accidental unplanned pregnancies among women living with HIV who have not achieved undetectable viral load. Thus, it prevents mother to child transmission of HIV. All these steps are being followed after a series of counseling sessions.

The Family Health Bureau provides condoms as an approach of basket of choice. It is one of the five temporary methods provided by the National Family Planning Programme. In addition to being an option of the contraceptive menu provided in family planning clinics, Public Health Midwives and Public Health Inspectors distribute them during domiciliary visits. The clients for whom condoms are offered include couples who want to space their pregnancies, those who want to limit their children, and those who need a back up method during instances like missed pills and starting another method after the first few days of the cycle.

When counseling a client regarding family planning, the client should be allowed to select a method after offering all suitable methods.

Advantages of condoms:

- Correct and consistent use of condoms is the only method that can help in preventing transmission of STDs such as Gonorrhea, Chlamydia, Syphilis and HIV infection that are transmitted through body fluids, and in preventing unwanted pregnancy. The protection offered for other STDs transmitted through skin to skin contact is lesser, as in the case of genital herpes and genital warts.
- Studies among sero-discordant couples have shown that consistent condom use reduces the risk of HIV transmission by 80% to 94%.
- The contraceptive benefit of male condoms is around 98% when used correctly and consistently (failure rate is 2% per year). However, incorrect and inconsistent use of condoms can result in a higher failure rate. This highlights the importance of proper counseling to improve the correct usage of condoms.
- Condoms can help to protect fertility by preventing transmission of STIs, such as chlamydia and gonorrhea that cause infertility. The women whose partners use condoms are at a 30% lesser risk of infertility due to sexually transmitted infections.

Please take necessary measures to maintain adequate stocks of condoms in your area (province/ district/ institution), and to regularize the distribution of them, taking necessary steps to maintain the quality of the product.

Further, please instruct the relevant staff to conduct condom education and demonstration sessions for the clients using the dildos provided and adhering to the Guideline for Condom Education and Demonstration (attached herewith).



Dr. Jayasundara Bandara
Director General of Health Services
Ministry of Health, Nutrition & Indigenous Medicine

Annexure 14- General Circular No 01-25/2015

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To all consultants
 - STD clinic - more room
 - HIV clinic

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 Ministry of Health & Indigenous Medicine

General Circular No:- 01-25/2015

All Provincial Directors of Health Services
 All Regional Directors of Health Services
 All Directors/Officers in Charge of Medical Institutions
 All Directors of Special programmes
 Director, National Institute of Health Science
 All Heads of Teaching/General/Base & District Hospitals
 All Medical Officers of Maternal and Child Health
 Chief MOH, Municipal Council, Colombo
 All Medical Officers of Health
 Presidents of Professional Colleges

Providing Sexual & Reproductive Health (SRH) Services to Adolescents

This is further to the DGHS circular on the same bearing Gen. Circular No: 02-29/2011 dated 07.03.2011.

Adolescents comprise one fifth of our population. Adolescence is a period of exploration and experimentation. Adolescents engage in various risk behaviors resulting in unexpected and unwanted consequences. Society expects them to grow in to responsible, productive and healthy adults. The majority of adolescents fulfill our expectations respecting cultural norms and societal values. However there is a minority, who need the specialized attention of service providers warranting secondary and tertiary prevention efforts.

We have observed several issues pertaining to legal aspects of health service provision for adolescents and legal clarifications were sought from the Attorney General's Department.

We would like to draw your attention to the following points highlighted by the Attorney General's Department by the letter dated 28.05.2013 bearing Reference No CH/CM3/353/10 the letter dated 26.01.2015 bearing Reference No: E-100/2014.

- Since non-disclosure of rape does not fall within the ambit of section 21 of the Code of Criminal Procedure Act and is therefore not punishable under section 199 of the Penal Code, healthcare workers including Medical Officers do not have a legal duty to inform law enforcement authorities of pregnancies among adolescents aged below 16 years, who access ASRH services.
- When providing reproductive health services to adolescents, **the best interest of the child** should be the basic concern of Medical Officers who provide such services. Decisions on best interest should be assessed by the Medical Officers on a case by case basis.

For example, the Medical Officer could consider providing Adolescent Sexual & Reproductive Health (ASRH) services to a minor (a person below the age of 18 years), if it is likely that such minor would begin or continue to engage in sexual intercourse which is detrimental to the physical or mental health of such minor, if such reproductive health services are not provided. Considering the norms of the country, the Medical Officer must take all reasonable measures to obtain parental/guardian consent prior to providing such services. However, where the Medical Officer is unable to obtain parental/guardian consent, reproductive health services should be provided even in the absence of parental consent, in the best interest of the child.

Adolescent Sexual & Reproductive Health (ASRH) Services in this document includes :Pre pregnancy care; Care for the pregnant mothers (antenatal care) ; Care during delivery (intra natal care); Care for lactating mothers including Post Natal care; Contraceptive /Family planning services; Post abortion care; Prevention, Care and management of STI and HIV/AIDS; Prevention, care and management of Gender Based Violence.

We are grateful for your support in providing equitable and adolescent-friendly health services for our young persons. For more details, please refer the "Guidelines for health staff on providing adolescent sexual and reproductive health services". Further information can be obtained from the Family Health Bureau (Tel: 0112692746).

Thank you,



Dr P.G. Mahipala
Director General of Health Services

Dr. P. G. Mahipala
Director General of Health Services
Ministry of Health & Indigenous Medicine
385, "Suwasiripaya"
Rev Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

Cc: Secretary / Health & Indigenous Medicine

Guideline for Condom Education and Demonstration

1.	Introduction to advantages of condoms
	<ul style="list-style-type: none"> • Prevention of sexually transmitted infections including HIV • Prevention of unintended pregnancies • Reduce infertility by avoiding STIs • Increase pleasure by psychological relief from knowing the gained protection from STIs and unwanted pregnancies, and by preventing premature ejaculation through use of medicated condoms • Once the condom use is discontinued, fertility returns immediately • There is no need to depend on the stage of the menstrual cycle for initiation and use of condoms • Easily accessible, without a medical prescription • Contraindicated only in latex allergy • Enhance sexual pleasure by using condoms of different flavors and shapes
2.	Educate the client to assess the quality of the condoms
	<ul style="list-style-type: none"> • Store condoms in a cool dry place • Do not keep the condoms in places where they are exposed to frequent pressure or friction • Importance of checking the expiry date • Check whether the packet is intact (air sealed), and lubricant is not leaking. • Keep away from insects • Prevent access to children
3.	Educate the client about opening the packet
	<ul style="list-style-type: none"> • Not to use teeth or a pair of scissors to open the packet • Open the packet by tearing from the saw toothed edge
4.	Educate the client on wearing the condom
	<ul style="list-style-type: none"> • Put the condom on before there is any oral, vaginal or anal contact • Condom should be worn only after penile erection. • Condoms should be worn during foreplay with partner's assistance • Take the condom out and find the correct side for use (Rolling edge should be facing out) • In a situation where the condom is put on upside down by accident, use a new

	condom
	<ul style="list-style-type: none"> • Before wearing the condom, retract the foreskin fully
	<ul style="list-style-type: none"> • Squeeze the teat of the condom with two fingers to expel air
	<ul style="list-style-type: none"> • Unroll the condom on the erect penis up to the base. If unrolling is difficult, suspect damage or rolling edges facing inside. May have to use a new one.
	<ul style="list-style-type: none"> • Once the sexual act is over the condom should be removed before the penis becomes flaccid. <p>Withdraw the condom by holding the rim (base) of the condom. If the condom is damaged, emergency contraception needs to be used to prevent a pregnancy. However, there is no way to prevent transmission of sexually transmitted infections.</p>
	<ul style="list-style-type: none"> • Use a tissue or paper to remove the condom to prevent direct contact with genital secretions.
	<ul style="list-style-type: none"> • Wrap the removed condom in a tissue or a paper and dispose it in a way similar to disposing garbage.
	<ul style="list-style-type: none"> • Avoid throwing the used condom into the toilet or open areas.
	<ul style="list-style-type: none"> • Do not wear two condoms at the same time.
	<ul style="list-style-type: none"> • Use only water based lubricants. Oil based lubricants can rupture the condom, so never use them (eg. creams).
	<ul style="list-style-type: none"> • Use lubricants for condoms during anal sex and if necessary during vaginal sex, to avoid condom breakage, or if either partner experiences irritation not attributed to an allergy.
	<ul style="list-style-type: none"> • Use a new condom with each act of intercourse or when having sex in different forms (oral, vaginal and anal)
	<ul style="list-style-type: none"> • Always keep a few extra condoms.

In the process of condom education and demonstration, always actively listen to the clients and attempt to get the ideas of them and clearly answer the questions posed by them.

In conclusion, summarize the points taught during the session and ask the client to demonstrate by using the dildo. Reinforce the correct and consistent use of condoms.

Annexure 15 - General Circular No 01-34/2016

General Circular No: 01 - 34 / 2016

My Number: DMH/A/18/2016
 Ministry of Health, Nutrition and
 Indigenous Medicine
 385, Ven. Baddegama
 Wimalawansa Thero Mawatha
 Colombo 10.
 16.06.2016.

All:

Provincial Health Secretaries,
 Provincial Directors of Health Services,
 Regional Directors of Health Services,
 Directors of Teaching Hospitals,
 Medical Superintendents of Hospitals,
 Heads of Specialized Campaigns,
 Heads of Health Institutions,
 Deans of Medical Faculties,

Issuing of Gender Recognition Certificate for Transgender Community

Transgender is an umbrella term for all people whose internal sense of their gender (their gender identity) is different from the sex they were assigned at birth. For example, a transgender woman is someone assigned male at birth who identifies as female (WHO 2015).

Transgender people are often socially, economically, politically and legally marginalized. Discrimination and vulnerable to harassment, violence and sexual assault and discrimination in access to public spaces like restaurants, cinemas, public toilets are common. Therefore amending the sex designation on a birth certificate is an extremely important step for a transgender person, to accurately reflect on this legal document the sex with which the individual identifies, and as required proof of sex to obtain other identity and legal documents.

Considering above facts, Ministry of Health, Nutrition and Indigenous Medicine has decided to establish services for transgender communities in every institution, with capacity of specialist psychiatric care (Consultant Psychiatrist).

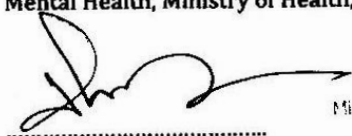
When a person requests service, the responsible consultant psychiatrist will provide the care which includes assessment, counseling and issuing a **Gender Recognition Certificate (GRC)** to assist with the process of changing the sex on a birth certificate. The certificate could be issued only to those above 16 years of age and it will indicate the desired gender as to be shown in birth certificate. This document has to be certified by a Consultant Psychiatrist and then the Head of the Institution working under the Ministry of Health.

When a person in the private sector requests it, he should be referred to the closest government hospital with a Consultant Psychiatrist to obtain the certificate.

A system is established on Transgender information management; maintain a register at the institution for effective monitoring of the services. The Directorate of Mental Health is currently taking steps to set up process for transgender information management. Two main documents need to be maintained.

- Transgender Notification Register (TNR); When a person is issued GRC, information such as name, date of birth, birth sex, desired gender, National Identity Card number, bed-head ticket/clinic number should be entered in the TNR. Register will be maintained in the Psychiatric unit of the institution.
- Gender Recognition Certificate will be prepared in triplicate with one to be issued to the person concerned, the second to be retained at the hospital and third to the Directorate of Mental Health, Ministry of Health.

Kindly make arrangements to make aware all the Consultant Psychiatrists and other relevant officers in your institution on the above to stream line services for transgender persons and issuing the Gender Recognition Certificate. A copy of the certificate and sample of the register is attached herewith for your information. More details can be obtained from the Directorate of Mental Health, Ministry of Health, Nutrition and Indigenous Medicine.



Dr. P. G. Mahipala
Director General of Health Services
Ministry of Health, Nutrition and Indigenous Medicine
"Sumanabaya",
305, Raj. Shaldegama Yakkalamawansa Thero Mawatha,
Colombo 10.

Dr. P.G. Mahipala
Director General of Health Services

Cc:
Secretary/Ministry of Health, Nutrition and indigenous Medicine
Deputy Director General (MS) I
Deputy Director General (MS) II
Deputy Director General (NCD)
Director/Mental Health
President/Sri Lanka College of Psychiatrists

H 1257

Gender Recognition Certificate**Ministry of Health- Sri Lanka**

This certificate is issued for the purpose of change the gender and name on Birth Certificate by the Section 27 and 52(1) of Birth and Death Registration Ordinance

A) General Information

1. Name in Full:
2. Name of the Father:
3. Name of the Mother:
4. Home Address:
5. National Identity Card number:
6. Birth sex : MALE/FEMALE (Underline the appropriate)
7. Date of Birth: Birth Place:
8. Registered No: Date:

B) Declaration of Gender

I..... (Full name) of
..... (Profession)
declare that the above mentioned person was assessed by me for his/her psychological status for gender reassignment. Based on the assessment I am able to make a diagnosis of male/female to female/male transsexualism according to the criteria of the World Health Organization- International Classification of Diseases 10th version.

The afore mentioned person was educated on identified concerns in the overall treatment plan in order to facilitate the process to provide the best available care in accordance with their clinical needs and goals for gender expression.

Following the required procedure the afore mentioned person was referred for hormone therapy and the necessary surgical treatment.

I hereby certify that the afore mentioned person underwent the gender transformation process according to the internationally recognized and accepted standards of care published by the World Professionals Association for Transgender Health (WPATH) and completed the social gender role transition as required.

I further declare that the afore mentioned person changed the gender from..... to..... on/...../..... and is eligible to apply for the change of gender and name in the birth certificate as mentioned below.

New name:

New gender:

Name:

Signature:

(Consultant psychiatrist)

(Head of the Institution)

.....
(Official seal)

.....
(Official seal)

.....
(Date)

.....
(Date)

Transgender Notification Register

Name of the Institution: Unit:

Date	Name	Date of Birth	NIC Number	Birth sex	Desired gender	Address	BHT/ Clinic No.	Remarks

Annexure 16 - General Circular No -01-19/2017

දුරකථන) 0112664192, 0112675011
 தொலைபேசி) 0112698507, 0112684033
 Telephone) 0112675449, 0112675280

දුරකථන) 0112693866
 தொலைபேசி) 0112693869
 Fax) 0112692913

විද්‍යුත් තැපෑල) postmaster@health.gov.lk
 மின்னஞ்சல் முகவரி)
 e-mail)

වෙබ් අඩවිය) www.health.gov.lk
 இணையத்தளம்)
 website)



සුවසිරිපාය
 சுவசிரிபாய
 SUWASIRIPAYA

ගනු ලබන)
 எனது இல)
 My No.) DDG/PHS-1/NSACP/2011

ඔබගේ)
 உமது இல)
 Your No.)

දිනය)
 திகதி)
 Date) 08.03.2017

සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍යාංශය
 சுகாதார, போசணை மற்றும் சுதேச வைத்திய அமைச்சு
 Ministry of Health, Nutrition & Indigenous Medicine

General Circular No.

01-19/2017

All Provincial / Regional Directors of Health Services,
 All Directors of Teaching Hospitals,
 All Heads of Specialized Campaigns,
 All Heads of Government Medical Institutions,

Management of healthcare workers following occupational exposure to blood and other body fluids and post exposure prophylaxis for HIV

A). The General Circular letter reference No-36/2001 dated 12th March 2001 on "Management of Health-Care Worker Exposures to HIV and Recommendations for Post Exposure Prophylaxis" is hereby cancelled.

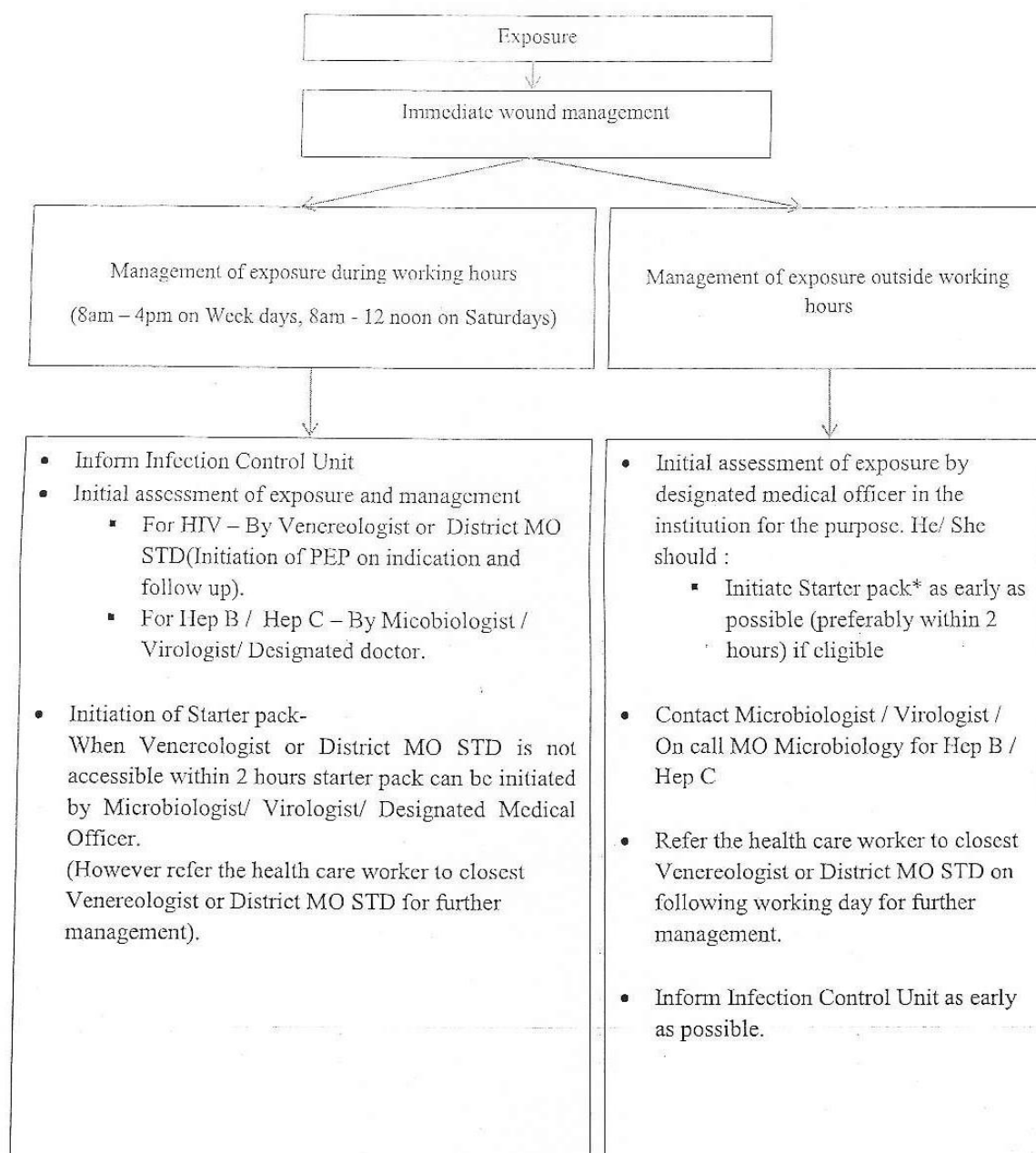
B). This circular outlines recommendations for the management of health care workers who experience occupational exposures to blood and other body fluids that might contain Human Immunodeficiency Virus (HIV).

C). Although preventing exposures to blood and other body fluids that might contain HIV is the primary means of preventing occupationally acquired HIV infection, appropriate post-exposure management is an important element of workplace safety. Department of Health has considered information available worldwide and recommends that the following procedure for post exposure prophylaxis (PEP) be followed in an accidental exposure. This circular recommends all health care workers with occupational exposures to HIV to attend to a STD clinic with the source blood sample as early as possible for management and follow up.

D). It is the responsibility of the head of the institution to make sure

1. That there is a functional system of management of healthcare workers following occupational exposure to blood and other body fluids.
2. That antiretroviral drugs (ARV) are available for PEP.

E). Management of occupational exposures



*Starter Pack -Antiretroviral medication for the post exposure prophylaxis for 5 days. We recommend keeping this starter pack in a readily accessible place / places such as OPD / ETU / ICU / PCU / Pharmacy.

F). Definition of a Health Care Worker (HCW) for the purpose of this circular

The term HCW refers to all persons working in the health care setting who has the potential for exposures to infectious materials, including body substances (e.g. blood, tissue and specific body fluids), contaminated medical supplies and equipment, and contaminated environmental surfaces(1).

G). Definition of Exposure

An “exposure” that may place a health care worker at risk for HIV infection and requires consideration of PEP is defined as follows:

1. Type of Exposure

- i. Percutaneous injury - Needle stick or cut with a sharp object.
- ii. Contact of mucous membranes
- iii. Non-intact skin- chapped, abraded or afflicted with dermatitis

2. Type of body fluid

With blood, tissue or other body fluids that are potentially infected.

(Semen, vaginal secretions, breast milk, cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid and amniotic fluid are considered potentially infectious)(2).

Saliva, urine, nasal secretions, vomitus and feces bear no risk of HIV infection in the absence of visible blood. Exposure to tears and sweat does not require post exposure prophylaxis (2)(3).

H). Risk of Occupational Transmission of HIV to HCWs from HIV infected blood

• Percutaneous injury	0.30%	95% CI = 0.2% - 0.5%.(1)(3)(5)
• Mucous membrane	0.09%	95% CI = 0.006% - 0.5%.(1)(3)

I). Management of the Exposed Site

Exposed sites should be cleansed of contaminated fluid as soon as possible after exposure. Wounds and skin sites are best cleansed with soap and water, avoiding irritation of the skin. Exposed mucous membranes should be flushed with water. Alcohol, hydrogen peroxide,

betadine or other chemical cleansers are best avoided. IICWs should be made aware to avoid “milking” or squeezing out needle-stick injuries or wounds (AII)(2)(3).

J). Evaluating the Exposure

- I. Prompt initiation of PEP is recommended for exposure to blood, visibly bloody fluids or other potentially infectious material from HIV-infected or HIV-unknown sources in any of the significant exposure situations outlined in Table 1(AII).
- II. Whenever a worker has been exposed to potentially HIV-infected blood, visibly bloody fluids or other potentially infectious material through the percutaneous or muco-cutaneous routes or through non-intact skin, PEP is indicated. For these exposures, prompt initiation of PEP followed by telephone or in-person consultation with a clinician experienced in HIV PEP is recommended.

Table 1 : Exposures requiring initiation of starter Pack

- Break in the skin by a sharp object (including hollow-bore, solid-bore, and cutting needles or broken glassware) that is contaminated with blood, visibly bloody fluid, or other potentially infectious material, or that has been in the source patient’s blood vessel.
- Bitten by a person with visible bleeding in the mouth that causes break in the skin or mucosa of the exposed worker.
- Splash of blood, visibly bloody fluid or other potentially infectious material to a mucosal surface (mouth, nose, or eyes).
- A non-intact skin (e.g.: dermatitis, chapped skin, abrasion or open wound) exposure to blood, visibly bloody fluid or other potentially infectious material

K). Determine the HIV status of the source patient and initiation of PEP

a. Known Positive patient

Start PEP immediately with available three drug regimen.

Contact Consultant Venereologist (STD clinic) as early as possible.

b. Sero-status is unknown

I. When source patient is available

Consent for HIV testing of the source patient should be sought (AII) (2). If facilities are available, rapid HIV test on source sample should be carried out. This can be done at closest STD clinic or any other lab where rapid test is available.

II. Consent for HIV testing

- When the source patient has the capacity to consent to HIV testing, informed consent is required.
- When the source person does not have the capacity to consent, consent may be obtained from a surrogate, or anonymous testing may be done if a surrogate is not immediately available (2).
- If the result from testing source patient is not immediately available, considering severity of exposure and epidemiological likelihood of HIV status of the source, starter pack can be initiated (preferably within 2 hours of the exposure) while source testing and further evaluation are underway (2).

III. When source patient is not available (e.g. needles in sharp bins and laundry)

Considering severity of exposure and epidemiologic likelihood of HIV exposure, starter pack can be initiated. Decision regarding continuation of PEP where source patient is not available should be made on a case by case basis by Venereologist / MO-STD.

L). Timing of the Initiation of PEP

- i. When a potential occupational exposure to HIV occurs, every effort should be made to initiate PEP as soon as possible, ideally within 2 hours (AII). A first dose of PEP should be offered to the exposed worker while the evaluation is underway (2).
- ii. Decisions regarding initiation of PEP beyond 72 hours post exposure should be made on a case-by-case basis with the understanding of diminished efficacy when timing of initiation is prolonged (AIII)(2).

M). Recommended PEP regimen

Three drug regimen

TDF 300mg daily

FTC 200mg daily

LPV/r 400/100mg 12 hourly or ATV/r 300/100mg daily

Venereologist could decide on alternative regimens according to circumstances.

N). Duration of PEP Regimen

PEP need to be considered for 28 days (1)(2)(3).

When the source patient is confirmed to be HIV-negative, PEP could be discontinued(1)(3).

O). Baseline testing for the exposed health care worker and Follow up

i. Confidential baseline HIV testing of the exposed worker should be obtained at the time the occupational exposure is reported or within 3 days of the exposure (AIII).

ii. All exposed workers receiving PEP should be re-evaluated within 3 days of the exposure. This allows for further clarification of the nature of the exposure, review of available source patient data and evaluation of adherence to and toxicities associated with the PEP regimen (1)(3).

iii. The exposed worker should be evaluated weekly while receiving PEP to assess treatment adherence, side effects of treatment, interval physical complaints and emotional status.

iv. Clinicians should provide risk-reduction counseling to HIV-exposed workers to prevent secondary transmission during the 16-week follow-up period. HIV-exposed workers should be educated and counseled on:

- I. Use of condoms to prevent potential sexual transmission.
- II. Avoiding pregnancy and Breast feeding (2).
- III. Avoiding needle shearing.
- IV. Refraining from donating blood, plasma, organs, tissue or semen.
- V. identifying symptoms of primary HIV infection and report as soon as possible.

Investigations recommended for the healthcare worker who are on PEP							
	Baseline	Week 1	Week 2	Week 3	Week 4	Week 10	Week 16
Clinic visit	✓	✓ Or by telephone	✓	✓ Or by telephone	✓		
Pregnancy Test	✓						
FBC */LFT and RFT	✓		✓		✓		
HIV Test	✓					✓	✓
*Follow-up FBC is indicated only for those receiving a Zidovudine-containing regime.							
Week 10 , 16 HIV testing should be done by using ELISA							
HIV testing recommended for the healthcare worker who are not on PEP at baseline, week 6 and 12 from the exposure date.							

P). Exposed workers who are pregnant and breast feeding

1. Pregnancy and breast feeding are not contraindications for PEP and recommended regimens can be used (2).
2. Before administering PEP to a pregnant woman, the clinician should discuss the potential benefits and risks to her and to the fetus (2)(3).
3. Clinicians should counsel women who may have been exposed to HIV through occupational exposure to avoid breastfeeding for 3 months after the exposure (All). If HIV infection is definitively excluded in the source patient at any time prior to 3 months post-exposure, the woman may resume breastfeeding.

Q). Exposure Report

If an occupational exposure occurs, the circumstances and post exposure management should be recorded in the HCW's confidential exposure report (Annex I).

R). References

- i. U S Public health service guideline. Updated US Public Health Service Guideline for Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendation for Post exposure Prophylaxis. *Infection Control and Hospital Epidemiology*. 2013;34:875-892
- ii. New York State Department of Health AIDS Institute. HIV prophylaxis following occupational exposure. www.hivguidelines.org. Updated October 2014. Accessed April 2016
- iii. Centers for Disease Control and Prevention. Updated U.S. Public Health Service guidelines for the management of healthcare worker exposures to HIV and recommendations for post exposure prophylaxis. 2013.
- iv. World Health Organization. Guidelines on post exposure prophylaxis for HIV and the use of co-trimoxazole prophylaxis for HIV related infections among adults, adolescents and children: recommendations for public health approach. December 2014 supplement to the 2013 guidelines.
- v. UK guidelines for the use of HIV post-exposure prophylaxis following sexual exposure. 2015.
- vi. AIDS EAGO. HIV post-exposure prophylaxis: guidance from the UK Chief Medical Officers' expert Advisory Group on AIDS (2008)2008.

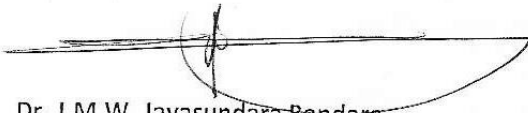
S). Level of evidence

A - High quality evidence

B - Moderate quality evidence

C – Low quality evidence

D – Very low quality evidence



Dr. J.M.W. Jayasundara Bandara

Director General of Health Services (Actg.)

J.M. W. Jayasundara Bandara
Director General of Health Services (Acting)
Ministry of Health, Nutrition & Indigenous Medicine,
No. 385, "Suwasiripaya",
Colombo 10, Sri Lanka

Exposure Report

1. Date :...../...../.....	2. Institution :.....	3. Name / Designation of HCW :.....
-------------------------------	--------------------------	--

4. Date / Time of Exposure /...../..... am / pm	5. Details of the procedure i. Laboratory / Theatre / Ward / Clinic / Labour Room / Others ii. How the exposure occurred :..... :.....
---	--

6. Details of the exposure
 Type of body fluid: Amount: Small / Large
 i. Percutaneous injury – Yes / No
 If Yes, Type of the device – Hollow bore needle / Solid needle / Other sharp devices / Blunt devices
 ii. Mucosal exposure : Yes / No
 If Yes, Site of exposure :.....
 iii. Non – intact skin : Yes / No

7. Details of the source

- Source identified : Yes / No
- If Yes
 - If Already A HIV Positive
 - Stage of the disease.....
 - Recent Viral Load.....
 - CD4 Cell Count.....
 - On ART - Yes / No..... If YesART Regimen.....
 - Resistance Details.....
 - If HIV status unknown.....
 - Rapid Test / ELISA Test done
 - Results - Positive / Weakly Reactive / Negative
 - If HIV Negative - Possibility of Acute Infection / High Risk behavior
Yes / No
- Other blood borne pathogens

8. Management of post exposure	
• PEP recommended	Yes / No
• PEP accepted by HCW	Yes / No
• If Yes....., ART Regimen

9. Follow up HIV Test on HCW	10. Name, Signature and Designation of Counselor
6 / 10 Weeks : Positive / Negative
12 / 16 Weeks : Positive / Negative

Annexure 17 - General circular no 02-125/1998

General Circular letter No. 02/125/98

My No: ~~Min/100/57/98~~ 02/125/98Ministry of Health & Indigenous
Medicine,385, Baddegama Wimalawansa Mawatha,
Colombo 10.

22 November, 1998.

To: Provincial Directors of Health Services,
Deputy Provincial Directors of Health Services,
Directors of Teaching Hospitals,
Heads of Specialized Campaigns
All Heads of Institutions.

Office E
Please circulate
among not
copy to note.
11/12/98

MANAGEMENT OF PATIENTS INFECTED WITH HUMAN
IMMUNE DEFICIENCY VIRUS

It is the policy of the Ministry of Health and Indigenous Medicine that all HIV/AIDS infected persons requiring institutional care be managed in the general wards. Based on this policy decision, the following procedures should be adopted.

- All persons with HIV related diseases should be managed in the general wards (medical, surgical or any other speciality) in Colombo and in out-stations.
- Patients with infectious complications requiring barrier nursing, eg. pulmonary TB, diarrhoea, discharging wounds etc. may be transferred to the Infectious Diseases Hospital IHM Angoda. Whenever facilities are available, such patients too should be managed in the respective health care institutions.
- Chronically ill patients should be encouraged to be managed at home/ in the community.

Please refer to General Circular Letter No.4521 for the clinical care definition for AIDS and for procedures to be followed when requesting a HIV antibody test.

Juni
Deputy Director General(MS)

Eg/ ~~100/57/98~~ Jeganathan
DIRECTOR GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & INDIGENOUS MEDICINE

Annexure 18 – Health protection plan for resident VISA applicants to Sri Lanka

General Circular Number: 01-37/2019

My No: PA/DDG PHS II/1/MHD/2019

Ministry of Health, Nutrition and Indigenous Medicine,

Colombo 10.

03/07/2019

Deputy Director Generals of Health Services

Provincial Directors of Health Services,

Directors of Ministry of Health/ Specialized Campaigns/ Epidemiology Unit

Regional Directors of Health Services,

Directors of Line Ministry Hospitals, Provincial General Hospitals,

Medical Superintendents of District General Hospitals, Base Hospital A & B,

DMOO of Divisional Hospitals,

MOOIC of Primary Medical Care Units,

Medical Officers of Health.

Circular on Implementation of Health Protection Plan (HPP) for the Residence Visa Applicants to Sri Lanka

Reference is made to the National Migration Health Policy of Sri Lanka and the previous Cabinet decisions CP No. 11/2140/509/159 dated 14.12.2011. Cabinet also granted approval to authorize the Ministry of Health, Nutrition & Indigenous Medicine to enter into the Memorandum of Understanding (MoU) with the International Organization for Migration (IOM) on the establishment and implementation of an Inbound Health Assessment Programme for Residence Visa applicants to Sri Lanka, (reference CP No. 18/0431/718/023 dated 20.03.2018). MoU was signed on 04.05.2018.

1. The Health Protection Plan (HPP) for migrants to Sri Lanka, applies to all the residence visa applicants (Exempted categories are mentioned in the web site of Department of Immigration and Emigration web site). The HPP includes a mandatory health assessment and a health protection cover through the government sector described under section 6.
2. The HPP is coordinated by the Immigration Health Unit (IHU) of the Quarantine Unit, Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka in collaboration with the In-bound Health Assessment Center/IHAC (currently operated by the designated panel physician - International Organization for Migration/IOM). The selected applicants will be issued an HPP card by the IHU at a charge of USD 75 and is valid for a period of one year.

General Circular Number:

3. IHAC is currently established at No: 80A, 10th floor, IBSL building, Elvitigala Mawatha, Colombo 08.
4. The health assessment comprises screening for Malaria, Tuberculosis, HIV and Filariasis. The technical instructions for the designated panel physicians for the health assessments (screening) for these four diseases have been developed by the national disease control programs of the Ministry of Health, Nutrition and Indigenous Medicine.
5. Those who screen positive for Malaria, HIV, Filariasis and Tuberculosis will be referred to the respective national disease control programs for confirmation, treatment and follow up.
6. The respective national disease control program will refer the patients for follow up to the decentralized units of the control program in the district of residence of the applicant. The community follow up should be done by respective MOOH and PHIs similar to the follow up of a Sri Lankan citizen.
7. The HPP in addition to the health assessment covers emergency care and ambulatory primary care at all government health institutions in Sri Lanka. The applicants with a valid HPP card are eligible to avail the above health services free of charge at the point of delivery.
8. The HPP will not cover hospitalization other than for emergency care in the government sector. For any non-emergency hospitalization, the existing conditions and fees applicable to any non-citizen accessing government services will apply. The HPP does not cover any services obtained from the private sector.
9. The HPP card carrying the Government of Sri Lanka logo gives the personal identification information and the period of validity (It includes name, date of birth, nationality, passport no, relevant agency/sponsor, residential address, contact number and photo of the Residence visa holder).
10. All Provincial Directors of Health Services and Regional Directors of Health Services should instruct heads of all health care institutions/ decentralized campaign units in their provinces / districts accordingly. All heads of institutions (Directors / Medical Superintends / DMOO / Medical Officer in-charge and MOOH) should inform their staff about the services provided to HPP card holders with approved residence visa.

General Circular Number:

11. The HPP is intended to adopt an inclusive approach for health services whilst preserving public health in Sri Lanka and is aligned with the efforts to keep Sri Lanka Malaria free, eliminate Filariasis and to reduce the burden of TB and HIV/AIDS.

.....
Dr. Anil Jasinghe

Director General of Health Services

Dr. Anil Jasinghe
Director General of Health Services
Ministry of Health, Nutrition & Indigenous Medicine,
"Suwasiripaya"
38, No. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

CC:

1. Secretary - Ministry of Health, Nutrition and Indigenous Medicine

Annexure 19 – Police circular- Use of condoms as evidence of sex work

Translation of the circular issued by the Deputy Inspector General of Police (Legal) regarding the use of condoms as evidence of sex work

CRTM 149

RTM 60

To: All senior DIGs
DIGs
Directors
Commanding officers
Provincial officers
District officers
Inspectors of Police

Regarding use of condoms as evidence of sex work

It has been observed that condoms are being produced to courts as an evidence to sex work practise during arrests under the vagrants ordinance.

The closest example was the incident reported by Lankadeepa newspaper on 30.09.2017 which highlighted in a subheading as “11 individuals including 8 women were arrested with 1064 condoms.”

Condoms are legal and safe health equipment which prevent sexually transmitted infections and control pregnancies, thus there is no legal barrier to keep or use them.

Such health equipment are used for public health safety. Therefore, all police officers should be informed that keeping condoms should not be a reason to arrest under Vagrants ordinance and condoms should not be produced as evidence to courts.

It is the duty of the officer in Charge of the police stations to make necessary arrangements to make all police officers aware about this issue.

DIG
Division of Discipline, behaviour and law
Police Headquarters, Colombo 01
October 2017

Annexure 20 – Booklet for paediatricians and obstetricians

Important messages to hospital based health care workers on Elimination of mother to child transmission of HIV and syphilis



Summary of guidelines for EMTCT of HIV and syphilis

- All pregnant women are to be offered screening for Syphilis and HIV before 12 weeks of gestation (preferably at the first visit). **The test is done on voluntary basis with the informed consent of the pregnant woman.**
- The information on reactive VDRL reports and HIV positive reports need to be informed to the MO, MOH or VOG and measures should be taken to **strictly maintain the confidentiality** of the information.
- All ward staff should be aware of the need for confidentiality in relation to the pregnant woman's HIV status. Staff members will be informed only on "need to know basis".
- All pregnant women with Syphilis or HIV should be provided appropriate services including institutional care, **without stigma or discrimination.**

Important points in the management

- Ensure privacy and confidentiality during consultations and reassure the woman that her HIV status will be kept confidential.
- Explain to the woman with whom the information will be shared with.
- Explain to the woman that she will have to follow routine antenatal care and give her confidence by discussing the management plan with her.
- Invasive perinatal diagnostic testing should not be performed until the viral load is adequately suppressed.
- Plan and discuss the mode of delivery with the pregnant woman during antenatal care. Give her instructions on when to get admitted for delivery and whom she should contact on admission.
- Health care workers should practice universal infection control measures at all time.
- HIV positive pregnant women should receive optimal care by a multidisciplinary team consisting of obstetrician, venereologist, paediatrician, MOH and infection control unit.
- When providing services regarding mode of delivery, family planning or infant feeding pregnant woman is counselled and her choice is respected.

When to start ART in pregnant and breast feeding women

- Antiretroviral therapy (ART) should be initiated as early as 14 weeks of gestation or as soon as possible thereafter during pregnancy.
- Even if they are identified late in pregnancy or post partum, ART should be initiated immediately as it is the most effective way to prevent MTCT.

When a HIV infected pregnant woman is admitted for delivery check for the following:

- ART has been taken as prescribed
- Recent viral load result
- Availability of syrup Nevirapine for the baby
- Infant feeding choice
- Availability of safe delivery kits
- Availability of post exposure prophylaxis in the event of an occupational exposure
- Choice of contraception and make arrangements to provide the required contraceptive method

Caesarian Section

Caesarian section before labour or rupture of membranes allows baby to avoid contact with maternal blood and cervical secretions. LSCS should be considered as the mode of delivery in HIV infected pregnant women with unknown viral loads or viral load > 50 copies/ml closer to delivery.

Recent studies indicate that there is no significant difference in the risk of MTCT of HIV in women with undetected viral load close to delivery when compared to those who have planned vaginal delivery and planned LSCS.

If vaginal delivery is considered or unavoidable:

If viral load is <50 copies/ml at 36 weeks the risk of MTCT is less in the absence of obstetric contraindications. In women for whom vaginal delivery is recommended, once labour has commenced obstetric management should follow the same principles as for the uninfected population.

- Head should be presenting and well engaged.
- Check if cervix is effaced and dilated and await spontaneous labour.
- Minimize vaginal examinations to reduce the risk of infection to the mother. Maintain aseptic techniques throughout labour.
- ART should be continued as recommended.
- Avoid Amniotomy, fetal scalp electrodes and blood sampling, instrumental delivery and episiotomy in pregnant women with HIV because of theoretical risk of transmission.
- Artificial rupture of membranes increases the risk of infection of the placental membranes.
- Avoid prolonged labour.

Management of pre labour spontaneous rupture of membranes:

- If maternal viral load is < 50 copies/ml immediate induction of labour is recommended preferably under antibiotic cover.
- If maternal viral load is > 50 copies/ml immediate LSCS is recommended.
- If maternal viral load is unavailable immediate LSCS is recommended.

Post partum care

Instruct her of the safe disposal of lochia and blood stained sanitary wear or other potential infectious material.

Women who have not received antepartum ART and women who present in labour without documentation of HIV status:

- Offer urgent HIV testing using rapid test. Counsel mother get informed consent and collect blood for rapid HIV test.
- If rapid test is positive start ART (emergency pack) immediately without waiting for serological confirmation.
- Send blood sample to closest STD clinic for HIV ELISA test. Decide continuation of ART based on the ELISA test results.

Management of the baby

Care for the newborn

- Avoid suctioning of mouth and pharynx of the infant which may cause trauma to the mucous membranes thus promoting MTCT.
- Clean the eyes of the baby with saline at delivery of head.
- Clamp the cord as soon as possible to minimize the risk of maternal fetal micro transfusions.
- Cover the umbilical cord with a swab when cutting to prevent blood spurting.
- Towel dry the baby.
- Clean the baby's skin thoroughly before any infusions or injections.

Starting syrup Nevirapine for the baby

- Baby should be commenced syrup Nevirapine soon after birth within 4 hours.
- Infants receiving replacement feeding should be given 6 weeks of daily syrup Nevirapine.

Preparation for infant feeding

- Pregnant woman is counselled by the paediatrician and venererologist regarding infant feeding options. The counsellor should support the HIV positive pregnant woman to use infant feeding option of her choice.

The following points will be considered during counseling for infant feeding.

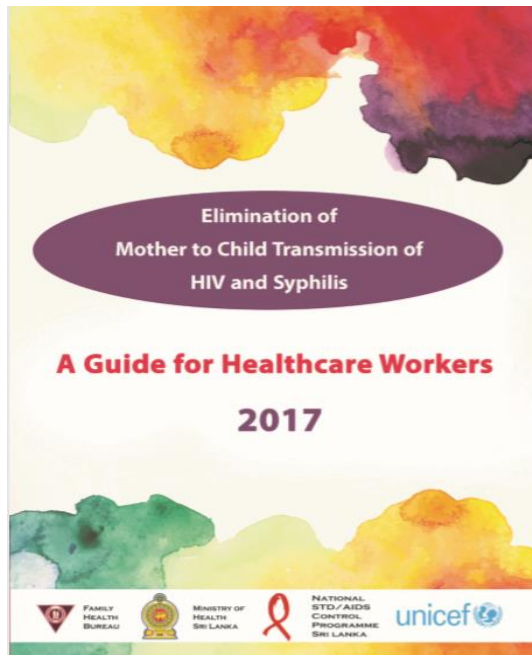
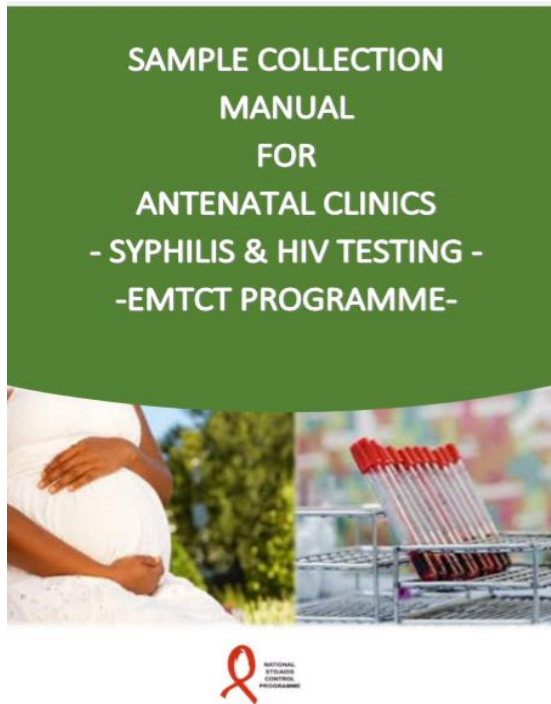
- Exclusive breast feeding for 6 months have benefits to any baby and is recommended to all pregnant women in Sri Lanka.
- Babies who are not infected at the time of birth are at risk of being infected after birth through breast feeding. If the pregnant woman is on ART with satisfactory viral suppression during breast feeding period the risk of transmission can be reduced.

- There is now enough evidence that triple ART given during prenatal period with safe delivery practices and safer feeding practices has substantially lowered MTCT of HIV.
- If a pregnant woman decides on formula feeding formula milk is provided free of charge for babies born to women with HIV through a NGO till the baby is one years old.

For further information please refer relevant guidelines
www.aidscontrol.gov.lk

Annexure 21 - EMTCT Guides and Manuals for field staff

EMTCT Guides and Manuals for field staff



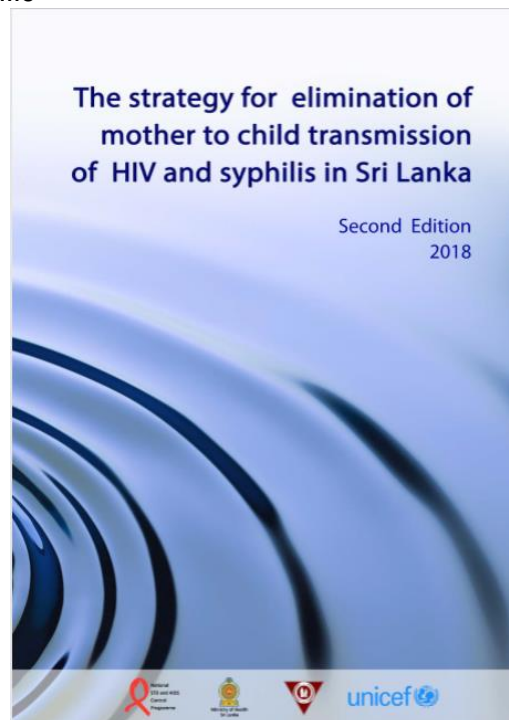
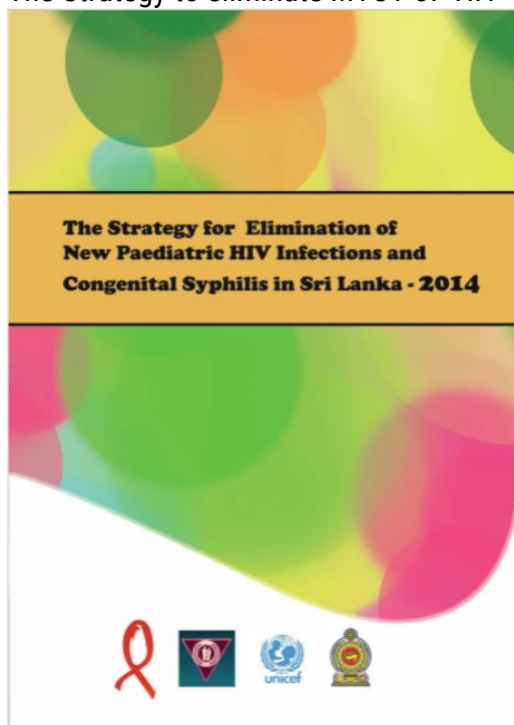
EMTCT Leaflet



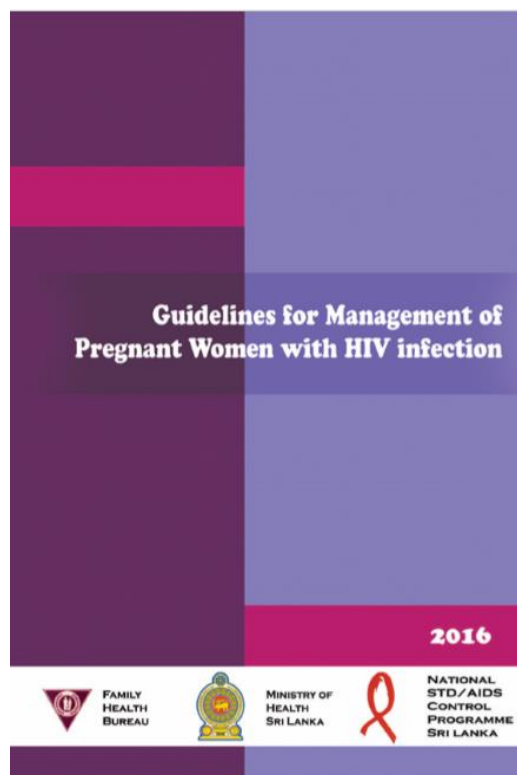
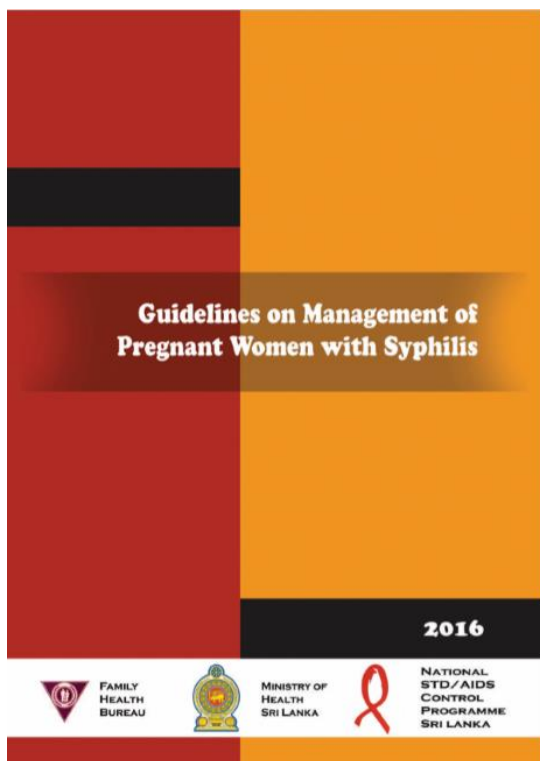
EMTCT Poster



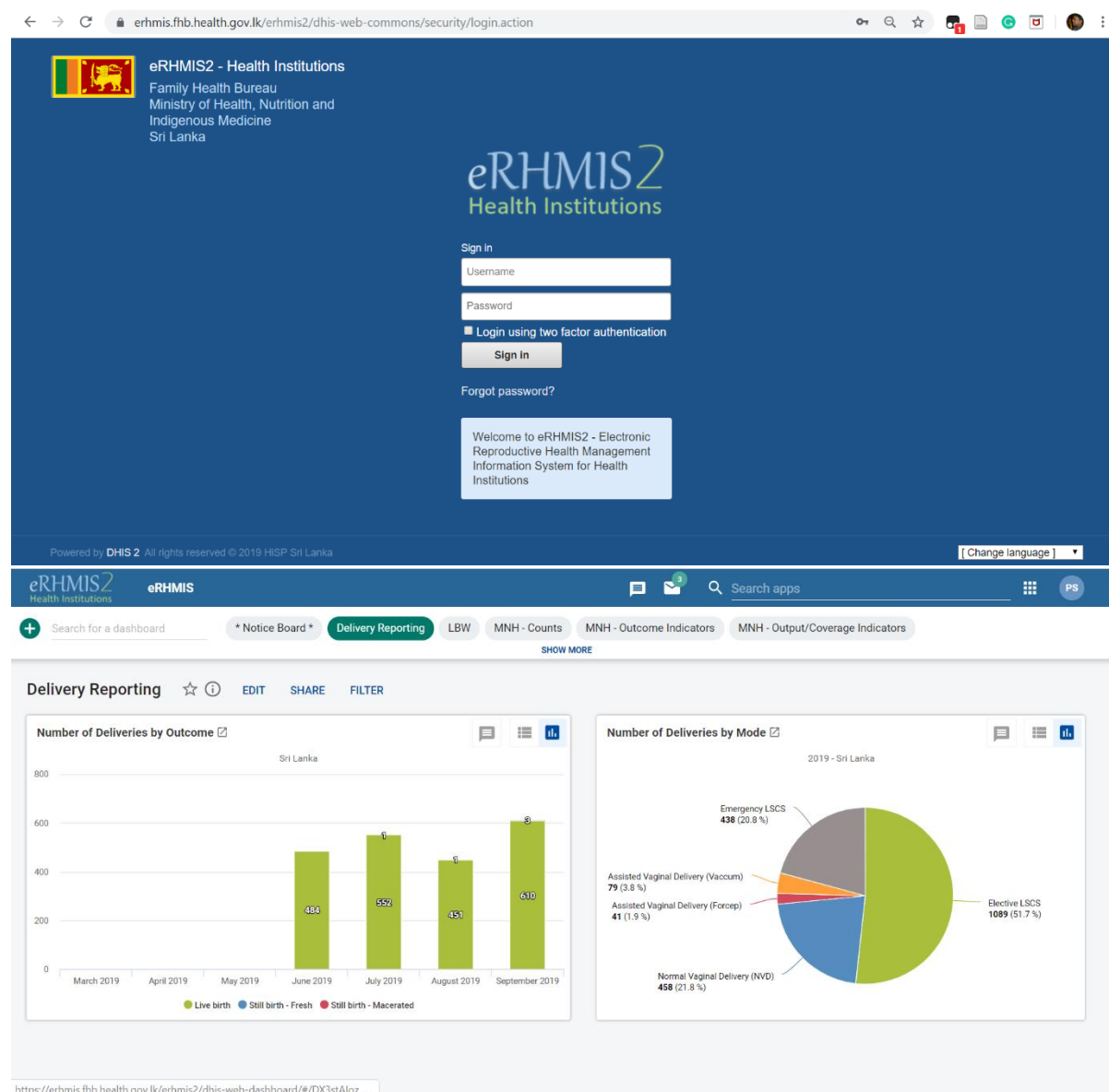
The Strategy to eliminate MTCT of HIV and dsyphilis

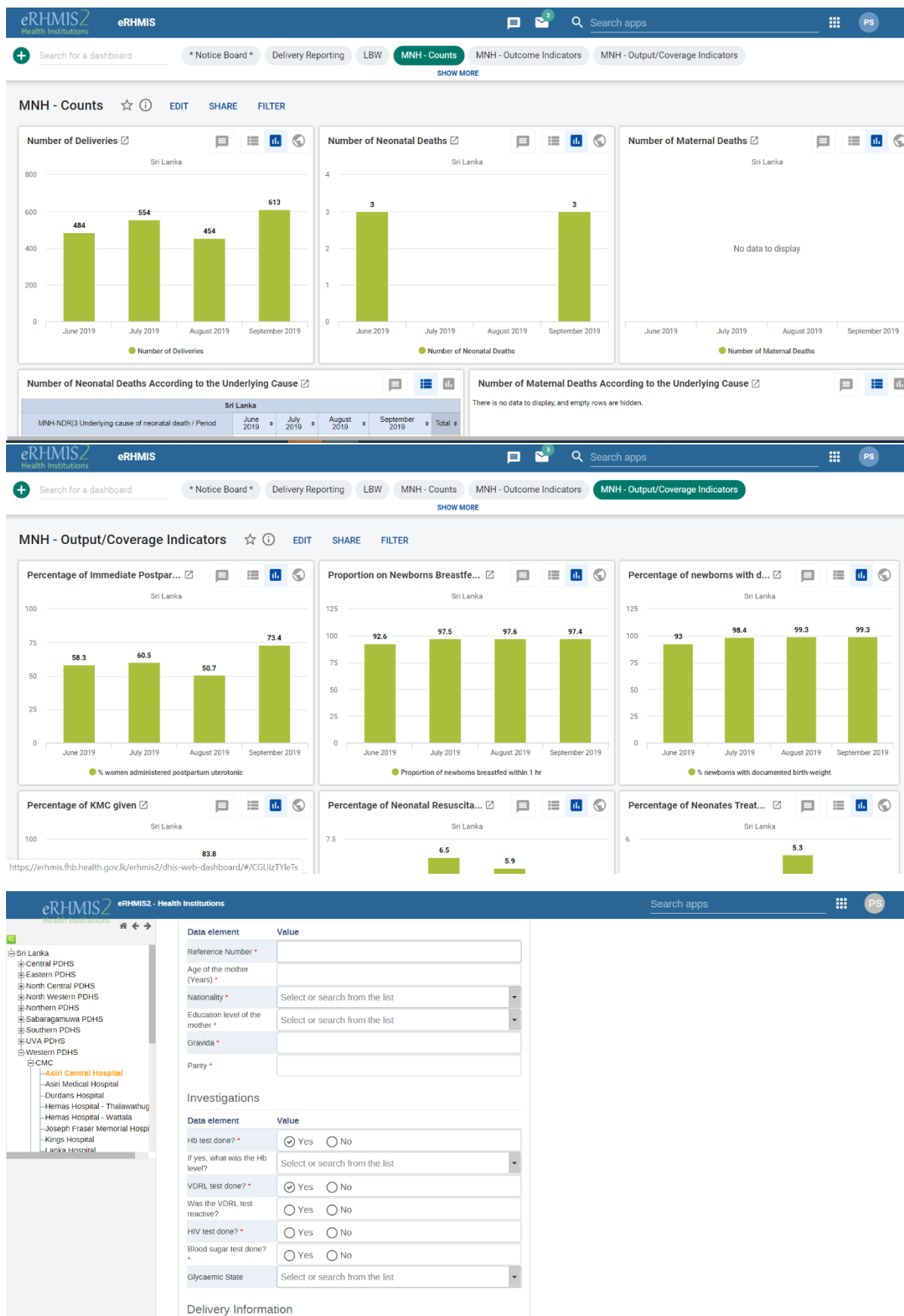


Guidelines to manage pregnant women with of HIV an syphilis



Annexure 22 - Private health sector data capturing





Annexure 23- External Quality Assessment

EQA – HIV ELISA

2017

oneworld ACCURACY | **NRL** National Reference Laboratory

Performance Report Page 2/4
Print Date 2019/Aug/30
Status Final

Participant: NRL0255 National STD/AIDS Control Programme
 Subscription ID: 149384 HIVC4310 HIV Serology
 Results Deadline: 2019/Jul/17

Assay: Bio-Rad Genscreen ULTRA HIV Ag-Ab EIA

Anti-HIV-1/2 / p24 Ag Interpretation

Sample	Result	Flags	Peer Group Counts				Reference Results (RR)	
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)		Concordant with RR (%)
A	Reactive		8	8	8	6	75	Reactive
B	Reactive		8	8	8	7	88	Reactive
C	Negative		7	7	7	7	100	Negative
D	Reactive		7	7	7	7	100	Reactive
E	Reactive		7	7	7	7	100	Reactive
F	Negative		3	3	3	3	100	Negative
G	Negative		3	3	3	3	100	Negative
H	Reactive		3	3	3	3	100	Reactive
I	Negative		3	3	3	3	100	Negative
J	Reactive		3	3	3	3	100	Reactive

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
13504	AS1	Detection	Bio-Rad Genscreen ULTRA HIV Ag-Ab EIA		

Flags: ♦ - Aberrant ● - statistical outlier; ■ - Removed Prior to Analysis ♦ NE - result not evaluated

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*seen!
Good!
ELISA test results
are called with Australia
lab results.
y. Dalme
sent*

EQA- Western Blot Assay

Performance Report Page 3/4
Print Date 2019/Aug/30
Status Final

Participant: NRL0255 National STD/AIDS Control Programme
 Subscription ID: 149384 HIVC4310 HIV Serology
 Results Deadline: 2019/Jul/17

Assay: MP Diagnostics HIV BLOT 2.2 WB (Rapid Assay)

HIV Immunoblot Interpretation

Sample	Result	Flags	Peer Group Counts				Reference Results (RR)	
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)		Concordant with RR (%)
A	Negative		7	7	7	7	100	Negative
B	Negative		7	7	7	7	100	Negative
C	Negative		7	7	7	7	100	Negative
D	Positive	NE	2	2	2	2	100	Positive
E	Positive		7	7	7	7	100	Positive
F	Negative	NE	1	1	1	1	100	Negative
G	Negative	NE	1	1	1	1	100	Negative
H	Positive		6	6	6	6	100	Positive
I	Negative	NE	1	1	1	1	100	Negative
J	Positive		6	6	6	6	100	Positive

Peer Group Description

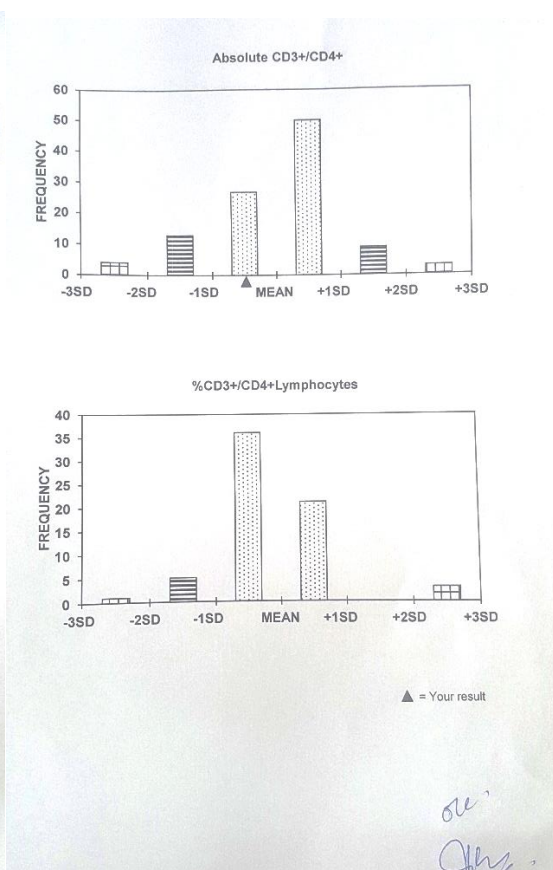
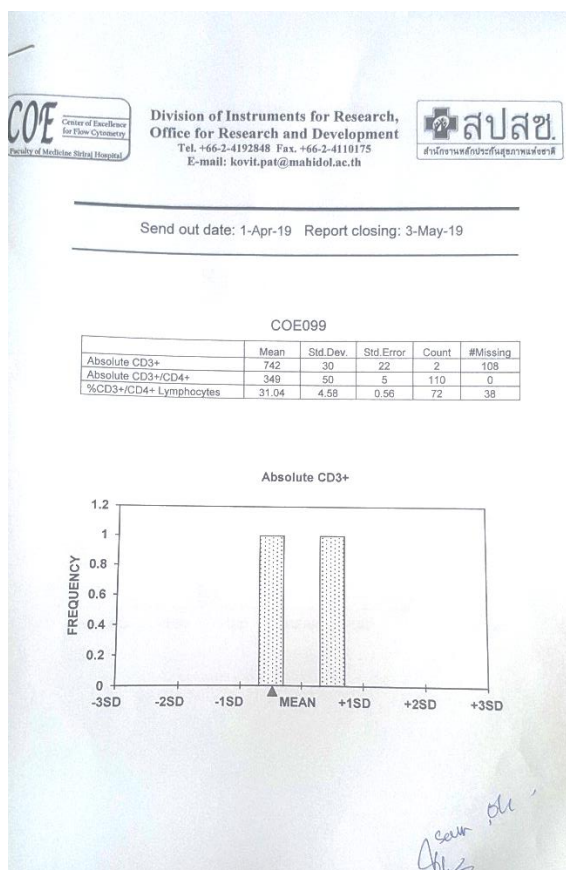
PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
116383	AS1	Detection	MP Diagnostics HIV BLOT 2.2 WB (Rapid Assay)		

Flags: ♦ - Aberrant ● - statistical outlier; ■ - Removed Prior to Analysis ♦ NE - result not evaluated

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*seen!
Good!
WB test results
were called with
Australia reference lab
results.
y. Dalme
sent*

EQA- CD4



EQA- HIV Viral load



FINAL REPORT

Dried Tube Sample

HIV RNA Viral Load and

Early Infant Diagnosis

DTSI435

Panel ID: 2019-07-17

NRL is:

- Accredited by NATA as a Medical Testing Laboratory compliant with ISO 15189;
- Accredited by NATA as a Proficiency Testing Provider compliant with ISO 17043, with NATA Accreditation Number 14253;
- Licensed by the Therapeutic Goods Administration as compliant with the Code of Good Manufacturing Practice;
- Certified by BSI for Quality Management, as compliant with ISO 9001;
- Certified by BSI for Safety Management, as compliant with AS 4801;
- A World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.

Report prepared by Liza Cabuang
and distributed in the week beginning 2019-08-05



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NATA
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NRL EQAS: DTSI435 Panel ID 2019-07-17

Page 2 of 6

1 INTRODUCTION

This report presents and discusses the results reported for the dried tube sample (DTS) human immunodeficiency virus (HIV) RNA Viral Load and Early Infant Diagnosis (EID) EQAS (DTSI435) Panel ID 2019-07-17.

The aims of this panel were to:

- examine the ability of participants to detect low concentrations of HIV RNA;
- examine the ability of participants to detect and distinguish between HIV-1 proviral DNA and viral RNA and;
- detect instances of cross contamination.

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2 METHODS

The reference results for the panel samples are presented in APPENDIX A. The panel samples were confirmed to be homogenous and stable.

For further information regarding methodology please [refer to this link](#).

3 RESULTS

Results from 30 participants were received for the DTSI435 Panel ID 2019-07-17.

Results were not received by the closing date for the acceptance of results from Participants MOHAB002, NRL0759 and NRL1238.

No participant appeared to have used a kit after the expiry date had passed.

3.1 Reviewing results

Information regarding the methods used by NRL to analyse the data can be found [in this link](#). The supplementary information also defines how NRL identifies aberrant and acceptable results, as well as outlining the appeals process.

In addition, the following participants should refer to Section 4 for discussion of results they submitted that may need review:

- | | | |
|------------|------------|-----------|
| • BI1001AI | • CM1002AI | • NRL0871 |
| • CI1001AI | • CM1003AI | • NRL0890 |
| • CI1002AI | • CRQ0124 | • NRL1065 |
| • CM1000AI | • NRL0757 | |
| • NRL1242 | | |

NRL EQAS: DTSI435 Panel ID 2019-07-17

Page 3 of 6

4 DISCUSSION

4.1 General observations

Two participants (CRQ0124 and NRL1242) reported viral loads for samples A, C and D that were not log₁₀ transformed. These viral loads were identified as aberrant. The purpose of performing viral loads is to monitor the efficacy of antiviral treatment. An indicator of efficient treatment is a decrease in viral load that is greater than 0.5 log₁₀ at least eight weeks after the start of treatment, when compared with the viral load prior to treatment. This is easier to calculate when viral loads have been log₁₀ transformed.

Participant NRL0008 is the only participant that submitted results for an HIV qualitative assay. All assay interpretations submitted by the participant were concordant with the reference results.

4.2 Detection and quantification of HIV-1 RNA

Sample A contained the lowest concentration of HIV-1 RNA provided in the panel (see Table A1). Twenty-seven participants submitted results for sample A. Of these, three participants reported "Below Linear/Detection Limit" (BI1001AI, CI1001AI and CI1002AI) and three participants reported "Not Detected" (CM1000AI, CM1002AI and CM1003AI) for sample A. The results submitted by these six participants were not evaluated.

Sample D contained the highest concentration of HIV RNA presented in the panel. Participant NRL0757 (testing in the Cepheid Xpert HIV-1 Viral Load) reported "Test Result Invalid" for sample D, which was not evaluated. All other participants (including those that did not log₁₀ transform their results) detected and/or quantified HIV-1 RNA in sample D.

4.3 HIV-1 proviral DNA

Sample C contained human CD4 cells that have been engineered to contain a single HIV-1 proviral DNA copy per cell. The results for this sample was analysed to examine the ability of participants to detect HIV-1 proviral DNA.

Participants CM1003AI (testing in the Biocentric Generic HIV Charge Virale) and NRL0890 (testing in the Cepheid Xpert HIV-1 Viral Load) each reported "Test Run Invalid" for sample C. These results were not evaluated. All other participants detected HIV-1 proviral DNA in sample C.

4.4 Samples that did not contain HIV nucleic acid

Duplicate samples B and E consisted of normal human plasma and did not contain any HIV nucleic acid. Sample carry-over was not reported by any of the participants in this test event.

Two participants (NRL0871 and NRL1065) reported a "0" (zero) viral load for both samples B and E. The importance of providing log₁₀ transformed data was discussed in section 4.1 of this report. For this reason, zero values cannot be log₁₀ transformed so the results submitted by Participants NRL0871 and NRL1065 were identified as aberrant. As noted in previous reports, participants should select the most appropriate interpretation as defined by the manufacturer's instructions for Use (IFU) when HIV nucleic acids are not amplified.

Two participants reported "Test Run Invalid" for both samples and these results were not evaluated.

Twenty-five participants submitted assessable results, with three participants reporting "Below Linear/Detection Limit" for samples B and E while the remaining participants reported "Not Detected".

NRL EQAS: DTSI435 Panel ID 2019-07-17

Page 4 of 6



Performance Report

Page 1 / 1
Print Date 2019/Sep/13
Status Final

Participant: NRL0255 National STD/AIDS Control Programme
Subscription ID: 169850 DTSI435 Dried Tube Sample HIV-1 Viral Load and Early Infant Diagnosis (EID)
Results Deadline: 2019/Jul/17

Sample Condition

Date samples were received (YYYY/MM/DD) 2019/Jul/13
Were the samples received in good condition? Yes
Were the samples received frozen? No

Assay Roche High Pure Viral Nucleic Acid Kit/Roche COBAS TaqMan HIV-1 Test, version 2.

HIV-1 RNA Viral Load log10 copies/mL

Sample	Run	Replicate 1			Replicate 2			Replicate 3			Peer Group Statistics				
		Result	Flags	SDI	Result	Flags	SDI	Result	Flags	SDI	Participants (n)	Results (n)	Statistical (n)	Mean	SD CV(%)
A	1	2.29	NE								2	2	2		
B	1	Not Detected									2	2	2		
C	1	6.11	NE								2	2	2		
D	1	4.93	NE								2	2	2		
E	1	Not Detected									2	2	2		

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
231983	AS3	Extraction	Roche High Pure Viral Nucleic Acid Kit		
		Amplification	Roche COBAS TaqMan HIV-1 Test, version 2.0		
		Detection	Roche COBAS TaqMan HIV-1 Test, version 2.0		

Flags: ◆ - Aberrant ● - statistical outlier, ■ - Removed Prior to Analysis ◆ NE - result not evaluated;

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APPENDIX A

Table A1. Composition and characterisation of DTSI435 Panel ID 2019-07-17

Sample ID by Programme	Group (Subtype)	Roche cobas (6800/8800) HIV-1 Quantitative Assay (log ₁₀ copies/mL)
DTSI435		
A	M(B)	3.20
B	NHP ²	Not Detected
C	M(B)	6.21
D	M(B)	6.07
E	Duplicate of sample B	

NHP²: Normal human plasma

EQA- VDRL test

WHO/CDC Syphilis Proficiency Testing Report 2019 Quarter 1

National Reference
Laboratory
990027
National STD/ AIDS
Control Program
No. 29, De Saram Place
Colombo 10 Sri Lanka
COLOMBO LK

Shipment: Shipment 1
Sample Received: 04/23/2019
Email address: aaakithsiri@gmail.com

Laboratory Score: 100.00

RPR/ RST/ TRUST			
	Your Results	Consensus Labs	Reference Labs
Specimen 1		Non-Reactive	Non-Reactive
Specimen 2		Reactive 1:1 Reactive 1:2 Reactive 1:4	Reactive 1:1 Reactive 1:2
Specimen 3		Reactive 1:4 Reactive 1:8	Reactive 1:4 Reactive 1:8
Specimen 4		Non-Reactive	Non-Reactive
Specimen 5		Non-Reactive, Reactive 1:1, Reactive 1:2	Non-Reactive, Reactive 1:1
Score			
Score Key			

EIA			
	Your Results	Consensus Labs	Reference Labs
Specimen 1		Non-Reactive	Non-Reactive
Specimen 2		Non-Reactive	Non-Reactive
Specimen 3		Reactive	Reactive
Specimen 4		Non-Reactive	Non-Reactive
Specimen 5		Non-Reactive	Non-Reactive
Score			
Score Key			

FTA-ABS			
	Your Results	Consensus Labs	Reference Labs
Specimen 1		Non-Reactive	Non-Reactive
Specimen 2		Non-Reactive	Non-Reactive
Specimen 3		Reactive	Reactive
Specimen 4		Non-Reactive	Non-Reactive
Specimen 5		Non-Reactive	Non-Reactive
Score			
Score Key			

VDRL/ USR			
	Your Results	Consensus Labs	Reference Labs
Specimen 1	Non-Reactive	Non-Reactive	Non-Reactive
Specimen 2	Reactive 1:4	Reactive 1:1 Reactive 1:2 Reactive 1:4	Reactive 1:1
Specimen 3	Reactive 1:16	Reactive 1:8 Reactive 1:16	Reactive 1:8
Specimen 4	Non-Reactive	Non-Reactive	Non-Reactive
Specimen 5	Reactive 1:2	Non-Reactive, Reactive weak, Reactive 1:1, Reactive 1:2	Non-Reactive
Score	100		
Score Key			

TP-PA/ TP-HA			
	Your Results	Consensus Labs	Reference Labs
Specimen 1	Non-Reactive	Non-Reactive	Non-Reactive
Specimen 2	Non-Reactive	Non-Reactive	Non-Reactive
Specimen 3	Reactive	Reactive	Reactive
Specimen 4	Non-Reactive	Non-Reactive	Non-Reactive
Specimen 5	Non-Reactive	Non-Reactive	Non-Reactive
Score	100		
Score Key			

OTHER			
	Your Results	Consensus Labs	Reference Labs
Specimen 1		Non-Reactive	Non-Reactive
Specimen 2		Non-Reactive	Non-Reactive
Specimen 3		Reactive	Reactive
Specimen 4		Non-Reactive	Non-Reactive
Specimen 5		Non-Reactive	Non-Reactive
Score			
Score Key			



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Consensus lab reporting (70% of labs) contribute to your score

Score Key

- A Qualitatively Incorrect: 0 out of 20 for non-paired samples
0 out of 15 for paired samples
0 out of 18 for treponemal tests
- B Non-paired sample titer within 1 dilution of reference/ consensus: 10 out of 20
- C Paired sample within 1 dilution of reference/ consensus: 7.5 out 15
- D Non-Paired titer outside of 1 dilution: 0 score
- E Paired sample outside of 1 dilution: 0 score
- F Form not fully completed: -5%
- G Form returned outside of 45 days: -5%

Annexure 24 - Documents Reviewed

1. [A guide to antiretroviral therapy – NSACP](#) (2016 December)
2. [A guide to HIV care services and management of opportunistic infections 2017](#)
3. [A Situation assessment of women and children infected and affected by HIV/AIDS in Sri Lanka 2015](#)
4. [A strategy for EMTCT of HIV and syphilis in Sri Lanka](#) (Second Edition 2018)
5. Annual Health Bulletin [2003](#) , [2014](#) , [2016](#) (Medical Statistics Unit – MoH)
6. [Annual Health Statistics 2017 Sri Lanka](#) (Medical Statistics Unit- MoH)
7. Annual Report – Family Health Bureau 2014, [2016](#)
8. [Births and deaths registration act](#)
9. Chapter 19 Penal Code
10. [Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection](#) (WHO, June 2013)
11. [Country Profile on Gender Based Violence in Sri Lanka](#) – (WHO Sri Lanka – 2018)
12. [EMTCT –MCH guide](#)
13. [Global AIDS update 2017](#)
14. [Global guidance on Criteria and Processors for Validation: EMTCT of HIV and syphilis](#) (Second Edition 2017)
15. [Guidance for use of WHO tool to estimatesyphilis in pregnancy and associated adverse outcomes](#)
16. [Guideline for private medical laboratory services – Private Health Services Regulatory Council – Guideline 07](#)
17. [Guidelines for management of pregnant women with syphilis 2016](#)
18. [Guidelines for the management of pregnant women with HIV 2016](#)
19. [Hand book for drug abuse information 2018](#)
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