Malaysia 2015 - 2016

VALIDATION OF ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV & SYPHILIS

MINISTRY OF HEALTH MALAYSIA

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Foreword

I wish to congratulate the Advisors, Technical Working Groups and the Public Health Programme of the Ministry of Health who have worked tirelessly to complete this report. This report would not have been possible without the collaboration and contribution from various sectors, departments, agencies and representatives of various government agencies, corporate bodies, the civil society and individuals from all over the country.

My sincere heartfelt thanks and appreciation goes to every single individual who have made it possible for us to produce the Country Report for Malaysia on *Elimination of Mother-to-Child-Transmission of HIV & syphilis* (eMTCT).

This report is specially prepared for the Regional Validation Team (RVT) for Asia Pacific Office of the World Health Organisation (WHO Asia-Pacific Region) for review and validation of eMTCT of HIV and Syphilis. I am deeply honoured to be leading this team, and I am equally proud that prevention, care and support for PLHIVs by this Ministry has been achieved because of multi-sectoral agencies' cooperation and collaboration. Indeed, we have come a long way since this pandemic first affected us in the late 80's.

Above all, I am very proud to showcase the Malaysia model for Prevention of Mother-to-Child Transmission (PMTCT) of HIV and Syphilis continuum of care. The success of Malaysia's eMTCT endeavor is a solid testament to these approaches that we have built over the years.

We have achieved most of our targets set and we shall continue to give our fullest cooperation to all our regional and global partners in health. It is my sincere hope that this intervention, which is an issue of national pride and importance shall be enhanced even further in the years to come, as reflected by the commitment by all key stakeholders.

My sincere regards,

DATO' DR HJ. AZMAN BIN ABU BAKAR
Deputy Director General of Health (Public Health)

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List of abbreviations

3TC	Lamivudine
AEM	AIDS Epidemic Model
Ag	Agglutination
AMO	Assistant Medical Officer
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
AWAM	All Women's Aid Society of Malaysia
AZT	Zidovudine
CAP	College of American Pathologists
C&C	Curative and Care services
CDCIS	Communicable Disease Control Information System
CIA	Chemiluminescence Immunoassay
CN	Community Nurse
CSO	Civil Society Organization
DNA	Deoxyribonucleic Acid
DOH	Department of Health
DCD	Disease Control Division
DHO	District Health Office
DMOH	District Medical Officers of Health
EFV	Efavirenz
EIA	Enzyme Immunoassay
ELISA	Enzyme-linked Immunosorbent Assay
EMTCT	Elimination of Mother-to-child Transmission
EPF	Employees Provident Fund
EQA	External Quality Assurance
FMS	Family Medicine Specialist
FTA-ABS	Fluorescent Treponema Antibody Absorption Test
FTC	Emtricitabine
FSW	Female Sex Worker
GA	Gestation age
GAM	Global AIDS Monitoring
GARP	Global AIDS Response Progress
GF	Global Fund
GDP	Gross Domestic Product
HAART	Highly Active Antiretroviral Therapy
HBsAg	Hepatitis B Surface Antigen
HIV	Human Immunodeficiency Virus
HKL	Kuala Lumpur Hospital
HRP	Harm Reduction Programme
IBBS	Integrated Biological Behavioral Surveillance
ICT	Information and Communication Technology
ID Physician	Infectious Disease Physicians
IEC	Information, Education and Communication
IMR	Institute for Medical Research
JAKIM	*Jabatan Kemajuan Islam Malaysia* (Department of Islamic Development of Malaysia)
K1M	*Klinik 1Malaysia* (1Malaysia clinics)
KP	Key Populations
LABQAS	Laboratory Quality Assurance Scheme
LIS	Laboratory Information System
LPV/r	Lopinavir/Ritronavir
LR	Labour Room
M&E	Monitoring and Evaluation
MLT	Medical Laboratory Technologist
MLE	Medical Laboratory Evaluation
MMT	Methadone Maintenance Therapy

MCH	Maternal and Child Health
MSM	Men who have Sex with Men
MW	Migrant Worker
MO	Medical Officer
MOH	Ministry of Health
MOE	Ministry of Education
MWFCD	Ministry of Women's, Family and Community Development
MTCT	Mother-to-Child Transmission
NAC	National AIDS Committee
NAP	National AIDS Programme
NARL	National AIDS Reference Laboratory
NCWO	National Council of Women's Organisation of Malaysia
NEQAS	National External Quality Assurance Scheme
NEQAP	National External Quality Assurance Panel
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NVP	Nevirapine
NNRTI	Non-Nucleoside Reverse-Transcriptase Inhibitor
NRTI	Nucleoside Reverse-Transcriptase Inhibitor
NTWHIV	Network of Malaysian Women Living with HIV
O&G	Obstetrics & Gynaecology
OI	Opportunistic Infection
OSCC	One Stop Crisis Centre
PA	Particle Agglutination
PCL	Primary Care Laboratories
PCR	Polymerase Chain Reaction
PCR (LTR)	Polymerase Chain Reaction (Long Terminal Repeat)
PCP	Pneumocystis Pneumonia
PDRM	*Polis DiRaja Malaysia* (Malaysian Royal Police)
PHNRL	Public Health National Referral Laboratory
PICT	Provider Initiated Counseling and Testing
PLHIV	People Living with HIV
PMTCT	Prevention of Mother-to-Child Transmission
PNC	Post-natal care
PO	Partner Organisations
POCT	Point of care tests
PWID	People Who Inject Drugs
PrEP	Pre-Exposure Prophylaxis
RCPA	Royal College of Pathologists of Australasia
RAL	Raltegravir
RH	Reproductive Health
RHC	Rural Health Clinic
RNA	Ribonucleic Acid
RPR	Rapid Plasma Reagins
RTK	Rapid Test Kit
SD-NVP	Single-dose Nevirapine
SN	Staff Nurse
STI	Sexually Transmitted Infection
SUHAKAM	*Suruhanjaya Hak Asasi Manusia* (Human Rights Commission of Malaysia)
TAQAS	Therapeutic, Research, Education and AIDS Training Asia Quality
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
TMP-SMX	Trimethoprim/Sulfamethoxazole
TPHA	Treponema Pallidum Haemagglutination Assay
TPPA	Treponema Pallidum Particle Agglutination Test
UK NEQAS	United Kingdom National External Quality Assurance Scheme
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNHCR	United Nations High Commissioners for Refugees
UNICEF	United Nations Children's Fund
UNFPA	United Nations Population Fund

VCT	Voluntary Counselling and Testing
VDRL	Venereal Diseases Research Laboratory
VL	Viral load
WAO	Women's Aid Organisation of Malaysia
WHO	World Health Organization
YFHS	Youth Friendly Health Services
YFHC	Youth Friendly Health Clinic

Executive Summary

Malaysia operationalized HIV screening among pregnant women in the 1997, which was subsequently rolled out country-wide in 1998 and later expanded to the private sectors. The first case of HIV/AIDS in this country was reported in 1986, and the initiative to introduce Prevention of Mother-To-Child Transmission (PMTCT) of HIV country-wide about a decade later signified the commitment of the government towards HIV/AIDS responses. PMTCT programmes that include HIV and syphilis testing have been integrated into Maternal and Child Health (MCH) services and forms part of a comprehensive package for all expectant mothers. Option B+ regimen that entails giving lifelong antiretroviral (ART) to HIV+ pregnant women have been incorporated into the current treatment protocol since 2012. To further minimise the risk of vertical transmission, free ART prophylaxis is provided for all HIV-exposed infants, as well as free infant formula feed (for a period of 24 months), regardless of nationality.

For the purpose of this validation exercise, the country is using spectrum modelling as its primary data source for HIV and WHO Syphilis Estimation tool for congenital syphilis impact indicators and these are supplemented by programmatic data. The following statistics clearly demonstrate that Malaysia has achieved elimination of mother-to-child transmission (MTCT) of HIV and syphilis:

i. MTCT rate declined from 16.12% in 2000 to 2.46% and 1.99% in 2015 and 2016.
ii. New paediatric HIV infections dropped significantly from 1.14 per 100,000 live births in 2011 to 0.38 and 0.39 per 100,000 live births in 2015 and 2016.
iii. Congenital syphilis declined from 6.0 per 100,000 live births in 2012 to 5.0 and 4.0 per 100,000 live births in 2015 and 2016.

Those achievements are made possible due to excellent antenatal care services as showcased below:

(1) Approximately 95.6% and 96.7% of pregnant women had at least one antenatal visit in 2015 and 2016. A population-based survey in 2016 (National Morbidity Health Survey) revealed at least 97.4% of women in Malaysia had a minimum of 4 antenatal visits as suggested by WHO.
(2) More than 95% of pregnant women (95.1% in 2015 and 95.8% in 2016) received HIV and syphilis screening.
(3) More than 95% of antenatal mothers living with HIV received antiretroviral therapy (97.2% in 2015 and 97.5% in 2016).
(4) 100% antenatal mothers with syphilis received appropriate treatment.

The success of the PMTCT programme in this country is one of many other government commitments to end AIDS. Combined with actionable policies, multi-stakeholder

participations and perseverance, Malaysia is ready to achieve and sustain the goals of eMTCT in the years to come.

Quality health care system

The Malaysian health care system is serviced by public as well as private health facilities. Public health care facilities are broadly divided into primary, secondary and tertiary care levels. Our public health care services are also being supported by other government stakeholders (e.g. the Ministries of Higher Education, Ministry of Defence, Ministry of Women, Family and Community Development, and the Local Housing Ministry), though the bulk of operations still lie within the Ministry of Health (MOH).

Malaysia has a well-co-ordinated health system that provides quality services throughout the entire country. This is supported by well-balanced public health programmes, good governance, a well-maintained health infrastructure plus a well-managed integrated surveillance system – all to ensure that MCH services remain as one of the key pillars of the Public Health Programme for many years to come. Our health-care workforce is almost 100% self-reliant. Currently, the doctor to population ratio in this country stands at 1 doctor to every 656 population. There are 257 family medicine specialists serving in just over 1,000 government health clinics in the country, thus reflecting that Malaysia's robust health care system is being managed by equally qualified trained personnel.

Malaysia is self-sustained for HIV responses, spanning prevention, control, treatment and support. More than 95% of the national HIV responses are publicly funded through domestic sources. National programmes guided by practical and actionable strategies, operational targets, and indicators have been developed through consensus meetings and workshops involving key stakeholders, including the community. The National Strategic Plan for Ending AIDS 2016-2030 (NSPEA) is a fine example of key stakeholders' involvement to attain the spirit of shared responsibilities in averting new HIV/AIDS infections in this country.

The MOH is always looking for innovative approaches in the management of mothers living with HIV, including their exposed infants and families. Currently, with the development of point-of-care testing (POCT) or rapid dual platform tests that are being implemented in many parts of the world, Malaysia is hopeful that this will benefit our target populations including those populations who are considered hard-to-reach.

Prevention of Mother-to-Child Transmission of HIV and Syphilis

The testing of pregnant women for syphilis has been part of the MCH service for more than 30 years, while HIV testing has been in place for about 20 years. The implementation of the PMTCT programme for HIV and syphilis is based on 4-pronged approach:

<u>Prong 1: Prevention of HIV and syphilis for women of reproductive age</u>

This is done through a 'life-stage approach'', starting from the early ages of life through to adulthood. This preventative approach aims to create awareness through health

education in various settings including schools, workplaces and tertiary education centres, to name a few. Condoms are widely available in retail outlets for easy access. In addition, free condoms can be freely obtained from clinics run by non-governmental organisations (NGOs). The prevalence of HIV among the population has remained below 0.05% for many years.

Prong 2: Prevention of unintended pregnancy in HIV+ women

Health care is regarded as a fundamental human right, and every citizen of the country is guaranteed access to basic public health services. All couples are given full freedom to make their own choice of conception regardless of their HIV status. High risk mothers are given correct information to make informed decision about conception. Pre-marital screening provides platform to couples for awareness on well-planned and safe pregnancies.

Prong 3: PMTCT of HIV and syphilis

The screening of antenatal mothers for HIV and syphilis has been in place for at least two decades in this country. Over time, the Ministry of Health Malaysia has produced numerous guidelines, policies and standard operating procedures to ensure that all affected mothers, their exposed infants and sexual partners are being cared for, from pregnancy to post-partum.

Prong 4: Continuum of care for HIV+ mothers, the exposed babies and partners

HIV positive mothers, their exposed infants and partners are continuously being monitored over time. The public health care providers and the community have taken the responsibility to provide vulnerable HIV positive women and their families with shelter homes amongst other benefit packages. More needs to be done, and we are confident that the rights of these individuals and their loved ones will not be compromised in years to come.

Overcoming the challenges and moving on to the next steps

The Ministry of Health (MOH) is fully committed in realizing the elimination of mother-to-child transmission (eMTCT) of HIV and syphilis. We strongly believe in learning from past experiences and moving forward to provide excellent services. However, there are still some areas that need improvements, especially in the following aspects:

(1) Reaching 'hard-to-reach' women, their exposed infants and families especially those in need of support and retention in care. This would improve adherence to treatment leading to better health outcomes.

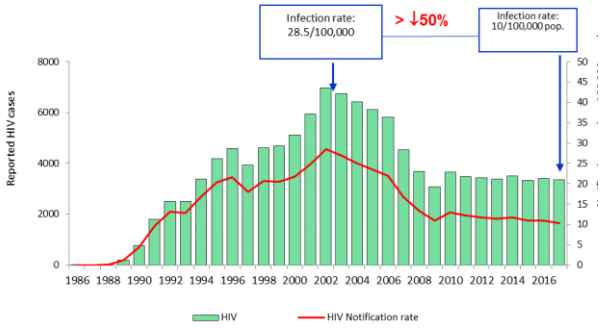
(2) Encouraging spouses/partners of pregnant women to undergo HIV and syphilis screening during the antenatal period to facilitate early intervention for couples.

(3) Upgrading diagnostics at the point-of-care, such as viral load (VL) testing, would contribute towards better and timely patient care and monitoring. The MOH has already begun working on this and is aiming to see the VL point-of-care test installed in selected primary care clinics by the end of 2018.

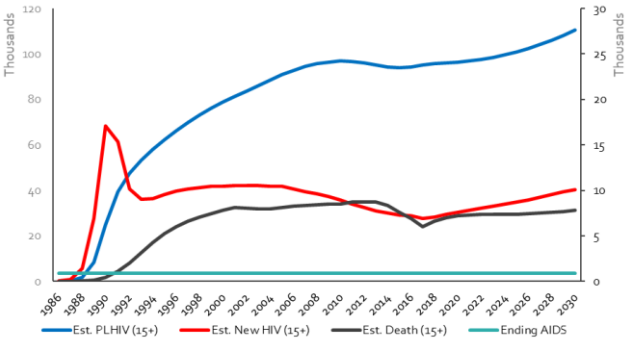
With respect to ending AIDS, we believe that HIV/AIDS and STI issues require a broad-based approach, enabled through a multi-sectoral approach and the engagement of multiple partners. It is therefore crucial that the strategic alliances and coalitions that we have created over the years between the private, public sectors, civil society and multilateral agencies be strengthened over time. The success of Malaysia's eMTCT endeavor is a solid testament to these approaches that we have built over the years.

EMTCT OF HIV AND SYPHILIS AT A GLANCE

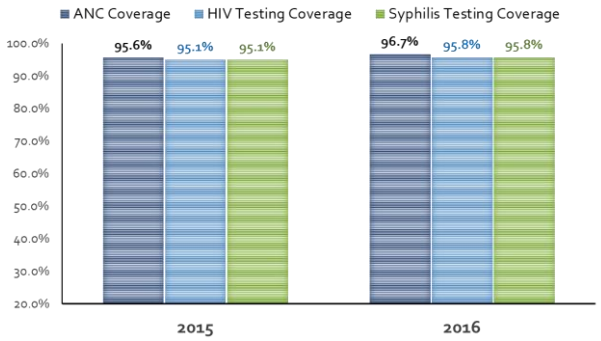
Reported HIV cases in Malaysia, 1986-2017



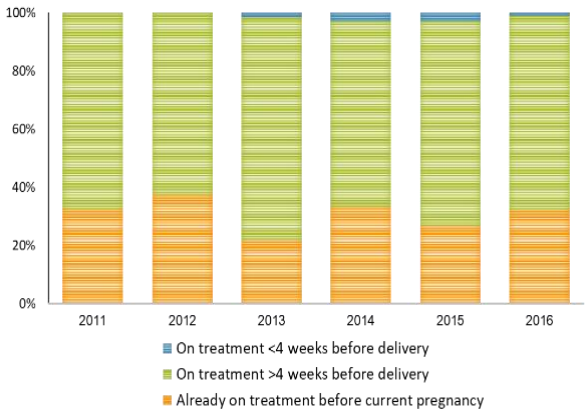
HIV Epidemic as projected by AEM 2017



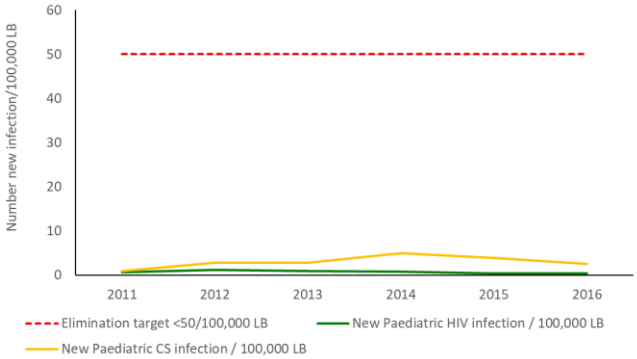
ANC, HIV and Syphilis testing coverage



ART coverage for HIV+ pregnant

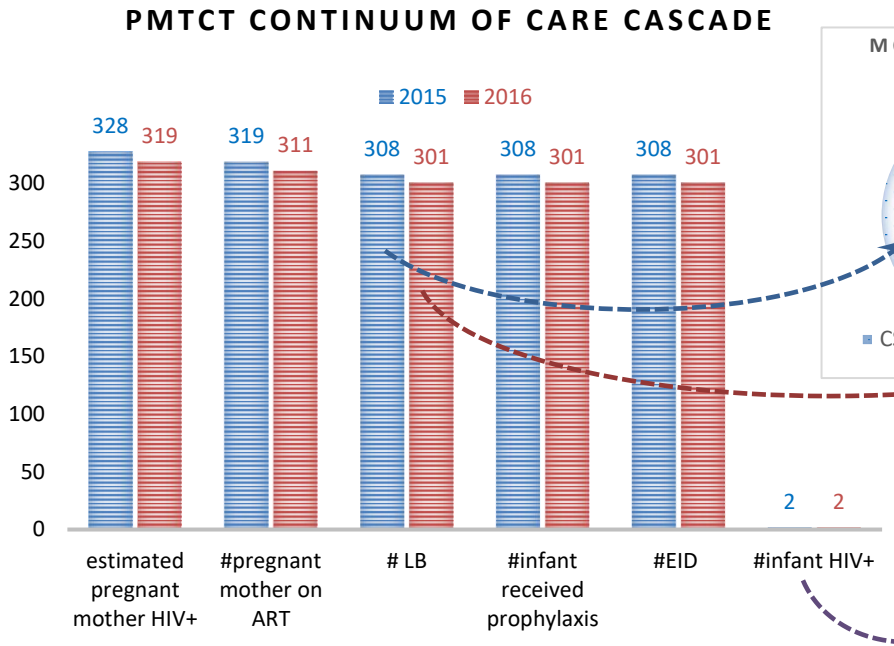


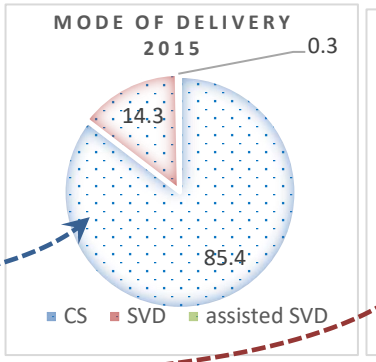
New paediatric infections of HIV and Congenital syphilis, Malaysia 2011-2016

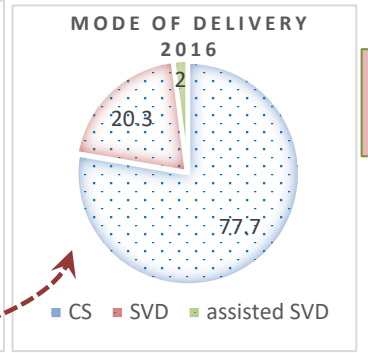


PMTCT Continuum of Care Cascade

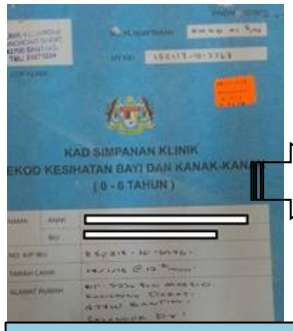
Year	Estimated pregnant mother	No. pregnant mother tested	Estimated pregnant mother HIV+	No. pregnant mother on ART	No. Live Birth	No. infant received prophylaxis	No. EID	#infant HIV+
2015	557,740	530,351	328	319	308	308	308	2
2016	544,661	521,523	319	311	301	301	301	2

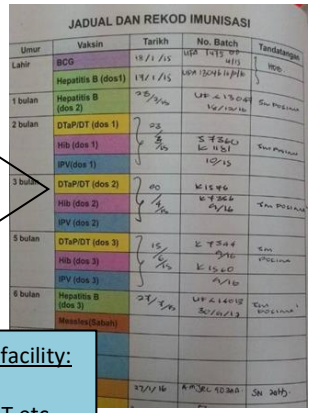






Note on Infant feeding:
2015: 100% formula feeding
2016: 99% formula feeding





Baby HIV+ on f/up at health facility:
Immunization
General health appraisal, ART etc.

THE EMTCT INDICATORS

INDICATORS	WHO eMTCT Target	2015			2016			2017[b]		
		%/ Per 100,000	N	D	%/ Per 100,000	N	D	%/ Per 100,000	N	D
MTCT rate (by HIV PCR)	<2%	**0.65**	2	308	**0.66**	2	301	**0.61**	2	330
MTCT rate (spectrum)*		**2.46**	8	334	**1.99**	6	322	**1.74**	6	337
Annual rate of new paediatric HIV infections per 100,000 live births by birth cohort (Program data)	≤50	**0.38**	2	521,136	**0.39**	2	508,203	**-**	2	NA
Annual rate of new paediatric HIV infections per 100,000 live births by birth cohort (spectrum data)		**1.54**	8	521,136	**1.18**	6	508,203	**-**	6	NA
Annual rate of congenital syphilis per 100,000 live births	≤50	**4.22**	22	521,136	**2.95**	15	508,203	**-**	2	NA
Annual rate of congenital syphilis per 100,000 live births (WHO Syphilis estimation tools)		**5.37**	28	521,136	**3.54**	18	508,203	**3**	17	NA
Antenatal coverage (at least one visit)	≥95%	**95.6**	533,226	557,740	**96.7**	526,874	544,661	NA	NA	NA
HIV testing coverage of pregnant women	≥95%	**95.1**	530,351	557,740	**95.8**	521,523	544,661	NA	516,590	NA
Syphilis testing coverage of pregnant women	≥95%	**95.1**	530,351	557,740	**95.8**	521,523	544,661	NA	516,590	NA
ART coverage of HIV+ pregnant women[a]	≥95%	**97.2**	319	328	**97.5**	311	319	**98.8**	330	334
Treatment coverage of syphilis+ pregnant women	≥95%	**100.0**	247	247	**100.0**	204	204	**100.0**	228	228

N-Numerator; D-Denominator
[a]Denominator for PLHIV pregnant women has included estimated number of PLHIV women not accessing antenatal care
[b]This is preliminary data; this data point is just for trending not for purpose of validation, thus some denominators cannot be included
*All parameters- %, numerator and denominator values are spectrum generated values. Spectrum generated MTCT rate is based on unrounded numbers

CHAPTER 1

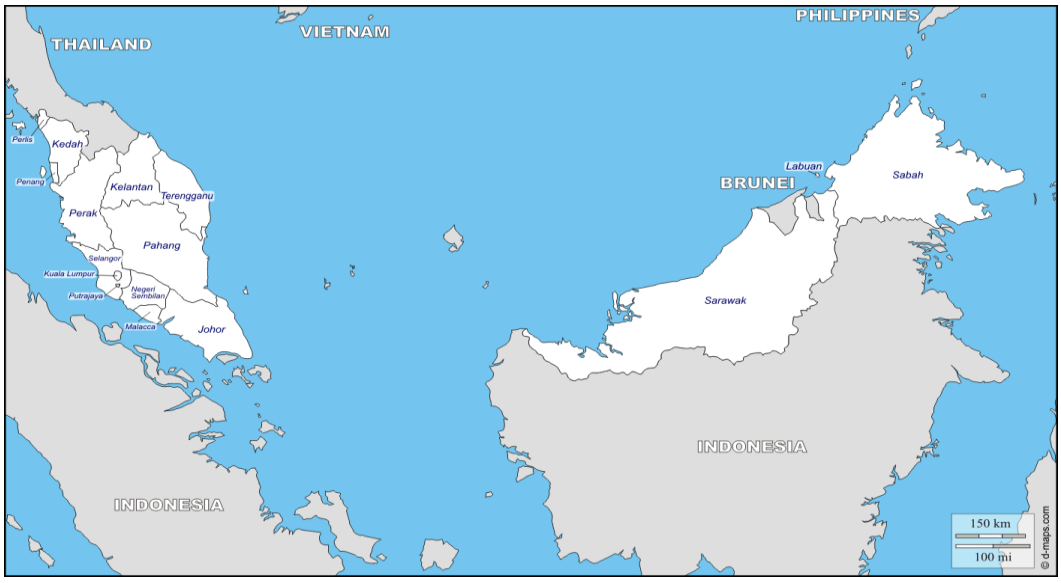
MALAYSIA COUNTRY CONTEXT

1.1 Geography

The Federation of Malaysia is located in Southeast Asia. It has a total land area of 328,657 square kilometers, separated by the South China Sea into two regions: Peninsular Malaysia (which comprises of 11 states and the Federal Territories of Kuala Lumpur and Putrajaya) and East Malaysia (which comprises of the states of Sarawak, Sabah and the Federal Territory of Labuan).

Peninsular Malaysia borders southern Thailand. The states of Sarawak and Sabah are situated in the island of Borneo and border Brunei and Kalimantan, Indonesia, respectively (Figure 1.1). Since gaining independence from the United Kingdom in 1957, Kuala Lumpur has been the nation's capital. The Federal Territory of Putrajaya was created in 2001 and has since been the administrative capital of the federal government.

Figure 1.1. Map of Malaysia



1.2 Population

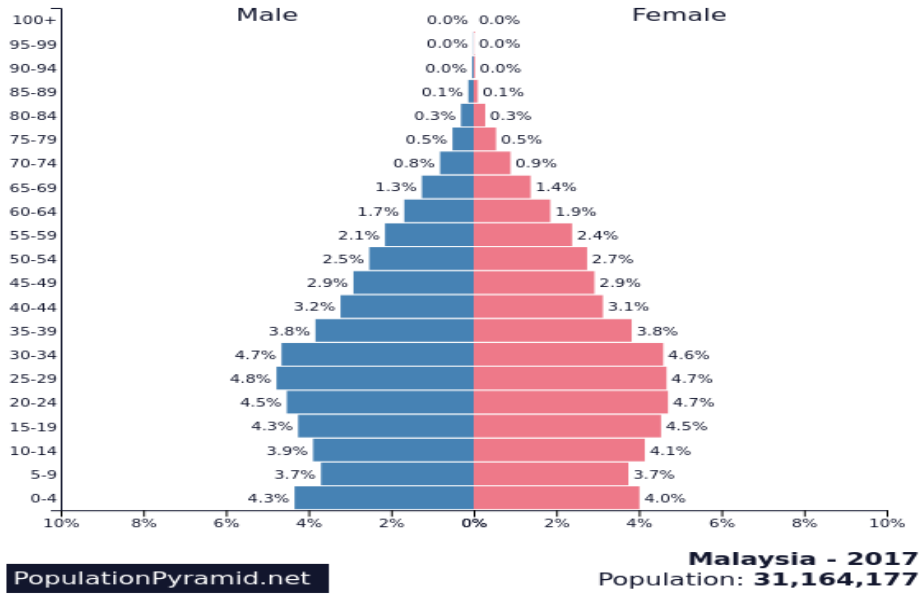
As of mid-2017, the population of Malaysia was estimated to exceed 31 million. Malaysia's population consists of a diverse array ethnicities, cultures and religions, comprising of 61.7% ethnic Bumiputera (Malay and indigenous), 20.8% Chinese, 6.2% Indian, 0.9% others and 10.4% non-Malaysian. Though Malay is the national language, English is widely spoken and understood.

The Malaysian Federal Constitution declares Islam as the state religion, with 61% of the population professing the Islamic faith. The constitution allows the free practice of other religions: 20% of the population practise Buddhism, 9% Christianity, 6% Hinduism, and the remaining 4% practise other religions.

As of September 2016, the male to female ratio was 1.07 (1). The vast majority (75%) of the Malaysian population currently resides in urban areas (2). With respect to age distribution, there is not much difference between the genders.

With respect to migration across the ASEAN region, Malaysia is currently the second largest migrant-receiving country, next to Thailand. In recent years, Malaysia has recorded a steady increase in the number of migrants emigrating from neighbouring countries in the ASEAN region. A report by the Asian Migrant Centre (2013) estimated that Malaysia was home to approximately 2.5 million documented migrant workers and an estimated 1.2 million undocumented migrants. Most migrants to Malaysia are of working age, with an approximate male to female migrant ratio of 1.42 (3).

Figure 1.2. Malaysian Population Pyramid 2017



Source: Department of Statistic Malaysia 2017

1.3 Government

Malaysia is a federal constitutional monarchy. Each of the nine Malay states has a Sultan (monarch). The overall head of state is the King (*Yang di-Pertuan Agong),* who is elected amongst the nine Sultans every five years. Legislative power is divided between federal and state administrations.

The bicameral federal parliament consists of the Senate and the House of Representatives. The Prime Minister and his Cabinet Ministers are appointed by the *Yang di-Pertuan Agong* from members of the House of Representatives.

Each state has a Legislative Assembly comprising of State Executives. Each assembly is chaired by a Chief Minister. They have the authority to make laws at the state level. Each state is divided into administrative districts headed by District Officers. At the lowest level, the local authority is under the purview of the state government.

1.4 Economy

Malaysia is classified as an upper-middle income economy, with a per capita Gross Domestic Product (GDP) of USD 9,768.3[1] (3). Historically, Malaysia's economy was largely driven by the rubber and tin industry. However, since the 1970's it has rapidly transformed to become a major exporting country, with predominant exported products including electrical appliances, electronic parts and components, palm oil, and natural gas (4).

1.5 Relevant public health information in Malaysia

1.5.1 Vital health statistics

Malaysia has made significant strides in providing essential health care to its population since gaining independence in 1957. This is reflected in the significant reduction of both maternal and child mortality in Malaysia in recent decades (see below):

Between 1965 and 1990, Malaysia's under-five mortality rate (U5MR) dramatically reduced from 70.2 to 16.8 per 1,000 live births. In that same period, the infant mortality rate (IMR) reduced from 48.5 to 13.1 per 1,000 live births (13). From 1990 to 2015, Malaysia further halved its U5MR and IMR to 8.4 and 6.9 per 1,000 live births, respectively (14).

Similar progress has been recorded for the maternal mortality ratio (MMR). Between 1970 and 1991, Malaysia had effectively reduced its MMR by two-thirds, from 142 per 100,000 live births, to 44 per 100,000 live births. From 1991, MMR further declined to 22.7 per 100,000 live births in 2014 (15).

[1] Data in 2016 Dollars

With respect to the fifth Millennium Development Goal (MDG 5) on maternal health, as of 2015, Malaysia had not yet met the specific target of not exceeding 11 maternal deaths per 100,000 live births. However, other aspects of maternal health care have clearly met international standards, namely 97% births attended by skilled health personnel, and 97.2% antenatal care coverage (16).

As of 2016, the estimated crude birth rate was 16.6 per 1,000 population, and the total fertility rate was 2.0 children per woman. Life expectancy at birth was 72.6 years for males (compared to 68.9 years in 1990) and 77.2 years for females (compared to 73.5 years in 1990), while crude death rate was 5.0 per 1,000 populations (2).

Table 1.1 Selected Health Statistics (1990-2015)

Year	GDP per capita (current USD 2016)	Crude birth rate	Life Expectancy at birth	Infant Mortality Rate (IMR)	Under-five Mortality Rate (U5 MR)	Maternal Mortality Ratio (MMR)
1990	2417	27.9	70.7	13.1	16.8	44
1995	4280	26.1	71.8	10.3	13.2	46.9
2000	4004	22.9	72.2	6.0	8.9	28.1
2005	5564	18.2	73.6	6.7	8.5	27.9
2010	9069	17.2	74.1	6.7	8.4	26.1
2011	10427	17.6	74.3	6.5	8.0	26.2
2012	10834	17.8	74.4	6.2	7.7	23.2
2013	10971	16.7	74.5	6.3	7.9	21.4
2014	11305	17.2	74.5	6.7	8.3	22.7
2015	9768	16.7	74.6	6.9	8.4	23.8

Sources: *1. Per-capita income from World Bank national accounts data 2016;*
2. Birth and death rates from Department of Statistics Malaysia.
Birth rates per 1000 population
IMR and U5MR per 1000 live births
MMR per 100000 live births

1.5.2 Health spending and access

Malaysia has a two-tier health care system consisting of both public and private sectors. The Ministry of Health, working in close collaboration with the Ministry of Higher Education and the Ministry of Defence, is the main provider of public health care services in the country.(5). With respect to maternal and child health services, as of 31st December 2015, there were 152 public hospitals, 183 private hospitals, 2,869 public clinics and 7,146 private medical clinics providing these services (6). Both public and private health sectors work in close partnership to provide primary, secondary and tertiary care across all districts and states in Malaysia.

The public health care system is largely funded by the government and is principally financed through public tax revenue. It encompasses a comprehensive array of services, ranging from primary care services (health promotion and preventative) through to

curative and rehabilitative care services. Besides the provision of individual health services, the Ministry of Health, with support from other government agencies, plays a significant role in the delivery of public health interventions at a population level. This includes the active presence of health awareness and promotion programmes in the community; demonstrable control of communicable diseases including various vector-borne communicable diseases; and adequate water and sanitation measures, including the availability of potable water supply, sanitary latrines and environmental hygiene.

Malaysians and non-Malaysians are entitled to seek care from either public (government) or private health facilities. For those seeking care in the public sector, the Fee Act 1951 and Fees (Medical) (Cost of Services) Order 2014 applies. Within this context, health services for Malaysians are heavily subsidized. Civil servants and pensioners have essentially free access to government healthcare. For the general public, outpatient primary care costs a nominal fee of MYR1 (0.23 USD) per visit, which covers consultations, investigations and treatment (7). Patients referred to government specialist outpatient care are charged MYR5 (USD1.2) per consultation (8).

The private health care sector provides services on a non-subsidized, fee-for-service basis, and mainly serves those who can afford to pay for their care. Private health care services are predominantly funded through point-of-service (out-of-pocket) payments as well as private health insurance schemes which individuals can choose to enrol onto. For salaried employees in the private sector, medical coverage is provided by employee-based funds such as the Social Security Organisation (SOCSO) Scheme or the Employee Provident Fund (EPF) (5).

In 2011, 49% of total outpatient cases and 74% of total hospital admissions occurred in the public sector (9). With regards to antenatal care, the National Health and Morbidity Survey (NMHS) 2016 reported that the majority (85%) women received such care in the public health sector, 14.5% received antenatal care in the private sector. With respect to deliveries, according to the same report a substantially higher proportion (80.5%) of women delivered in public health facilities, compared to only 18.6% in private health facilities (10).

For all non-Malaysians (documented and undocumented), there is unrestricted access to all ranges of health facilities in both public and private health sectors. With the exception of several medical conditions (see below), under the Fee Act 1951 (amended 2014), non-Malaysians must bear the full cost for all medical consultations, investigations, and procedures (11). (For the purposes of this report, migrant populations in the Malaysian healthcare system context are henceforth termed as “foreigners”.) With respect to obstetric and gynaecological (O&G) outpatient services, a foreigner is charged MYR40 (USD9.5) per visit, MYR30 (USD7.1) for VDRL tests, and MYR60 (USD14.3) for HIV confirmation tests. Healthcare service provision for non-Malaysians is primarily funded through out-of-pocket payments or private health insurance schemes purchased by the individual (12). Refugee populations (with cards issued by the United Nations High Commission for Refugees (UNHCR)) are entitled to 50% subsidisation of costs for all health services, including HIV treatment.

As mentioned above, certain sub-groups of non-Malaysians are exempted from payment under the Fee Act 1951 (amended 2014). This includes those affected by “high impact” infectious diseases such as HIV, sexually-transmitted infections (STIs) and tuberculosis (TB). For example, a non-Malaysian antenatal mother diagnosed with HIV positive status whilst resident in-country, is currently entitled to receive free anti-retroviral treatment (ART) throughout pregnancy. In addition, the exposed infant is entitled to receive free ART prophylaxis and treatment (as appropriate) as well as free formula feed until the age of 24 months.

To ensure service continuum, the medical practitioner is obligated to write referrals for mothers wishing to return to their own countries for delivery. Non-Malaysians with UNHCR cards are entitled to 50% discount for continuation of ART. Such policies have been undertaken as part of Malaysia’s efforts towards eliminating mother-to-child transmission of HIV and syphilis.

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CHAPTER 2

MALAYSIA'S HEALTH SERVICE DELIVERY SYSTEM

2.1 Introduction

The vision of the Ministry of Health Malaysia (MOH) is for "Malaysia to be a nation of healthy individuals, families and communities, through a health system that is equitable, affordable, efficient, technologically appropriate, environmentally adaptable and consumer friendly, with emphasis on quality, innovation, health, promotion, and respect for human dignity and which promotes individual responsibility and community participation towards an enhanced quality of life" (1). To achieve this, one of the core strategies of the MOH to build multi-disciplinary partnerships with the health sector, in order to create environments that support individuals to make healthy lifestyle choices and attain their full potential in health. Their vision is to motivate communities to appreciate health as a valuable asset; and to take positive actions to improve and sustain their health status so that they are able to enjoy a better quality of life.

Malaysia's bimodal health care delivery system comprises of both governmental (public) and private health care sectors. Basic health care including antenatal care (ANC) is provided through the extensive network of government and private clinics. All states have general hospitals that serve as referral centres for district hospitals and primary care networks (Table 2.1).

Table 2.1: Health facilities in Malaysia, 2015

Types of Facilities (Public)	Number (ANC*)	Type of Facilities (Private)	Number (ANC*)
Hospitals	143 (143)	Hospitals	183 (183)
Special Medical Institutions	9 (0)	Maternity Homes	14 (14)
Health Clinics	1,061 (1,061)	Nursing Homes	16 (0)
Community Clinics	1,808 (1,808)	Hospice	3 (0)
Mobile Health Teams	203 (203)	Clinics (GP)	7,146 (7,146)
Flying Doctor Services	6 (6)	Dental Clinics	1,867 (0)
1 Malaysia Clinics** *(Klinik 1Malaysia)*	334 (49)		
Non-Ministry of Health Hospitals	9 (9)		

Source: Annual Report MOH, 2016

** Number that provide ANC*

*** 1Malaysia Clinics are public health facilities which provide urban poor communities with basic health care services manned by allied health professionals (Assistant Medical Officers and Nurses) under the supervision of Medical Officers from Health Clinics. Some of the services provided include basic outpatient treatment, wound dressings and simple laboratory testing.*

In Malaysia, public health care consists of three levels - primary, secondary, and tertiary care services – which are provided to the community through a wide network of public health clinics and hospitals. These include outpatient and inpatient care services, ranging from primary care at the health clinics to advanced medical care at the tertiary care centres.

(a) Primary Care services are the first point of contact, comprised of outpatient services, maternal and child health services, dental services, school health services and support services such as laboratory and imaging facilities, pharmacy and registration.

Note:
As part of decentralisation of health services in Malaysia, anti-retroviral therapy (ART) is available for adult PLHIV (people living with HIV) care at primary care clinics (HC) especially the first line regimen while all paediatric cases are seen by Paediatricians in the hospital. In private facilities, PLHIV are mostly referred to public facilities for free ART. For complicated cases, patients are referred to hospitals for secondary or tertiary care. As of December 2016, more than 35,000 PLHIV are receiving ART across Malaysia. Likewise, the majority of TPHA+ antenatal mothers are also being treated at these HCs.

(b) Secondary care services comprise of General Medicine, General Surgery, Obstetrics and Gynaecology, Paediatrics, Orthopaedics, Anaesthesiology, Psychiatry, Dermatology, Medical Rehabilitation, Pathology, Imaging, Dental, Ear, Nose and Throat (ENT), Ophthalmology and Geriatrics.

(c) Tertiary care services consist of highly specialised care in the following areas: Cardiology, Cardiothoracic Surgery, Geriatrics, Paediatric Surgery, Neurology, Neurosurgery, Respiratory Medicine, Urology and Nephrology, Plastics Surgery and Burns, Maxillofacial, Radiotherapy and Oncology, and Endocrinology.

(d) The Family Doctor Concept (FDC) is one of the MOH initiatives to help strengthen primary healthcare services in Malaysia. Their core vision is 'One Family, One Family Doctor', whereby each family is assigned to a local primary care team consisting of doctors and paramedics. The doctor and primary care team will assess the health risks of the local population, provide advice, counsel, and institute necessary treatment and systematic follow-up to individuals in the family. Amongst other objectives, one of the aims of the FDC is to render continuous and comprehensive treatment to individuals and their families, including referrals to secondary care. The FDC rests on the theory that having the same health provider enables the establishment of a therapeutic patient-doctor relationship, thus enhancing the quality and continuity of care as well as the client's compliance. In the context of HIV, for HIV+ mothers, HIV-exposed infants and HIV infected children; the FDC approach ensures the continuum of care and patients compliance. For HIV-exposed infants or HIV infected infants, clinical management of HIV is provided by hospital paediatricians. However, general health care and immunisation will continue to be provided by the local designated primary care team. There is strong collaboration between hospitals

and the primary care system, which ensures continuity of care for patients (e.g. defaulter tracing, home visits, ensuring compliance etc.)

The FDC also acts as a gatekeeper role, reducing inappropriate referrals to secondary care, thus minimising unnecessary costs for the client. As mentioned in the previous chapter, 49% of total outpatient cases and 74% of total inpatient admissions occur in the public sector.

There are 1,061 HCs across Malaysia (Table 2.1) in which 257 Family Medicine Specialists (FMS) are currently based. FMS are clinical specialists by training and are regarded as the "gatekeepers" of the primary care services in Malaysia. In line with the Malaysia's "elimination of mother-to-child transmission of HIV" (eMTCT) project, the FMS's role in initiating and providing ART to HIV+ antenatal mothers as well as diagnosing and treating TPHA+ antenatal mothers are considered crucial. These gatekeepers of the primary care services have managed to reduce unnecessary referrals from primary health clinics to secondary or tertiary health care services (hospitals).

(e) Mobile health care

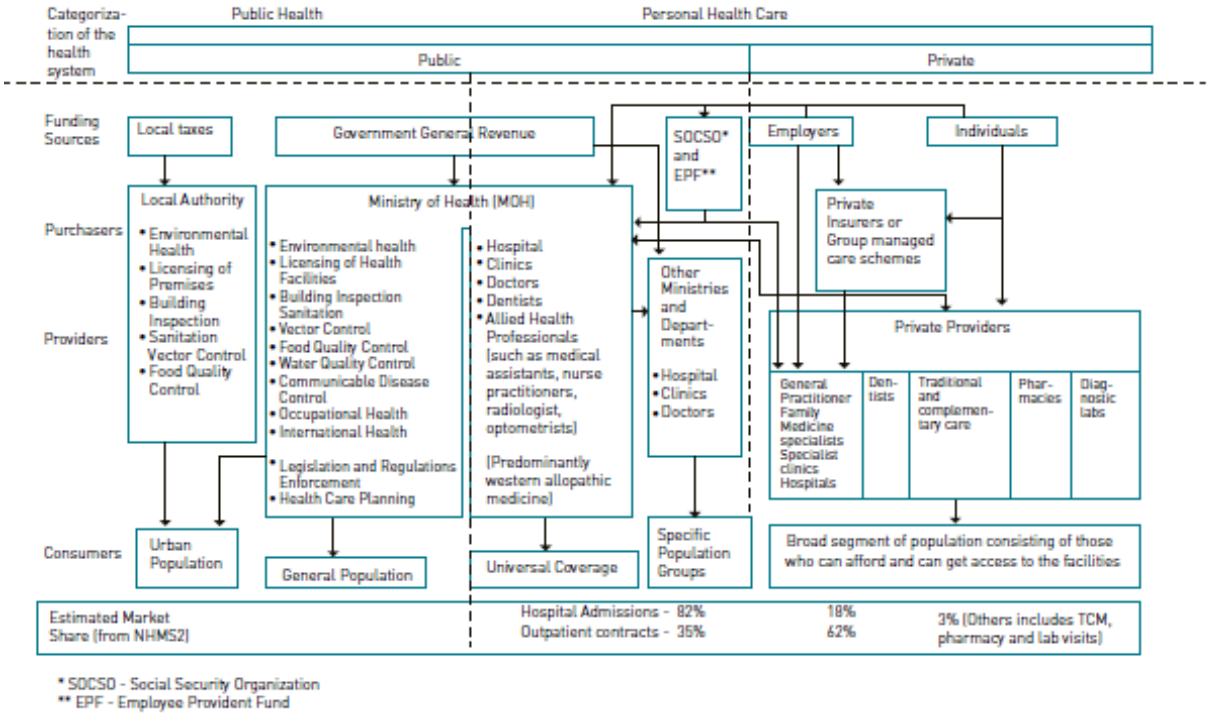
In places with inadequate static facilities, such as remote or rural areas, the communities are provided with outreach services, including mobile clinic services whereby the medical team may travel by land, water or air (also known as the flying doctors' service) in order to reach these remote communities. The medical team consists of a medical officer, pharmacist, assistant medical doctor, staff nurse, community health nurse and health attendant from nearest static health clinic. The scope of services provided includes maternal and child health (MCH), outpatient care, screening of health risk, health education, follow up of chronic illness, referral of cases, minor procedures and dispensing drugs. MCH services are provided to the same standard of care as seen in static facilities.

2.2 Organisation and governance of the Ministry of Health Malaysia

The administration of the health delivery system begins at the national level in which the MOH has a lead role and responsibility in the governance of the health sector. At the central (Headquarters) level within the MOH, there are several divisions focusing on different areas of health services. At the state level, each of them will have a State Health Department headed by a State Health Director (Appendix 4).

The bimodal Malaysian healthcare system consists of public tax-funded, government-run universal services and a fast-growing private sector. Public sector health services are organized under a civil service structure and are centrally administered by the MOH. The MOH plans and regulates most public health sector services and much of the pharmaceutical and food industries.

Figure 2.1. Schematic Overview of the Malaysian Health System



Source: Malaysia Health System Review 2013

2.3 Human resources

Malaysia has 1 doctor for every 656 people, 1 nurse for every 305 people and 1 pharmacist for every 2,900 people (1). Malaysia Primary Health Care is fully integrated where all health conditions are managed at the same clinic.

Table 2.2 Selected number of health personnel in relation to EMTCT program in Malaysia

	MOH	Other Government Agency	Private	Total
Doctors	33,541	Not-available	12,946	46,487
Pharmacists	6,423	185	3,903	10,511
Nurses	64,016	5,574	30,335	99,925
Community Nurses	24,926	54	195	25,175

Source: Annual Report Ministry of Health 2016

2.4 Health service delivery Systems in Malaysia (reference to eMTCT)

Public primary health services are provided through a two-tier system consisting of 2,869 static health clinics and community clinics, 1,808 community clinics and 203 mobile

health teams (1). The implementation of eMTCT of HIV and syphilis in Malaysia is channelled through the various sectors of the MOH i.e. from the grass-root levels right up to the Minister of Health.

Note:
Health clinics will use the standard HIV rapid tests (purchased centrally) for screening of antenatal mothers and use the algorithm procedures for the confirmation of HIV tests as stipulated in the Director General of Health's circular. Treatment and follow-up of HIV+ mothers and exposed babies are based on the standard operating procedures (SOPs) as underlined by the MOH. For RPR tests, the Health Clinics will use several types of tests as outlined by the respective State Health Departments and follow the treatment guidelines as stipulated by the MOH. All these sectors will follow the same SOPs for notification, treatment guidelines for both mothers and their exposed infants.

2.4.1 Governance, policies, strategies & decision making

The main policy goals of the control and prevention (inclusive of treatment and aftercare policies) of HIV/AIDS and sexually-transmitted infections (STIs) have been outlined in the *National Strategy Plan Ending AIDS 2016-2030* (NSPEA) blueprint, which was launched by the Deputy Minister of Health during the national World AIDS Day (WAD) celebrations in 2015 (2). This document conforms to the WHO Health System Blocks which covers areas pertaining to estimates of PLHIV in the country, epidemiology (AIDS epidemic model), budget, human resources, data management, services and support systems. This document will be reviewed every 2-3 years (mid-term review) and be updated from time to time.

The eMTCT is emphasised in the latest NSPEA document i.e. National Strategic Plan Ending AIDS 2016-2030. This document also outlines that in order for Malaysia to achieve the objectives of NSPEA 2016-2030, relevant stakeholders must:

(a) Provide quality, comprehensive national eMTCT services, to be in line with WHO's recommended 4-pronged strategies;

(b) Strengthen community awareness towards HIV through enrolment in eMTCT programmes and other related activities;

(c) Ensure the availability of eMTCT services for HIV and syphilis is available in all ANC facilities.

Note:
The above strategies are integrated into national action plans, some of which have been outlined in page 89 of the NSPEA. For collaborative efforts among the various agencies involved, please refer to chapter 6 on the surveillance, monitoring and evaluation of the eMTCT in Malaysia.

The translation of policy / strategies / plan of actions as outlined by the NSPEA into action is done via respective officers at the state and district levels. These officers will have joint meetings and discussions with their public (government) / private / civil society and non-governmental organisation (NGO) counterparts on the local level. If warranted, some of the issues updated during such meetings and discussions will be presented to the central level for further action or discussion.

The MOH believes in the value of having in-depth discussions around evidence-based data gathered locally or abroad, through various forums, round table discussions and seminars. Most of the decisions taken need to be adapted to suit local conditions in the Malaysian context.

2.4.2 Infrastructure

MCH services in relation to the eMTCT programme (universal testing for pregnant women for HIV and syphilis)

The Rapid HIV Test Kit (RTK) has been used as a test tool for pregnant women in public HCs since the national implementation of this activity in 1997/1998. The selection of the type of RTK to be used is done through an open tender system, subject to technical evaluation and additional evaluation by the Institute for Medical Research (IMR). One of the pre-requisite standards that has been adopted is to ensure that these RTKs used by health clinics should have 99.9% sensitivity and 99.8% specificity rates (3)**.** It is also standard practice that each batch of the consignment of these RTKs will be evaluated by IMR.

Syphilis screening among pregnant women is done using RPR tests in HCs, which will be confirmed by TPHA / TPPA tests in designated hospitals (4). Confirmation of HIV / syphilis, PCR and viral load blood samples are done in the designated hospitals throughout the country. Currently, there are 2 reference laboratories, 14 state hospital laboratories and 53 major and minor specialist hospital laboratories providing the confirmation tests for both HIV and syphilis.

There are 257 primary care physicians (FMS) based in health clinics who will initiate ART and provide specialist care for pregnant women living with HIV. These primary care specialists also provide syphilis treatment for mothers who are TPHA positive. To date there has been no reported stock-out of syphilis treatment (Benzathine penicillin).

As part of the SOP to ensure optimum ante- and post-natal care (including safe delivery), HIV positive and TPHA positive mothers are referred to hospitals for “joint care” under a multidisciplinary team consisting of infectious disease physicians, obstetrics and gynaecology (O&G) specialists and paediatricians. The exposed infants will be followed up by paediatricians in hospitals for a minimum of 2 years post-delivery.

Also included in this package is free infant formula, provided both by the hospitals and health clinics, for HIV-exposed infants up to age 24 months old, regardless of nationality. According to Malaysia’s National Breastfeeding Policy 1993 (revised 2006), all mothers are encouraged to exclusively breastfeed their infants under six months. By contrast, HIV positive mothers are encouraged to avoid breastfeeding – this is repeatedly emphasised through counselling during ante- and post-partum home visits. The National Health and Morbidity Survey (NHMS) 2016 found that the overall prevalence of exclusive breastfeeding among infants under six months old was 47.1%, suggesting that potential stigma arising from choosing not to breastfeed may not be significant (5).

Loss-to-follow-up of HIV cases (adult and children) regardless of nationality is minimised through contact tracing activities carried out by the District Health Office. Such cases will be alerted by the attending physician to the nearest District Health Office (DHO), and the respective Health Inspector and/or paramedics will initiate communication with the client, followed by a home visit.

2.4.3 Human resources

The MOH firmly believes that personnel (Table 2.2) involved in the eMTCT programme needs to be trained periodically. Personnel at clinics, wards, outpatient departments are trained from time to time on eMTCT, which will include (but not limited to) topics as outlined below:

(a) HIV/AIDS/STI and adherence counseling
(b) Clinical aspects of HIV/AIDS/STIs (inclusive of antiretroviral therapy)
(c) The Harm Reduction programme
(d) Data management in HIV/AIDS/STIs
(e) STI Client Friendly Clinics
(f) Role of NGOs in the prevention, control of HIV/AIDS/STI in Malaysia
(g) Care and treatment of syphilis / HIV AIDS in pregnancy
(h) Laboratory diagnosis of common STIs in HCs / Hospitals in Malaysia
(i) Contact tracing / public health aspects of HIV/AIDS/STI management in Malaysia

The above topics are integrated into training modules, and target health providers who are in frequent contact with HIV/AIDS/STI patients at outpatient clinics (hospitals) and primary health clinics. State AIDS Officers are obliged to conduct training courses for their staff every year, which should include the topics stipulated above.

The importance of the management aspects of caring for HIV positive / TPHA positive pregnant women is emphasised through training on good counselling practice. These aspects of antenatal care are also touched on in the following topics: *"Treatment of antenatal mothers for syphilis and HIV"* and *"ARV treatment for HIV/AIDS patients".* At present, it is quite common for the civil society and community-based organisations (CBOs) to be involved and deliver relevant topics to government health staff. Some of the relevant topics which rely on the involvement of CBOs include counselling, harm reduction, care and treatment, support groups and role of NGOs (list not exhaustive). Currently, the HIV/AIDS sector of the MOH is devising a module entitled *"Effective communication for Environmental Health Officers"* which aims to reduce stigma and discrimination amongst medical officers during the interview process with HIV/AIDS/STI patients.

To further enhance health providers' knowledge and expertise, in 2008 the MOH approved a 6-month intermediate-level course for nurses and assistant medical officers (AMO) on HIV/AIDS counselling. This course aims to better equip personnel who are

strategically placed in hospitals and HCs to facilitate HIV care at service delivery centres (outpatient care and health clinics).

2.4.4 Data management in eMTCT

In Malaysia, under the provisions of the Control of Communicable Diseases Act (CDC Act 342 1988), all attending medical practitioners (public and private) are required to notify cases of selected communicable diseases, including HIV and syphilis, to the nearest District Health Office (DHO). This can be done either manually or electronically (*e-notification) (6).* All confirmed HIV/AIDS cases are subsequently registered in the electronic National AIDS Registry (NAR)**.** Notification is conducted using unique identifiers (identification number for Malaysians and passport number for non-Malaysian) to avoid duplication. The mandatory notification of infectious diseases by law is deemed an important public health measure, to curb the spread of infectious diseases in the country.

Data entry is usually done by nurses, assistant medical officers (AMOs) or Environment Health Officers who are stationed at hospitals, health clinics or DHOs. The District Medical Officers of Health (DMOH) are directly responsible for staff training, data validation and verification, monitoring and evaluation and data management at the local level. Confidentiality is strictly maintained at all levels; data entry and passwords at local levels is only available to designated officers who are responsible for data management (the data that is to be keyed-in is not accessible by other staff members who are not involved. For example, personal information keyed-in in District A will not be available in District B, and vice versa. Data keyed in health clinics will also not be available by staff in the hospitals and vice versa).

2.4.5 Budget (refer also to Appendix 7 i.e. Benefits package for PLHIV in Malaysia)

Government funding is channelled from the Ministry of Finance to the MOH or other ministries, including the HIV/AIDS/STI funds. Almost 95% of the total budget for the HIV/AIDS & STI prevention and control programmes in Malaysia (inclusive of treatment, care of PLHIV and the PMTCT programme) is funded by the government. In 2014, total government expenditure on HIV and AIDS programmes exceeded RM195 million (USD48 million) (Table 2.3). Of this total, HIV/AIDS care and treatment (inclusive of for the purchase of HIV/AIDS drugs constituted a major portion of government spending) accounting for 65.1% of total expenditure.

Table 2.3 Source of approximate AIDS expenditure, Malaysia 2015 - 2016

Source of funding	2014 (RM)	%	2015 (RM)	%	2016 (RM)	%
Domestic Public	184,902,731.22 (USD45,089,230)	94	192,907,428 (USD43,086,998.93)	95	216,270,981 (USD45,089,230)	98
Domestic Private	1,835,679.81 (USD447,727)	1	1,190,763 (USD548,090)	1	324,7294 (USD447,727)	1
International	8,966,402.00 (USD2,186,927)	5	8,039,013 (USD1,643,705.8)	4	1,694,818 (USD2,186,927)	1
Total	195,704,813.03 (USD47,723,884)	100	202,137,204 (USD45,278,794.73)	100	221,213,095 (USD47,723,884)	100

Source: Ministry of Health, Malaysia, 2016

2.4.6 Service delivery in eMTCT in Malaysia

(i) Basic maternal and child services

In Malaysia, pregnant women (Malaysian and non-Malaysian) can access health services at any hospital and HC (government or private) across the country (Table 2.1). HIV positive pregnant women are managed by a multidisciplinary team which includes community healthcare personnel.

Malaysian pregnant women can access antenatal care (ANC) and postnatal care (PNC). This includes free HIV services in public health facilities. Following the implementation of the new Fee Act 2014, non-Malaysian pregnant women must now pay for basic ANC consultations in the public sector (Table 2.4). However, if she is confirmed HIV positive, she will receive free ART (option B), free HIV prophylactic treatment for her infant and free infant formula feed for 24 months. The following services are provided to all HIV positive pregnant women in the public sector:

(a) Blood screening (HIV & syphilis) during pregnancy
(b) Blood investigations (e.g. confirmation tests, PCR, other relevant tests)
(c) HIV / syphilis treatment and care during and post-delivery
(d) Treatment and care to the exposed infants plus blood investigations
(e) Free infant formula up to 2 years for the HIV exposed infants and advise on breast feeding practices
(f) Referral for treatment and care to the mother and infants (either during delivery and post-partum)
(g) Couple counselling
(h) Home visits by nurse post delivery
(i) Paediatric follow-up by paediatricians for the exposed infants
(j) Referral to other relevant services (e.g. social welfare, religious departments, NGOs, shelter homes etc.)

As aforementioned, there are 1,061 HCs in Malaysia, of which currently 257 are manned by FMS. HIV diagnosis, treatment, care and support services can be accessed at these HCs, hospitals and some private hospitals. Cases with complications (e.g. those with AIDS defining illness, multi-drug resistance) are referred to secondary or tertiary hospitals, where Infectious Disease physicians (ID Physicians) and O&G specialists can take over clinical management.

Despite medical charges imposed on non-Malaysians within the public health sector, the majority of non-Malaysian pregnant women prefer access ANC services in the public sector (77.7% versus 19.5% accessing ANC services in the private sector) (NHMS 2016). The overall prevalence of all women (15-49 years) accessing ANC services varies by type of health facility, with 83.1% accessing ANC services in public facilities, 9.2% in private facilities, and 7.3% accessing care in a combination of private and public facilities (unpublished data - analysis done upon request).

With regards to safe delivery, the NHMS 2016 reported that 99.5% of births were delivered by skilled birth attendants (midwife or doctor). The majority (80.5%) of deliveries took place in government facilities, followed by private facilities (18.6%). Only 0.5% of births occurred at home and 0.4% occurred in other places outside health facilities. The three main reasons given for home delivery were fast labour, no transportation and distance to health facility.

(ii) Treatment for HIV positive women, children and laboratory services network (refer to chapter 8 on Laboratory services network)

Special algorithms have been developed by the MOH for screening and confirming cases of HIV infection in Malaysia. Malaysia introduced Option B plus for HIV infected antenatal mothers in 2012, and this was reaffirmed in 2014 (refer to *Consensus Guidelines on Antiretroviral Therapy 2014).*

(iii) Special institution

Maternal and child health services are also provided to pregnant women and their babies in institutions such as prisons, drug rehabilitation centres and juvenile delinquency centres. In these institutions, health care including ANC is provided either by the visiting health care provider from the nearest health clinic or residential doctor (especially in prison). For HIV positive mothers, ART is initiated by the Family Medicine Specialist from the nearest health clinic, while continuation of ART can be done in the institution. In Malaysia, the Prison Regulations 2000 (Regulation 13) provides that the children under the age of 3 years will be admitted with his/her mother, and the child will be provided with basic necessities for their maintenance and care. Female prisoners with children are placed in a special cell that mimics a home-like environment, in order to ensure normal social and mental development for the child. The treatment of HIV-exposed infants follows the same algorithm as for children of non-imprisoned HIV positive mothers. As for children of HIV positive women in the general population, their treatment is managed under the specialist care of a paediatrician.

Table 2.4 Fee structure imposed on non-Malaysian pregnant women in public facility

Types of services	RM	USD
Health clinic (not including laboratory test and medication):		
1. General clinic	40	10
2. Specialist clinic	120	30
Hospital outpatient clinic (not including laboratory test and medication):		
1. General clinic	40	10
2. Specialist clinic	120	30
3. Emergency unit	100	25
Specialist clinic (not including laboratory test)		
1. Referral from government clinic	40	10
2. Referral from private clinic	120	30
Klinik 1 Malaysia (not including laboratory test and medication):	40	10
Klinik Desa (not including laboratory test and medication):	40	10
Child health services	40	10
Delivery charges (not including laboratory test and medication):		
1. Normal delivery	2,593	648
2. Caesarean	3,021	755
3. Forceps / vacuum	2,593	648
4. Breech	2,593	648
Postnatal services (not including laboratory test and medication):	40	10
Hospital fee / per day (not including laboratory test and medication):		
1. Intensive care unit (adult)	360	90
2. Intensive care unit (children)	300	75
3. Nursery	60	15
4. Nursery (Special treatment)	140	35
5. Nursery (with incubator)	170	43
Laboratory tests:		
1. Urine pregnancy test	40	10
2. Blood grouping	11	3
3. Full blood count	40	10
4. Rhesus	20	5
5. HIV	60	15
6. VDRL	20	5
7. TPHA	30	8
8. PCR	100	25

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CHAPTER 3

METHODOLOGY OF ASSESSMENT AND ITS LIMITATIONS

3.1 General assessment and methodology

According to the WHO guidance on criteria and processes for validation for EMTCT, Various methods have been used to quantify and assess data verification and impact assessments of eMTCT of HIV and syphilis in Malaysia. The technical working groups (TWG) used various methods to maintain the quality of assessments which includes surveys, consensus discussions, workshops, meetings, desktop reviews of reports, program data, and revision of guidelines, SOPs and other verified sources. We also used other "unconventional methods", such as focus group discussions (FGD) especially among HIV positive mothers who have gone through the eMTCT programme to gauge feelings, experiences and expectations since these women have gone through real life experiences within the framework of eMTCT. TWG also conducted quick assessments and surveys (e.g. Short survey on private / non-MOH Hospitals in Klang Valley) to determine the extent of the eMTCT programme implementation outside non-MOH facilities.

Below are some of the methodologies used.

(a) Committees and the formation of Technical Working Groups (TWG)
(b) Workshops and report writing
(c) Assessment of programmes and services
(d) Data verification
(e) Short surveys
(f) Review of reports and surveillance data
(g) Focus groups discussions (FGDs)
(h) Other relevant methods

3.1.1 Formation of committees and the TWGs

After the approval of the Deputy Director General of Health (Public Health) during the management meeting in 2016, four TWGs were formed (Data, Service Delivery (programme), Laboratory Services and Human Rights issues, together with their terms of reference (TOR) as stipulated by the WHO for the eMTCT guidelines. These TWGs were headed by various technical offices who are experts in their own fields (epidemiologists, public health physicians, pathologists, civil society representatives, clinicians).

3.1.2 Workshops and country report writing

Four national workshops were held in 2017 and early 2018 as part of the validation preparation process. Besides clarifying the TOR, the secretariat outlined Malaysia's eMTCT country report based on the guidelines as required by the validation process. For example, workshops were held in stages i.e. The first workshop was held to identify Malaysia's strengths and weaknesses in reference to the eMTCT programme (especially in maternal & child health services, data, SOPs, guidelines, laws, regulations, available reports and studies), steps to validate data, overall programmes, and activities in HIV & syphilis.

The subsequent workshops were held to collate available data, identifying important flowcharts, charting milestones, identifying important chapters of the country report, assignments of various tasks to the TWGs.

After the approval of the Deputy Director General of Health, the first draft of the country report was sent in June 2017, and subsequently the second, third and fourth drafts were made. All of the drafts of the country report were sent to WHO regional office via the WHO country office in Cyberjaya, Malaysia.

There was constant communication with regard to the country report between Malaysia MoH and the officers of WHO Regional Office, UNAIDS, and UNICEF.

3.1.3 Assessment using the validation tools (checklists)

The validation tools were used to evaluate the performance of eMTCT Malaysia for following four thematic areas;

(a) Data quality
(b) Programme assessment
(c) Laboratory quality assurance
(d) Human rights, gender equality and community engagement

(a) Data quality

Assessing quality of the eMTCT monitoring and surveillance system is the cornerstone of eMTCT validation process. In this tool provided by WHO, checklists for data collection processes and mechanisms are included to assist reviewers in evaluating national-level, sub-national levels and the service delivery levels. Some of the relevant documents and systems review include the electronic surveillance systems, case definitions, routine surveillance reports, progress reports, monitoring and evaluation reports, and legislation.

The MoH also made use of 2 important sources of data for validation:

i. Triangulated data based on programme records aggregated from facilities, surveys, estimates from national bodies (Department of Statistics, monthly

reports from the Ministry of Health), quick surveys, population-based surveys, and another verified source

ii. Estimates were generated using the Spectrum software version 5.63 for estimation of impact and population level denominators. The Spectrum, mathematical modelling software uses demographic data, information on adult and child treatment coverage and assumptions about the epidemiology of HIV to generate estimates of national (adult and child) HIV prevalence, incidence, mortality and treatment needs. Estimates with regard to congenital syphilis were also generated using the WHO estimation tool.

There were also numerous consultations with officers from UNAIDS, WHO, Family Development Division, the Informatics Unit of the Ministry of Health, Health Systems Research Unit of the Ministry of Health in order to obtain verified methodologies and data. Series of workshops and consensus meetings were also held with the AIDS Officers of the sub-national units to gather more information / data.

(b) Programme evaluation and assessment

The purpose of this tool is to review the programmatic component relevant to the elimination strategy including Comprehensive ANC services, HIV and syphilis testing and treatment programmes, and treatment and care for infected pregnant and postpartum women, their infants and their male partners. This method is also used to verify whether services are sufficient in scope, accessibility and quality to sustain the eMTCT targets.

Key informants for this assessment include officers from the national, sub-national units as well as at the service delivery units. Besides visits to the service delivery sites and sub-national units, regular discussions are also held with our Family Health Development Division counterparts as part of the process.

(c) Laboratory quality assurance

WHO guidance requires laboratories that contribute data to the surveillance system to have

i. A quality management system in place to ensure that tests are procured, stored and used according to international standards, such as WHO pre-qualification or another regulatory equivalent;

ii. Personnel performing the tests who have been trained in accordance with nationally recommended algorithms;

iii. A laboratory quality assurance mechanism which is routinely and consistently applied and verified through participation in an external quality assessment (EQA) programme for HIV and syphilis testing, in addition to internal quality assurance.

Overall, laboratory assessment has four components.

(1) Laboratory quality management.

This is an assessment of the general organization and functioning of the national

HIV/syphilis laboratory programme.

(2) Quality of tests
This is an assessment of tests to evaluate whether they have acceptable and operational characteristics as specified by international and national organizations such as WHO.

(3) Quality of testing
This is an assessment of staff competency in general through professional licensure as technologists or appropriate training of other health-care workers, and staff proficiency in performing the tests selected.

(4) Laboratory data management
This is an assessment of the laboratory information management, specifically focused on a functional laboratory information system for EMTCT for HIV and syphilis.

(d) Human rights, gender equality, and engagement of the civil society
A key requirement for validation of a country for eliminating MTCT of HIV and syphilis is that the interventions to reach the targets have been implemented in a manner consistent with international, regional and national human rights standards, have engaged the community of women living with HIV and have taken gender equality into consideration. In this regard, Malaysia Ministry of Health is fortunate to have the Malaysian AIDS Council (MAC) as one of our key strategic partners during this important assessment. The principles need to be comprehensively examined for rights-based EMTCT of HIV and syphilis include following;

i. Non-criminalization of HIV/syphilis transmission in law and policy, and in practice;
ii. Ensuring voluntary HIV and syphilis testing and treatment in law and policy, and in practice;
iii. Ensuring informed consent in law and policy, and in practice;
iv. Ensuring the elimination of forced, coerced and otherwise involuntary sterilization, contraception and/or abortion in law and policy, and in practice;
v. Ensuring confidentiality and privacy of HIV and health information in law and policy, and in practice;
vi. Ensuring gender equality and non-discrimination in law and policy, and in practice;
vii. Ensuring accountability, community engagement and participation of people affected by HIV and other key populations;
viii. Ensuring availability, accessibility, acceptability and quality of services in law and policy, and in practice;
ix. Ensuring access to justice, remedies and redress in law and policy, and in practice.

Some of the “unconventional methods” were also performed, including having FGD to explore feelings, expectations, and desires of people living with HIV who have gone through the eMTCT programme.

3.2 Usage of tools and checklists for in-country evaluation of the 4 required components

Using the latest check-list of the evaluation tools, the secretariat proceeded to have consensus meetings with our key partners with regard to eMTCT and to identify key areas. The TWGs went through the questionnaires and discussed the response. Two national consensus meetings were held to discuss the response, and the questionnaires and responses, were returned to WHO secretariat via the national secretariat.

3.3 Limitations of the evaluation methods during the in-country evaluation process

The methods for in-country evaluation have some limitations. However, wherever possible, we made our best efforts to have data which can be inferred or best describe and represent the country's situation on eMTCT. Some of the most important limitations of the methods in this evaluation include the following:

(a) Lack of clear definition and guideline on congenital syphilis
For congenital syphilis, there was no clear definition for surveillance purpose. Thus, most cases reported to surveillance system were based on clinical (including presumptive) diagnosis. Although there is stillbirth surveillance, however, syphilitic stillbirth cannot be linked.

(b) Limited number of non-Malaysians included in the surveys and the data
The available data mostly focused on Malaysians, and there are not necessarily sufficient data for non-Malaysians. As it would be the same for other countries, it is especially challenging to obtain the data for the "undocumented migrants / foreigners", and these data are not within the purview of the Ministry of Health.

(c) Limited information from private health facilities
Survey among non-MOH (including private) facilities was limited to Klang Valley only and not widely distributed geographically. Thus, findings may be biased.

Next steps

Most of the recommendations by the Regional Validation Team during the initial phase of the assessment were extremely useful and valid. Based on the recommendations, the Ministry of Health Malaysia will continue to strive to improve the eMTCT Malaysian model, which could be emulated by other countries in this region.

CHAPTER 4

AN OVERVIEW AND ACHIEVEMENTS OF THE ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION (EMTCT) OF HIV & SYPHILIS IN MALAYSIA

4.1 Overview

For many decades, Malaysia has implemented a comprehensive package for pregnant women seeking antenatal care (1). The evolution of this comprehensive package started by the maternal and child health (MCH) activities of primary care clinics which started in the 20th century (during the British colonial era) right up to present times. It has been recognised by our government and Ministry of Health (MOH) that the MCH services should always remain one of the main pillars of primary care in this country.

Malaysia has been implementing the prevention of mother-to-child transmission (PMTCT) of syphilis for more than two decades. Syphilis was introduced as part of the package more than 30 years ago followed by HIV a decade later. MOH Malaysia has been one of the early implementers of PMTCT programme of HIV in Asia with nationwide expansion of the national programme in 1998 (1,2). The PMTCT program in Malaysia is based on universal voluntary HIV testing during the antenatal period (Prong 2), the provision of antiretroviral (ARV) prophylaxis to the mother and the baby, safer modes of delivery and safer infant feeding practices (Prong 3) – strategies that rely on early antenatal care and early HIV diagnosis, timely commencement of ARV prophylaxis and to the mother and the baby and excellent early neonatal follow-up. Primary prevention of HIV in women (Prong 1) and extended community-based care and support for families living with and affected by HIV (Prong 4) are linked the program.

There has been constant revisions of the HIV & Syphilis PMTCT programme, and after years of implementation, the current PMTCT programme is at the same level with established PMTCT programmes elsewhere around the world. Though there are challenges, the programme has provided services to all population groups of this country without discrimination including from key populations and migrants irrespective of their legal status.

All health care services are provided free for Malaysians citizens and can be accessed by a fee for service and medicines for non-Malaysian citizens. Private health insurance schemes are also offered to private employees, whilst the health benefits for the government employees are covered by the state. PMTCT of HIV and syphilis like most infectious diseases services are heavily subsidised by the government. The first line treatment regimen for HIV is provided free by the government like medicines for most other infectious diseases. As for non-Malaysian, both documented and undocumented, they can access PMTCT services in both government or private facilities of their choice without legal redress.

All pregnant women are expected to have an average of 8 visits during pregnancy, out of which at least one visit managed by a qualified medical practitioner. As part of the comprehensive antenatal package, pregnant women will be recommended universal testing for syphilis, HIV, haemoglobin, urine and blood group analysis. Universal hepatitis B testing for pregnant women has been initiated in the state of Sabah.

4.2 Implementation of PMTCT of HIV and syphilis in Malaysia

4.2.1 Implementation of PMTCT of HIV

The first case of HIV was reported in Malaysia in 1986. Over the past years, significant efforts have been made to increase early HIV diagnosis through expanding access to voluntary HIV testing in both community-based settings and health facilities resulting in the significant rise in the detection of HIV/AIDS cases. Voluntary universal HIV testing is routinely recommended to inmates in drug rehabilitation centres and prisons, voluntary and anonymous testing services, harm reduction services, TB, hepatitis B and C patients and STI patients, PLHIV contacts, premarital and antenatal mothers. Surveillance records from the Ministry of Health show that the first antenatal case of HIV positive Malaysian was recorded in 1998.

Mother-to-child transmission (MTCT) is the most common and important source of HIV infection in children and in the absence of intervention, between 30% to 45% of children born to HIV infected mothers will become infected with HIV during pregnancy, labour or delivery, or through breast feeding. Supported by findings from clinical trials, Malaysia embarked on national PMTCT Program in 1998. It encompasses four core strategies: a) early detection of HIV infection using a rapid HIV point-of-care test, with confirmatory testing if indicated; b) provision of counselling for infected mothers and their partners; c) provision of oral Zidovudine (ZDV) to infected mothers according to the Paediatric AIDS Clinical Trials Group 076 (PACTG-076) protocol, i.e. from as early as possible in the second trimester of pregnancy until the onset of labour, switching to intravenous ZDV during labour, and with oral ZDV for the baby for the first 6 weeks of life; and d) early detection of HIV infection among babies born to HIV infected mothers.

These strategies are supplemented by safer modes of delivery including caesarean section and free formula milk (supported by Ministry of Health) for infants born to HIV positive mothers for 6 months and since 2012 for 24 months (3). Since the inception of PMTCT program in 1998, MOH encourages to avoid breastfeeding among HIV positive mothers as the strategy that will most likely give infants the greatest change of HIV-free survival. The decision was based on WHO guidelines on HIV and infant feeding, and the high socioeconomic standard of Malaysia. About 96% households in Malaysia have access to clean water supply (Malaysia Health Facts 2017), hence, formula feeding for HIV positive mothers is considered safe. Health education and counselling on exclusive breast feeding for first six months are offered to all pregnant women including those who are HIV positive opting for breastfeeding at every ANC follow-up and home visit. Despite the advice on benefit of avoiding breastfeeding, mothers have the liberty to choose the infant feeding method. Regardless of her decision, the health care services to both mother and child will continue.

With the advancement of highly active antiretroviral therapy, and in accordance with WHO guidelines, ARV regimen was upgraded to option B in 2008 and to option B plus in 2012. Provision also exists for women who present in labour with no record of antenatal care or HIV testing. HIV testing using rapid point-of-care test is carried out by the bed side and infants of women found to have a reactive HIV rapid test in labour are managed according to the post-natal component of the PACTG-076 protocol.

To ensure comprehensive care, all HIV positive mothers and their exposed infants are referred to a "combined care" team made up of Infectious Disease Physicians (ID Physicians), Obstetrics & Gynaecologists (O&G Specialists), Paediatricians and Family Medicine Specialists (FMS). The objective of this joint care team is to ensure healthy and HIV-free babies and long-term follow-ups for mothers, their spouses and infants. Wherever and whenever needed, appropriate referrals could be done.

4.2.2 Implementation of PMTCT of syphilis in Malaysia

The prevention and control of syphilis in Malaysia is generally integrated within the HIV/AIDS prevention and control programmes with Disease Control and Family Health Development Divisions being the 2 main Divisions responsible for the implementation of elimination of mother-to-child transmission (eMTCT) of syphilis. Most of the approaches / strategies towards implementing eMTCT of syphilis in Malaysia are being reflected on the implementation of eMTCT of HIV as well.

Screening of syphilis among pregnant women has been part of the comprehensive package of maternal and child health services in Malaysia for many years. Pregnant women are tested for syphilis at least one, and in some cases, these mothers are tested for the second time during their 28th week of pregnancy if a health care provider suspects that the mother is at high risk to acquire HIV/STI infection e.g. if the mother or her partner have a history of injection drug use or if mother has a history of sex work.

Due to the importance of following up antenatal mothers who are syphilis positive and its consequences, during the past year, the MOH has started several initiatives which can be summarised as follows:

(i) Development of format to investigate antenatal mothers who are syphilis positive
(ii) Development of investigation format for congenital syphilis
(iii) Development of line listing for antenatal mothers who are syphilis positive
(iv) Implement stillbirths reporting system to all health facilities – government and private

The above initiatives are in the early phase of being field tested. We hope these initiatives will enhance the surveillance of syphilis among antenatal mothers and their exposed infants in the future. Family Health Development Division MOH Malaysia has been collecting data on stillbirth since year 2013 through System of Under-Five-Mortality and Reporting System (SU5MR). All public and private hospitals are participating in the reporting of stillbirths in this surveillance as required by the 2015 Circular issued by the Director General of Health Malaysia (4).

The classification of causes of stillbirth was based on a Modified Pathophysiological Wigglesworth Classification, therefore it is not possible to link the causes of stillbirth due to syphilis. From the preliminary results based on the data for year 2015 and 2016, the cause of stillbirth due to infection-related cause was 0.2% and 0.1 % respectively.

4.3 Achievements of eMTCT of HIV and syphilis targets

4.3.1 Achievements of eMTCT of HIV

To understand the population level eMTCT achievements in Malaysia, the country has used spectrum HIV estimation tool (internationally accepted HIV estimation tool) to measure the impact indicator - final transmission rate of mother-to-child transmission of HIV. The outputs from spectrum (version 5.63) indicated that Malaysia has already achieved the impact target for the validation of eMTCT, i.e. <2% MTCT rate among non-breastfeeding population in 2016 and 2017.

(a) Antenatal attendance

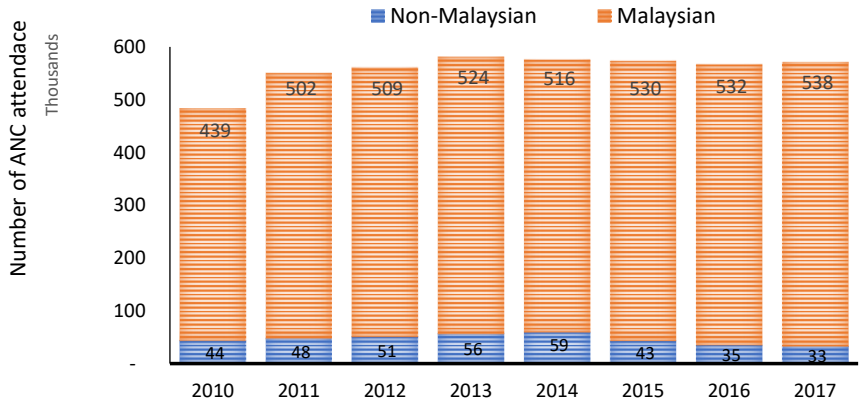
For years, Malaysia has provided free ANC services regardless of nationality in government health facilities. In 2014, with implementation of the new Fee Act, non-Malaysian (excluding those married to Malaysian and those with Malaysian identity card) were charged a fee for health services. All including non-Malaysians (documented and non-documented) are guaranteed access to all health services including ANC in both government and private health facilities. For every antenatal mothers registered, two (2) health record book will be issued; one to be kept by mother and the other for clinic record. All important information related to mothers' health care will be recorded in duplicate. For mothers requesting continuation of care in other health facility, she will be referred to the recipient clinic together with her health record books. Earlier arrangement will be made between health staff in the referring clinic and the recipient clinic. Sensitive information will be recorded only in the clinic copy to maintain confidentiality.

In general, the total number of antenatal attendance (at least 1 visit) in both government and private health facilities stabilised between 570,000 to 575,000 in the last 4 years (Figure 4.1). While the number increased among Malaysians, the new fee structure resulted in a significant reduction of ANC attendance among the non-Malaysians (Figure 4.1).

For the past 5 years, the ANC coverage was reported in the range of 93% - 98% based on programmatic data (2). These data include reporting units from all government health clinics (1,061), hospitals (143) and more than 7,000 private health facilities. Denominator for estimated pregnant women derived from triangulation of reported live births, stillbirths and miscarriages from both private and public facilities in 2015 and 2016. Total number of deliveries from both private and public facilities were adjusted-up with number of stillbirths and abortions to estimate the total number of pregnancies. The numerator was down-scaled by 7% assumed as duplication (Appendix 1). This is based on NHMS 2016 findings, whereby 7% of mothers had both public and private ANC. The adjusted total ANC attendance coverage were 95.6% and 96.7% between 2015 and 2016; 99.1% and 98.2% for Malaysians only (Figure 4.2).

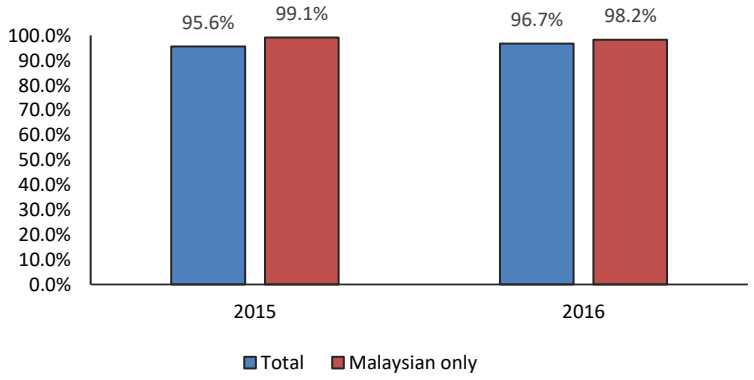
The National Health and Morbidity survey in 2016 (NHMS 2016) further confirmed the ANC coverage above. It was noted that 97.4% of women surveyed (n=10,260) had a minimum of 4 antenatal visits; higher among Malaysians (97.6%) compared to non-Malaysian counterpart (93.2%) (5). Almost 70% of women were booked in the first trimester (less than 12 weeks of gestation). Regarding handling of the HIV-exposed infant, MOH has standard guideline and protocol in both hospital and primary health care setting to ensure hygiene and cleanliness. We also practice the routine procedures that protect both the health care workers and patients from contact with infectious material.

Figure 4.1 ANC attendance (at least 1 visit), Malaysia 2010-2017



Source: Family Health Development Division, Ministry of Health Malaysia, 2017

Figure 4.2 Adjusted ANC attendance (at least 1 visit) coverage 2015 – 2016



Source: Family Health Development Division, Ministry of Health Malaysia, 2016

(b) HIV testing coverage

It is a practice that all new pregnant women attending ANC in government health facilities are universally recommended to receive HIV testing as part of ANC blood screening package regardless of known or unknown prior HIV status. However, the private health facilities will only test mothers without known HIV test result attached in their ANC card, thus numbers reported from private facilities will be much lower.

The HIV testing coverage (Malaysians and non-Malaysians) has constantly reached above 95% between 2015 and 2016 (Table 4.1) (2). This HIV testing of antenatal mothers covers both the public and private facilities.

The MOH conducted a survey in May 2017 to determine the testing coverage and achievements among non-MOH Hospitals. Although these hospitals are not categorised under the 'mainstream' government hospitals, they are answerable to the Director General of Health Malaysia and expected to follow the standard operating procedures (SOP) or guidelines as stipulated by the MOH.

Out of 50 hospitals surveyed, 33 (66%) responded i.e. 2 university hospitals, 1 military hospital and 30 private hospitals in the Klang Valley (which covers the states of Selangor, Negeri Sembilan and Kuala Lumpur). Majority of these hospitals provide universal HIV testing (97%), while all the hospitals surveyed reported that they provide both VDRL / TPHA either 'in-house' or via private laboratory services for syphilis testing. Only 1 centre (university hospital) out of the 33 hospitals provide HIV treatment while the others refer HIV positive mothers to MOH hospital for ART.

Eighteen percent (18%) of the 33 hospitals provide treatment for syphilis in-house while the rest refer TPHA+ antenatal mothers to MOH facilities. HIV screening coverage were at an average of between 72% - 76% in 2014 and 2016. Upon further questioning, all hospitals in this survey did not repeat HIV tests for mothers already tested elsewhere or known to be HIV positive (PLHIV), hence coverage of HIV testing was relatively lower compared to MoH facilities (Refer to survey summary findings as in Appendix 3).

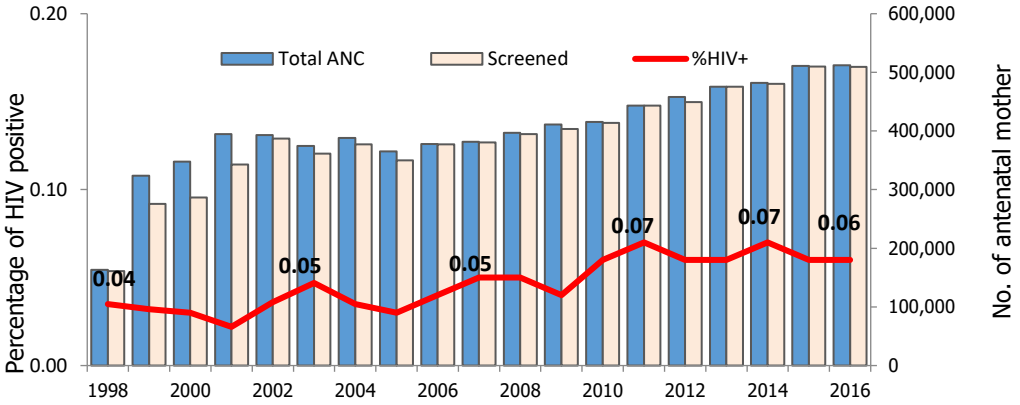
(c) HIV prevalence among antenatal mothers

The HIV prevalence as reported by the programme has stabilised at 0.06 - 0.07% (Figure 4.3) **(2).** However, some states were having increasing prevalence among antenatal mothers (e.g. in the states of Kelantan, Pulau Pinang, Melaka, Sabah and Sarawak) with Kelantan recording the highest rate at 0.13% in 2016 above the national rate (Figure 4.4). Kelantan, with other east-coast states like Terengganu and Pahang the majority of new HIV infections occur among PWID. Although the prevalence of HIV among PWID has declined overall it has remained at a high level in Kelantan at around 30% (IBBS 2017) (unpublished). Women married to PWID are at higher risk of getting HIV infection through sexual transmission, thus prevalence of HIV is higher among women in Kelantan than in other states. Selangor is the most developed and populated state in Malaysia. Hub for industries and job opportunities, it attracts millions of people from all walks of life, Malaysian and non-Malaysian alike to work and reside in Selangor. It is indeed a

huge challenge in ensuring provision of quality health care including ANC in this diverse multi-cultural community.

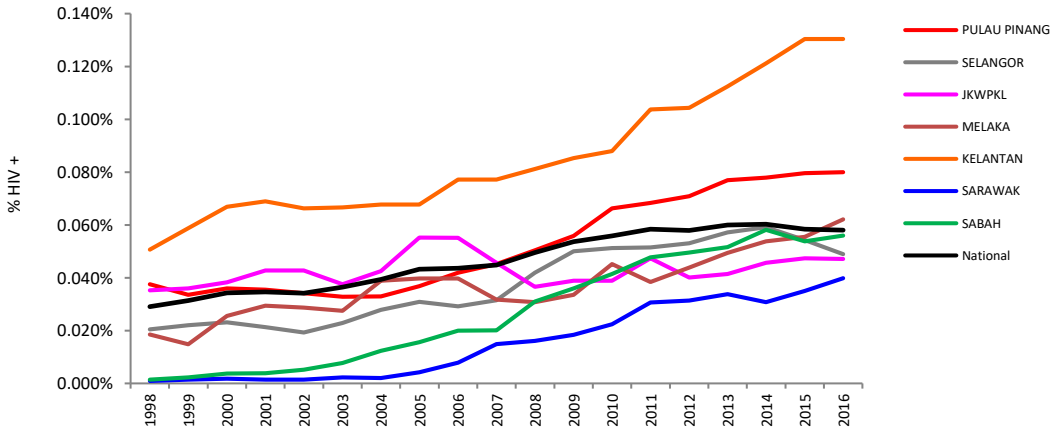
Data from various sources were used to triangulate and estimate the number of HIV-positive pregnant women in high-risk and vulnerable populations that may not seek antenatal care (i.e. women who inject drugs, female sex workers, and teenage mothers) (Appendix 1). The purpose of this triangulation exercise is a) to have an understanding about the fraction of vulnerable populations that the programme may miss to capture and b) to make down adjustment of programmatic coverage such as ART coverage among HIV-positive pregnant women. Though undocumented migrants are one of the populations that may not seek antenatal care, lack of reliable data deters the inclusion of undocumented migrants in this exercise

Figure 4.3 HIV screening and seropositive rate among antenatal mothers, Malaysia 1998-2016



Source: HIV/AIDS/STI/Hepatitis C Sector, MOH Malaysia, 2016

Figure 4.4 Seven-year moving average of HIV seropositive rate among ANC mothers in selected states in Malaysia, 1998-2016

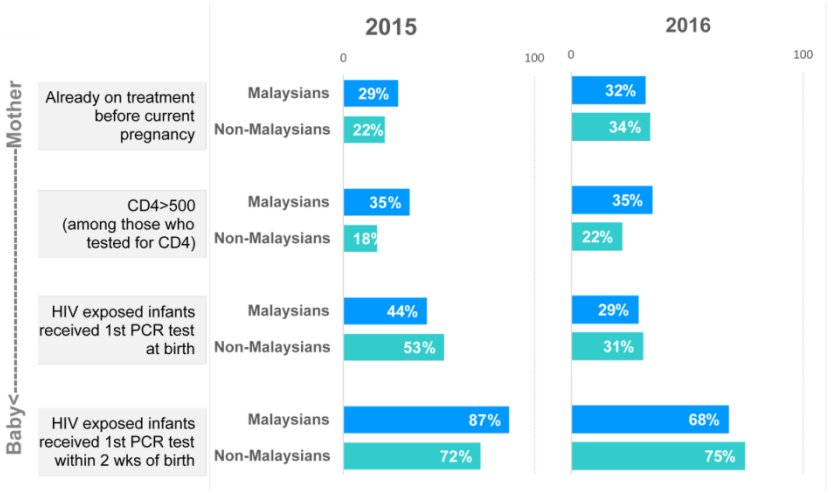


(d) ART coverage

Based on the findings of eMTCT in the other parts of the world, Zidovudine was used as the standard treatment for the eMTCT in Malaysia in the late 90's which was later changed to option B in 2008 and eventually to option B plus in 2012 as recommended in the WHO guidelines. To ensure better outcomes and impact on the eMTCT programme, the government has given the mandate that free antenatal coverage, prophylaxis and treatment be given to antenatal mothers living with HIV, resulting most antenatal mothers who are HIV positive (including those from private facilities) get referred to government facilities. While Malaysian women received the Option B plus, the non-Malaysians (documented and non-documented) received free ART coverage of Option B. However, all HIV-exposed infants regardless of nationality receive free prophylaxis, replacement feeds and ART for those who are HIV positive irrespective of being Malaysian and non-Malaysian. Therefore, we are confident that majority of antenatal mothers who are living with HIV in Malaysia (97.6% in 2015 and 96.9% in 2016) have benefited from the ART accordingly (Table 4.1).

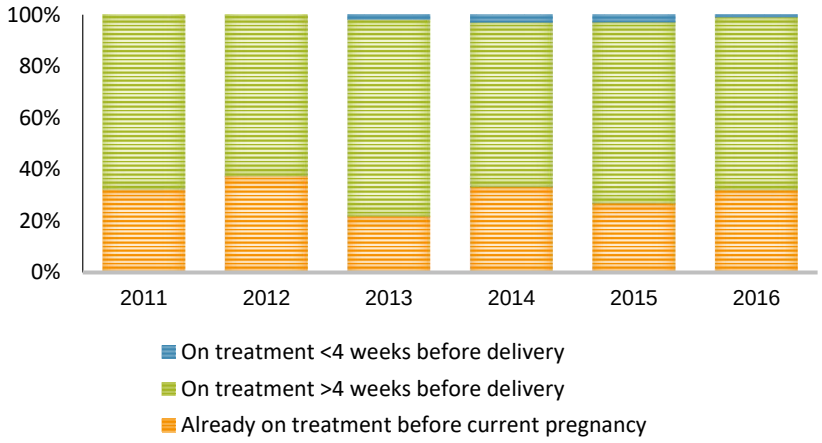
Majority of pregnant women living with HIV had received ART more than 4 weeks before delivery (60% to 80%) (Figure 4.6). About one third of pregnant women living with HIV were already on treatment before the current pregnancy - either through premarital testing, previous antenatal testing or other testing programmes. Increasing proportion of women are already on treatment before current pregnancy- 32% among Malaysians and 34% among non-Malaysians in 2016 (Figure 4.5) Premarital HIV prevalence among women (15-49 years) is showing a declining trend (Figure 4.7), thus women (on treatment before current pregnancy) would most likely had a known HIV status and were on ART either from previous pregnancies or through other testing programmes.

Figure 4.5 Early initiation of treatment (before current pregnancy) among pregnant women and early infant diagnosis (Malaysian vs. non-Malaysian) 2015-2016



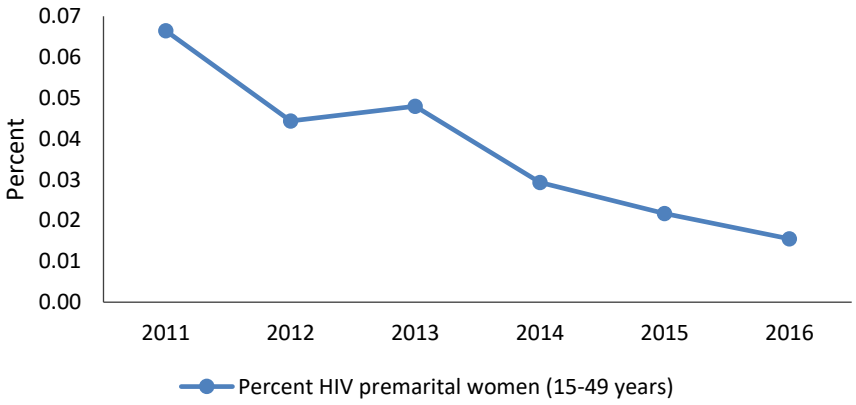
Source: *HIV/AIDS/STI/Hepatitis C Sector, MOH Malaysia, 2016*

Figure 4.6 ART coverage among pregnant women living with HIV (PLHIV), Malaysia 2011-2016



Source: HIV/AIDS/STI/Hepatitis C Sector, MOH Malaysia, 2016

Figure 4.7 HIV prevalence among premarital women (15-49 years), Malaysia 2011-2016



Source: HIV/AIDS/STI/Hepatitis C Sector, MOH Malaysia, 2016

Table 4.1 Spectrum and Programmatic data for impact and key indicators in accordance with eMTCT of HIV and Syphilis (Malaysian and Non-Malaysian), 2015-2017

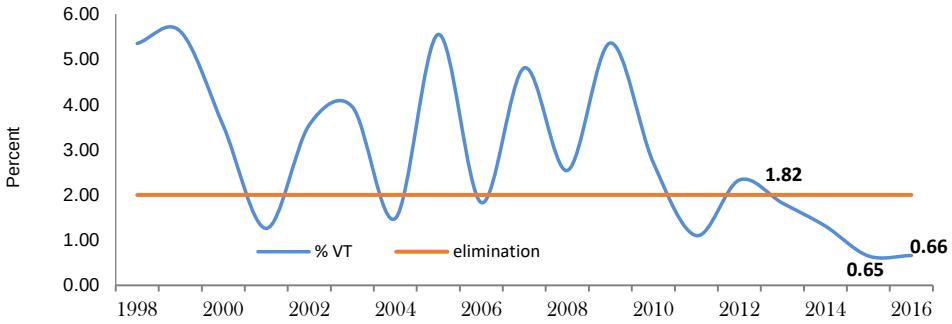
INDICATORS	WHO eMTCT Target	2015			2016			2017[b]		
		%/ Per 100,000	N	D	%/ Per 100,000	N	D	%/ Per 100,000	N	D
MTCT rate (by HIV PCR)	<2%	**0.65**	2	308	**0.66**	2	301	**0.61**	2	330
MTCT rate (spectrum)*		**2.46**	8	334	**1.99**	6	322	**1.74**	6	337
Annual rate of new paediatric HIV infections per 100,000 live births by birth cohort (Program data)	≤50	**0.38**	2	521,136	**0.39**	2	508,203	**-**	2	NA
Annual rate of new paediatric HIV infections per 100,000 live births by birth cohort (spectrum data)		**1.54**	8	521,136	**1.18**	6	508,203	**-**	6	NA
Annual rate of congenital syphilis per 100,000 live births	≤50	**4.22**	22	521,136	**2.95**	15	508,203	**-**	2	NA
Annual rate of congenital syphilis per 100,000 live births (WHO Syphilis estimation tools)		**5.37**	28	521,136	**3.54**	18	508,203	**3**	17	NA
Antenatal coverage (at least one visit)	≥95%	**95.6**	533,226	557,740	**96.7**	526,874	544,661	NA	NA	NA
HIV testing coverage of pregnant women	≥95%	**95.1**	530,351	557,740	**95.8**	521,523	544,661	NA	516,590	NA
Syphilis testing coverage of pregnant women	≥95%	**95.1**	530,351	557,740	**95.8**	521,523	544,661	NA	516,590	NA
ART coverage of HIV+ pregnant women[a]	≥95%	**97.2**	319	328	**97.5**	311	319	**98.8**	330	334
Treatment coverage of syphilis+ pregnant women	≥95%	**100.0**	247	247	**100.0**	204	204	**100.0**	228	228

N-Numerator; D-Denominator [a]Denominator for PLHIV pregnant women has included estimated number of PLHIV women not accessing antenatal care
[b]This is preliminary data; this data point is just for trending not for purpose of validation, thus some denominators cannot be included [c,d]Summary of cases is in Appendix14
*All parameters- %, numerator and denominator values are spectrum generated values. Spectrum generated MTCT rate is based on unrounded numbers

(e) MTCT rate

For impact indicator of MTCT rate, Malaysia uses Spectrum v5.63 as primary data source. The spectrum output showed declining MTCT rate from 5.28% in 2014 to 2.46% in 2015 to 1.99% in 2016 and 1.74% in 2017 (Appendix 2). This trend is consistent with the programmatic data, that recorded declining trend of vertical transmission rates below 2% from 1.31% to 0.66% between 2014 and 2016 (Figure 4.8) (2). This is in line with the Option B and B plus implementation in 2008 and 2012. In addition, premarital HIV testing increases the number of women knowing their status. The outcome of HIV-exposed infants is far better if the HIV+ mothers were detected and treated early before pregnancy.

Figure 4.8 Vertical transmission rate[a] of HIV (%VT), Malaysia: 1998-2016



Source: HIV/STI/Hepatitis C Sector, MOH Malaysia, 2016

[a]HIV infection in infant is based on early infant diagnosis (EID) with 2 concordance PCR at birth (0-2 weeks) and at 6 weeks post-partum.

Table 4.2 Overall summary of HIV exposed and infected infants (programmatic data), Malaysia, 2015-2016

Year	No. of mother on ART	No. abortion/ stillbirth/ TOP	No. of live birth	Delivery by LSCS	Formula feeds*	No. with EID (PCR)	No. HIV infected**	MTCT rate (by PCR)
2015	319	11	308	258	306	308 (100%)	2	0.65%
2016	311	10	301	232	297	301 (100%)	2	0.66%

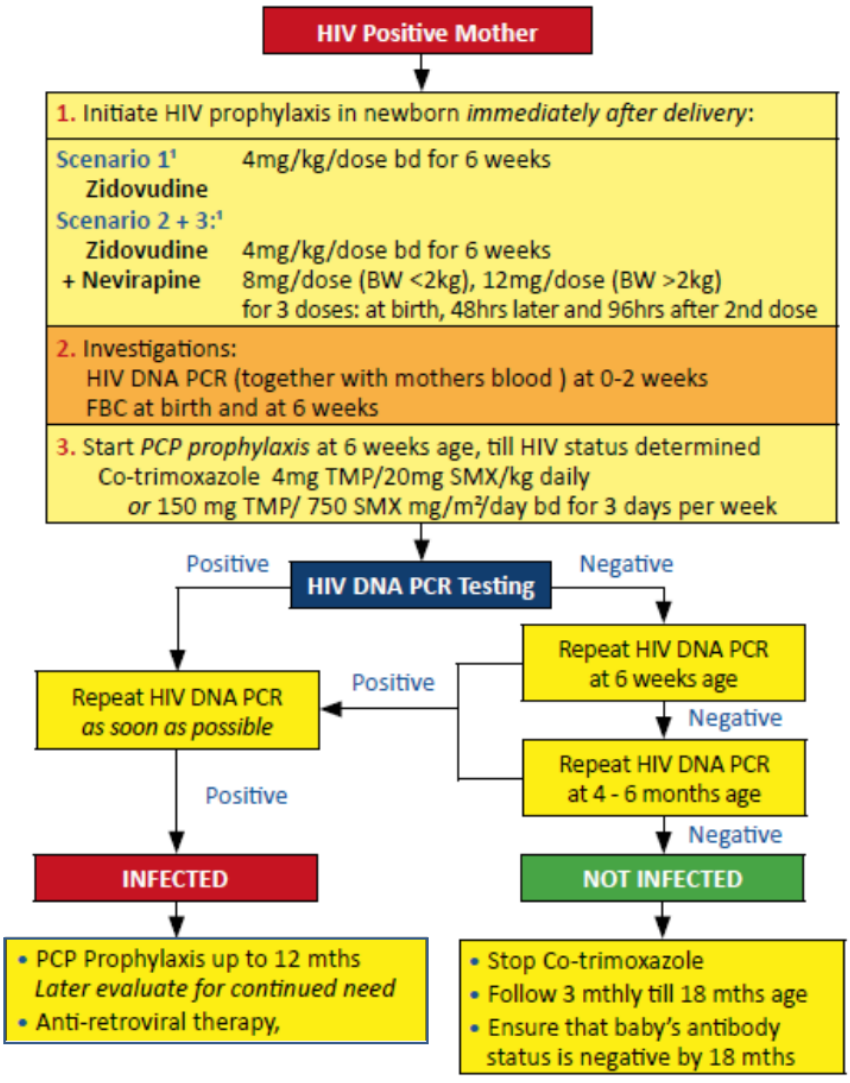
**Some went back to country of origin / transferred out*
***Vertical transmission of HIV is taken as infant born from HIV+ mother with two (2) concordance PCR positive.*

Source: HIV/STI/Hep C Sector, Ministry of Health, Malaysia, 2016

(f) New paediatric HIV infections

A new HIV paediatric infection is defined when an HIV-exposed infant has two concordance EID (PCR) positive at birth (0-2 weeks) and 6 weeks of life (Figure 4.9). The national surveillance system reported a constant decline of new paediatric HIV infection from 11.7 to 0.39per 100,000 live births between 2011 and 2016 (It is noteworthy that proportion of infants who received PCR test by 2 weeks of age among HIV-exposed infants born to non-Malaysian mothers were even higher that of Malaysian mothers in 2016 (Figure 4.5). This is the indication of quality of care that non-Malaysians received through health facilities in Malaysia.

Figure 4.9 Management of HIV-exposed infants

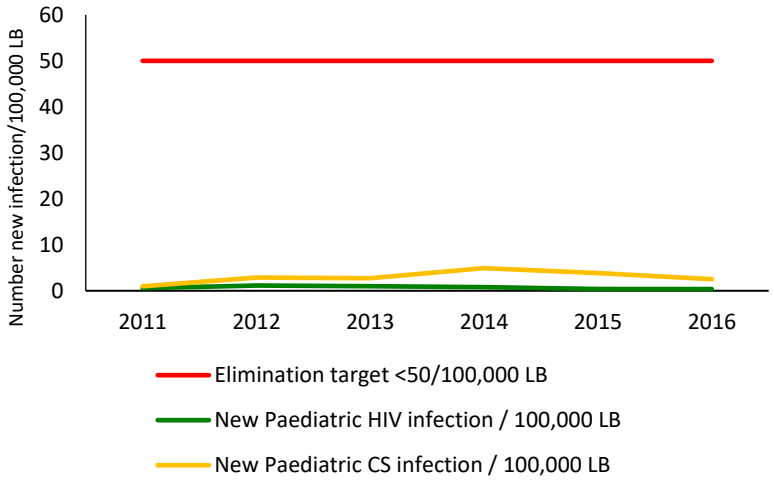


Scenario 1: HIV infected pregnant mother who is on HAART
Scenario 2: HIV infected mother at delivery who has not received adequate ARV Scenario 3: Infant born to HIV infected mother who has not received any ARV

- ARV should be served as soon as possible (preferably within 6-12 hrs of life) and certainly no later than 48hours.
- Dose of Syr ZDV for premature baby >30 wks: 2mg/kg 12hrly for 2 wks, then 2mg/kg 8hrly). If oral feeding is contraindicated, use IV ZDV 1.5mg/kg/dose.

Abbreviations:
ARV, Antiretroviral prophylaxis; HAART, Highly active antiretroviral therapy; PCP, Pneumocystis carinii pneumonia.

Figure 4.10 New paediatric infections of HIV and Congenital syphilis, Malaysia 2011-2016



Source: HIV/STI/Hepatitis C Sector, MOH Malaysia, 2016

4.3.2 Achievements of eMTCT of syphilis in Malaysia

As outlined in 'Case Definitions for Infectious Diseases in Malaysia', a confirmed case of congenital syphilis must be notified. Confirmed case is defined as a clinically compatible case that is laboratory confirmed, following the criteria below (also see Appendix 11)

(a) Clinically compatible with congenital syphilis

i. A condition caused by infection in utero with *T. pallidum*. A wide spectrum of severity exists, and only severe cases are clinically apparent at birth.

An infant or child (< 2 years) may have signs such as hepatosplenomegaly, characteristic skin rash, condyloma lata, snuffles, jaundice (non-viral hepatitis), pseudo paralysis, anaemia, or oedema (nephrotic syndrome and / or malnutrition).

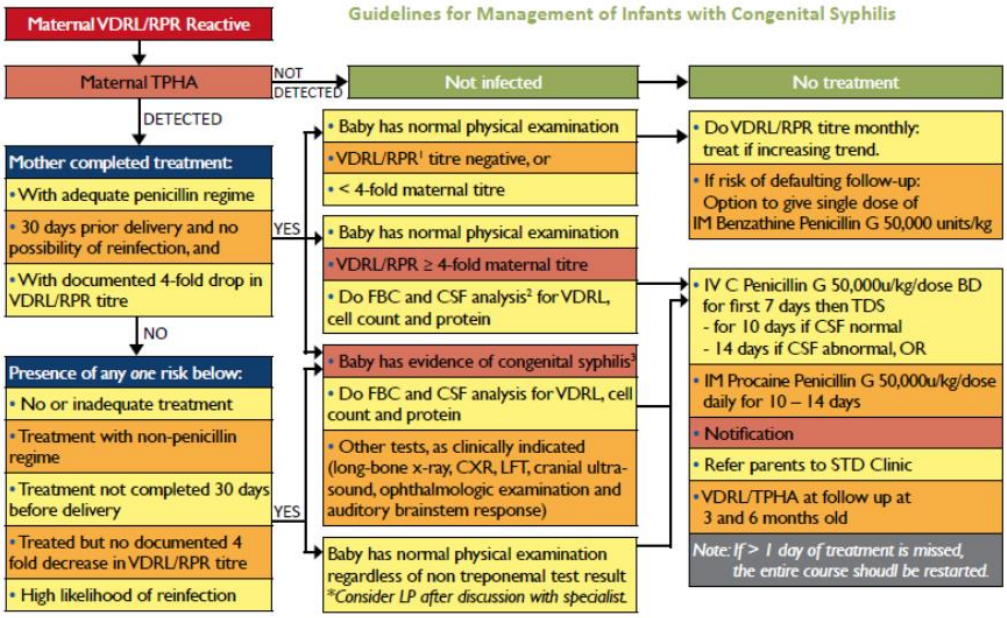
ii. An older child may have stigmata such as interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson teeth, saddle nose, rhagades, or Clutton joints

(b) Laboratory criteria for diagnosis

- demonstration of T. pallidum by dark field microscopy
- serology (not specifying type of serology)

This is further elaborated in the Paediatric Protocols for Malaysian Hospitals (3rd Edition) (Figure 4.11)

Figure 4.11 Guidelines for management of infants with congenital syphilis



1. VDRL/RPR test on venous blood sample as umbilical cord may be contaminated with maternal blood and could yield a false-positive result.
2. Clinical features of congenital syphilis: non-immune hydrops, IUGR, jaundice, hepatosplenomegaly, rhinitis, skin rash, pseudo paralysis of extremity.
3. Recommended value of 5 WBCs/mm3 and protein of 40mg/dL as the upper limits of normal for "non-traumatic tap".

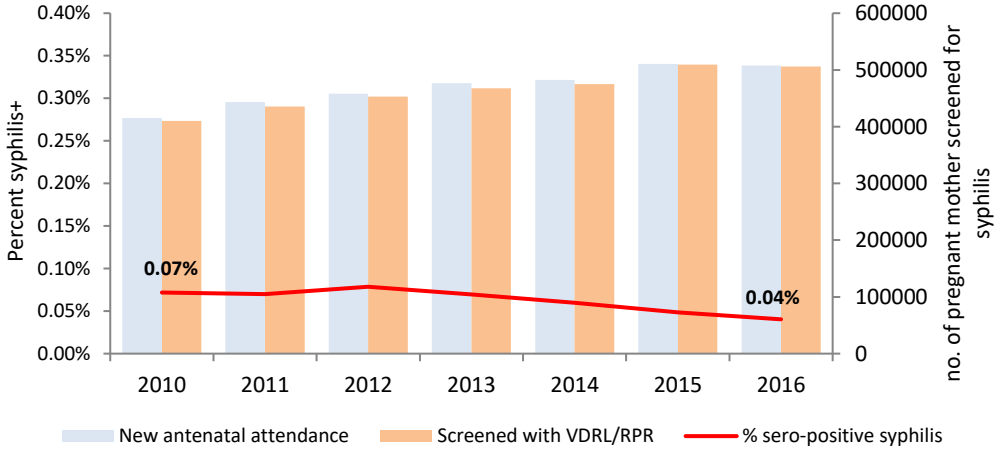
(a) Syphilis testing coverage among antenatal mothers

Malaysia has integrated syphilis screening as part of antenatal care in all government health facilities for more than 30 years. Screening for syphilis usually starts with the RPR tests followed by TPHA / TPPA confirmatory tests. Data for syphilis screening has been part of the routine antenatal surveillance system for the past 3 decades. All new antenatal mothers attending primary care will be given health education on antenatal care including package of basic test that include blood group, rhesus, HIV screening, syphilis and full blood count. A consent that include checklist of basic test will guide mothers and care provider to ensure all basic tests are not missed.

As shown in Figure 4.12, the screening coverage has been above 95% (95.1% in 2015 and 95.8% in 2016) among all pregnant women with a declining seropositive rate from 0.07% in 2010 to 0.04% in 2016 (1). Records show that 100% of pregnant mothers received treatment for syphilis in Malaysia to prevent mother to child transmission of syphilis in 2015 and 2016 (Table 4.1) (3).

In a study conducted in 33 non-MOH hospitals, all the hospitals which responded reported that they provide syphilis screening as part of routine antenatal care. (Appendix 4).

Figure 4.12 Antenatal Syphilis Screening in Malaysia: 2010-2016

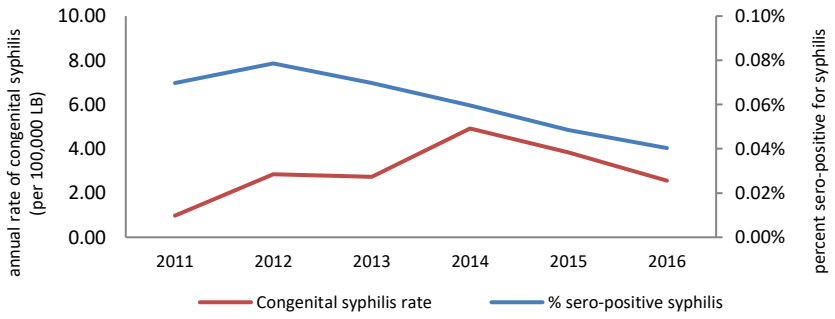


Source: Disease Control Division, MOH Malaysia 2016

(b) MTCT rate of syphilis

All syphilis infected mothers (Malaysian and non-Malaysian) were given adequate free treatment according to the standard operating procedure as in Figure 4.12. Over the past decade, syphilis seropositivity among mothers have been declining, the same pattern seen for MTCT of syphilis (Figure 4.13). The annual rate of congenital syphilis detected by the national surveillance system has declined by about 50% from 4.92 to 2.95 cases per 100,000 live births between 2014 and 2016 (Figure 4.10); this trend is also in line with estimates calculated using WHO Syphilis estimation tools (Table 4.1).

Figure 4.13 Seropositive syphilis mother and rate of congenital syphilis, Malaysia 2011 - 2016



Source: Ministry of Health Malaysia 2016

In summary, with the achievements described above, Malaysia is reaffirming our commitment towards achieving the goal of elimination of MTCT of HIV and syphilis.

Towards achieving this mission, it is our sincere desire that the objectives of eMTCT be realised and achieving its full potential. We are also committed towards sustaining this programme and making progress in the years to come. Various task forces, joint committees, working groups, guidelines etc have been formed and on-going efforts have taken place in response to make “Ending AIDS by 2030” a reality.

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CHAPTER 5

IMPLEMENTATION OF PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT) OF HIV & SYPHILIS PROGRAMME IN MALAYSIA: OVERVIEW OF ACHIEVEMENTS AND OVERCOMING THE CHALLENGES

Malaysia has taken initial steps implementing PMTCT programme for HIV in 1998, whilst syphilis testing for pregnant mothers started more than 3 decades ago. Currently, the eMTCT of HIV and syphilis programme in Malaysia has been integrated into the Maternal and Child Health Services (MCH). These antenatal services are part of a comprehensive package for all pregnant women seeking care in HC and similar packages are offered in the private sector. The National Health and Morbidity survey 2016 showed approximately 85% of pregnant women attended antenatal services in government facilities.

Services provided by the health care providers respect the rights of the clients according to international standards without discriminating any population group.

5.1 Implementation of eMTCT of HIV in Malaysia

5.1.1 Important milestones / achievements

(a) Countrywide PMTCT programme

HIV testing was included as part of routine antenatal testing in 1998 following the issues of circulars, guidelines, clinical practice guidelines (CPGs), and standard operating procedures (SOPs). Management of HIV positive pregnant women detected during pregnancy was subsequently expanded to include paediatric care, feeding practices, free infant formula provision and immunisation practices. These initiatives have been implemented in collaboration with various government agencies as part of the PMTCT programme. In 2016, 521,523 pregnant women had routine HIV testing (1). Although partner or spousal testing is not mandated under the current PMTCT policy, all government health clinics provides testing through provider-initiated testing and counselling (PITC).

(b) Treatment options for HIV-infected mothers

Within the PMTCT context, universal HIV testing is offered with an “opt-out” approach to pregnant women, for whom pre-test counselling routinely takes place with a “group basis”. These services take place primarily in antenatal clinics. Treatment options for HIV-infected mothers have evolved over time; started with single AZT at 14 weeks of gestation in 1998, the regime was later changed to combination of AZT and single dose Nevirapine (WHO Option A). In 2008, the regime was changed to highly active antiretroviral therapy (HAART) (WHO Option B). Option B plus (HAART initiated as early as possible and continued lifelong for all HIV positive pregnant women) was

recommended early in 2008 (Refer to Clinical Practice Guideline of Management of HIV infection in pregnant women) but introduced countrywide in 2012 (2).

(c) Management of babies born to HIV positive mothers and follow-up

All HIV-exposed infants are given prophylaxis for HIV immediately after delivery for 6 weeks while PCP prophylaxis with Co-trimoxazole is started at 6 weeks of age until HIV infection is negated. The HIV-exposed infant is given infant formula for 2 years. Infant formula is provided free for all Malaysian and non-Malaysian by the Ministry of Health Malaysia as directed by the Director General of Health since 2002 (3). To ensure that mothers understand and accept exclusive formula feeding, continuous education and counselling on risk of breast milk and mixed feeding is given during antepartum and postpartum care and regular home visits. Sanitation and hygiene are also emphasized to avoid water borne diseases. Despite the advice on benefit of avoiding breastfeeding, mothers have the liberty to choose the infant feeding method. Regardless of her decision, the health care services to both mother and child will continue.

Early infant diagnosis using HIV antibody testing was started in 2000. In 2004 the HIV DNA PCR test was introduced for the diagnosis of infants for all babies born to HIV positive mothers. All HIV-exposed infants are tested with DNA PCR at birth and at 6 weeks (3). In some cases, paediatricians prefer to test babies with DNA PCR within the first 2 weeks of life.

5.2 Implementation of eMTCT of syphilis in Malaysia

5.2.1 Background information

Universal syphilis testing for pregnant women has been a part of the antenatal package for more than 30 years. Health clinics routinely perform RPR for syphilis testing, and confirmatory tests are performed using TPHA in designated hospitals. The usual turn-around time for confirmation of syphilis is about 5-7 working days.

(a) Routine antenatal screening for pregnant women

As part of the antenatal package for pregnant women, all pregnant women are routinely tested for syphilis during the first visit (4).

(b) Treatment options for TPHA positive pregnant women

For early syphilis (primary, secondary and early latent), recommended treatment regimen is IM Benzathine Penicillin 2.4 million unit (MU) in a single dose or IM Procaine Penicillin G 600,000 units daily for 10 days (5). For late syphilis (excluding neurosyphilis), recommended regimen is IM Benzathine penicillin 2.4 MU weekly for 3 weeks or Procaine penicillin G 600,000 units daily for 17 days. For those with penicillin allergy alternative regimen is recommended (refer Malaysian Guidelines for the Treatment of Sexually Transmitted Infections). The treatment options are being monitored closely by the Family Medicine Specialists (FMS) and/or Medical Officers who have been trained.

(c) Follow-up of mothers and babies born to TPHA positive mothers

Mother who is positive for syphilis will be offered a contact tracing for her sexual partner. For asymptomatic partner of mother with early syphilis, treatment with IM Benzathine penicillin 2.4 MU single dose is recommended. Both mother and partner are being followed up closely by primary care physicians. All babies born to mothers who have syphilis will be monitored with blood and cerebrospinal fluid test where necessary and treated as needed according to "Guidelines for Management of infants with Congenital Syphilis" (Figure 4.11) and the 'Paediatric Protocols for Malaysian Hospital' and will be routinely followed-up by paediatricians in the hospitals (6).

5.3 Malaysia's eMTCT programme linkage with the Global eMTCT strategy

Implementation of the eMTCT strategy in Malaysia has incorporated the integration and services of various global vertical programmes and activities. The PMTCT programmes and activities in Malaysia has similarly evolved over the years and has integrated the following services; sexual & reproductive health, adolescent health, men's health, STI, maternal and child health, HIV / AIDS treatment and care support services.

As underlined by UNGASS Declaration of Commitment in June 2001, the 4-pronged approach below best describes how Global eMTCT Strategy has been incorporated in Malaysia (Figure 5.1);

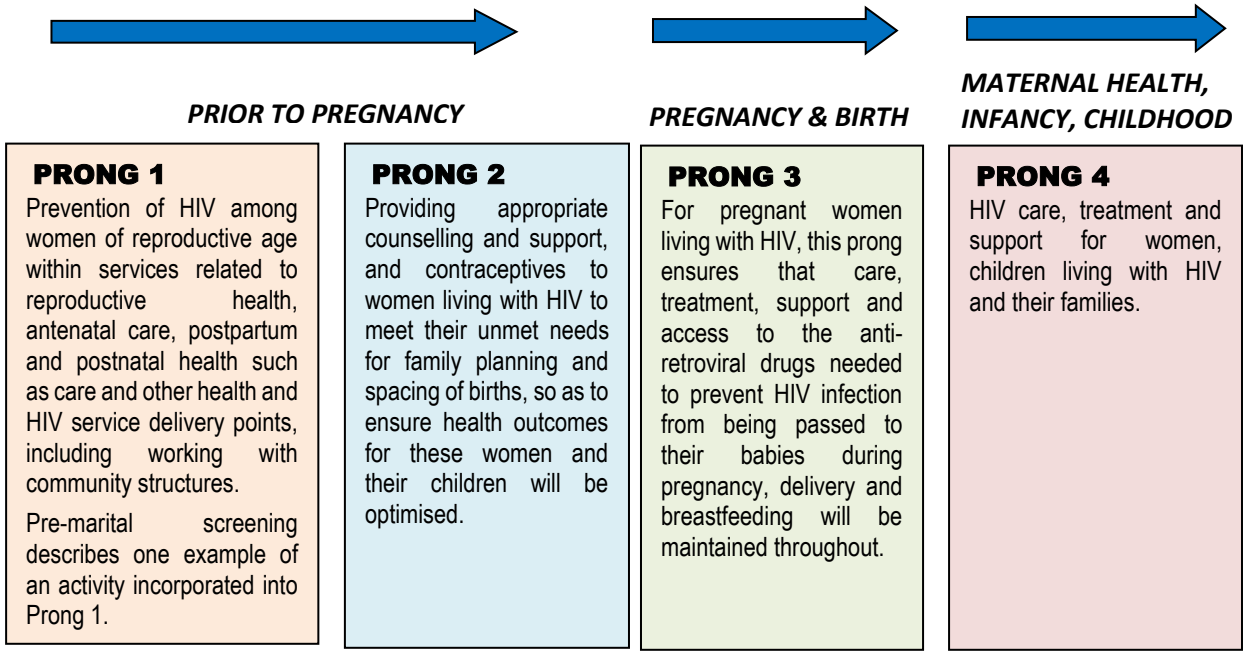
Prong 1 : Prevention of HIV in women of reproductive age

Prong 2 : Prevention of unintended pregnancy in HIV+ women

Prong 3 : Prevention of mother-to-child transmission of HIV through:
- (a) ART prophylaxis during pregnancy
- (b) Safer delivery practices
- (c) Counselling and support on infant feeding methods

Prong 4 : Care, treatment and support to HIV-infected parents, infants and families

Figure 5.1 Summary of the 4-pronged approach by the Ministry of Health Malaysia



Malaysia has taken initial steps implementing PMTCT programme for HIV in 1998, whilst syphilis testing for pregnant mothers started more than 3 decades ago. Currently, the eMTCT of HIV and syphilis programme in Malaysia has been integrated into the Maternal and Child Health Services (MCH). These antenatal services are part of a comprehensive package for all pregnant women seeking care in HC and similar packages are offered in the private sector. The National Health and Morbidity survey 2016 showed approximately 85% of pregnant women attended antenatal services in government facilities.

Services provided by the health care providers respect the rights of the clients according to international standards without discriminating any population group.

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CHAPTER 6

EPIDEMIOLOGY OF HIV AND SYPHILIS IN MALAYSIA

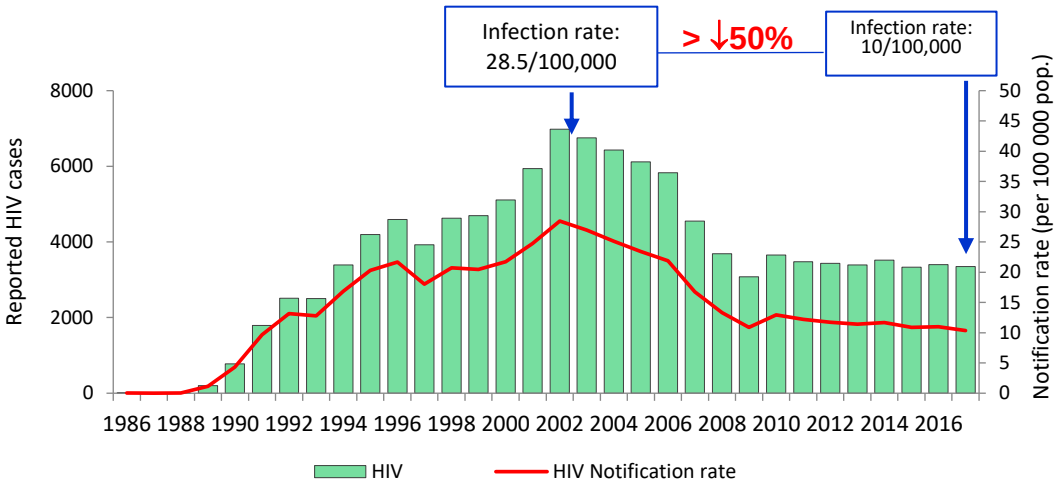
6.1 HIV burden in Malaysia

The first case of HIV infection in Malaysia was reported in 1986. People who inject drug (PWID), female sex workers (FSW), transgender (TG) and men who have sex with men (MSM) represent the populations most affected by the epidemic with infection rates exceeding 5% (1).

At the end of 2016, there are an estimated number of 87,122 people living with HIV (PLHIV) in which 72,399 (83.1%) have been reported through the surveillance system. As reported by the National HIV Surveillance System, males made up 89% of the cases. However, the male to female ratio has been declining from 9.6 in 2000 to 6.3 in 2017 (1).

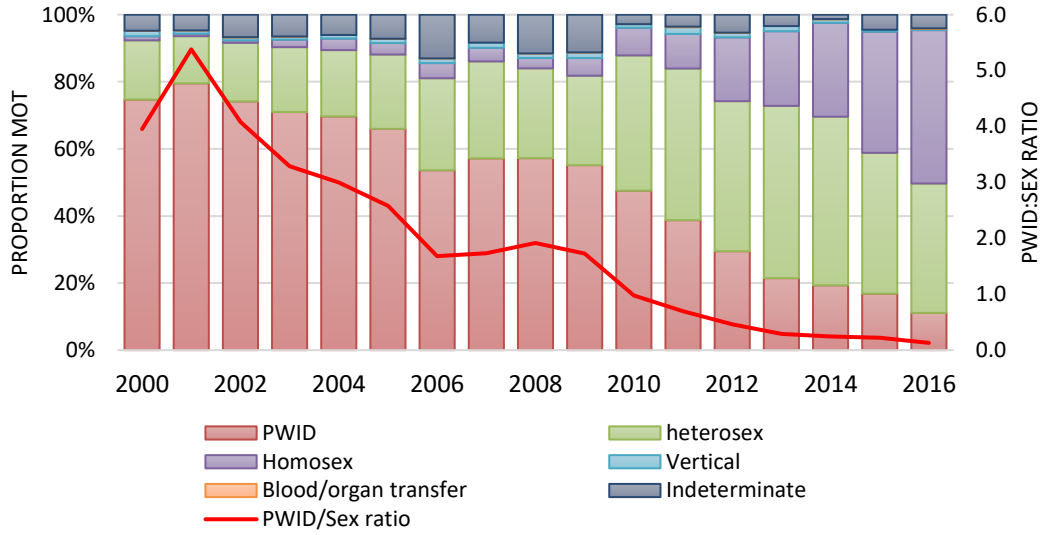
In 2016, approximately 1.6 million screening tests were undertaken, with only 0.1 percent of those screened being HIV positive. In 2002, notification rates were at highest i.e. 28.45 per 100,000 population before it gradually declined to the present levels (Figure 6.1). With continuous and dedicated efforts, Malaysia has successfully halted and reversed the HIV epidemic when it reached 50 percent reduction of notified infections between 2000 (22/100,000 population) and 2015 (11/100,000 population) (1).

Figure 6.1 Reported HIV cases in Malaysia, 1986-2017



Source: Surveillance Data, HIV/STI/Hepatitis C Sector MoH Malaysia, 2017

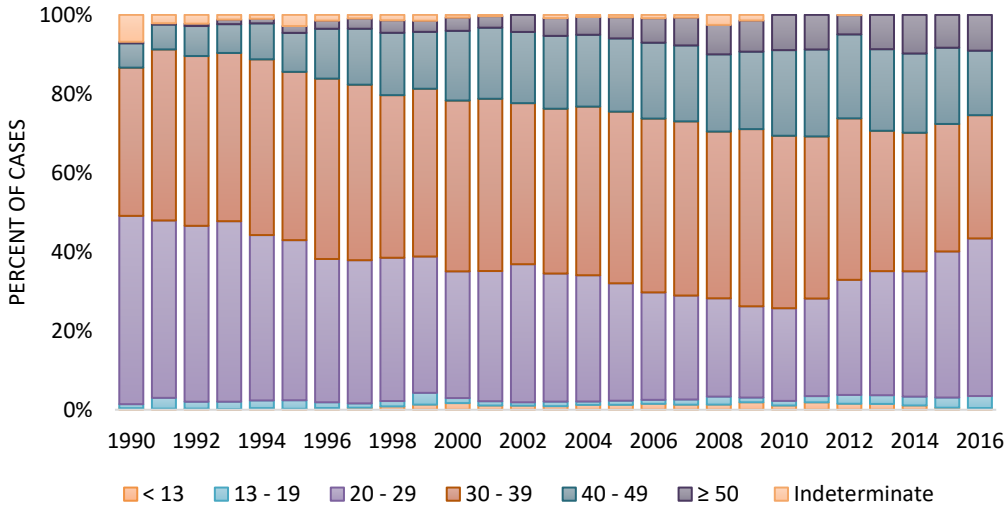
Figure 6.2 Changing Trends of HIV Transmission Modes in Malaysia, 2000-2016



Source: Surveillance Data, HIV/STI/Hepatitis C Sector MoH Malaysia 2016

The initial epidemic in Malaysia was largely confined to the PWID, but this pattern has shifted to increasingly sexual modes of transmission patterns with the PWID: sexual ratio declining from 4.0 to 0.1 between 2000 and 2016 (Figure 6.2) (1). About 75% of the HIV infection occurs in young people aged 20 to 39 while children under the age of 13 years old consists of about 1% of the total HIV infections (Figure 6.3).

Figure 6.3 Distribution of reported HIV, by age group, Malaysia: 1990-2016

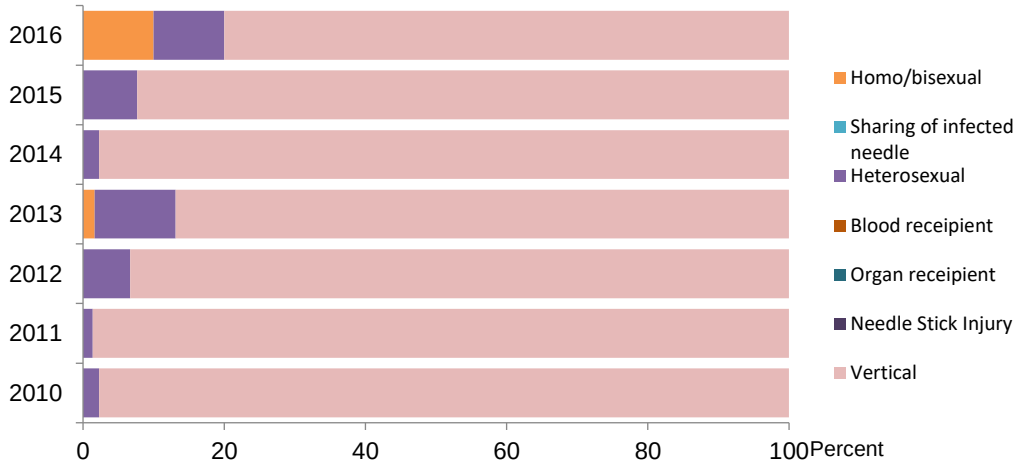


Source: Surveillance Data, HIV/STI/Hepatitis C Sector, MOH Malaysia, 2016

6.2 HIV Infection in children and adolescents in Malaysia

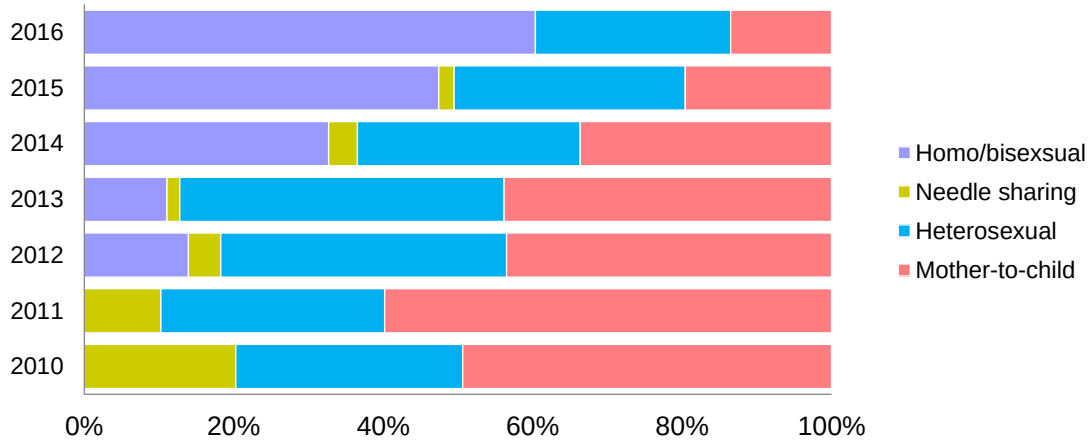
The notification system provides a useful tool to assess trends and shows a significant decline in the number of new HIV cases in children. Surveillance data showed majority (80%) of children (0-14) years were transmitted vertically (Figure 6.4). eMTCT program has a significant impact in bringing down the number of new paediatrics infections in Malaysia to a level less than 2% of vertical transmission rate and less than 50 annual rates of new infections per 100,000 live births in the past few years. However, the trend among adolescents 15-19 years has shifted from predominantly vertical transmission to homosexual/bisexual in the last couple of years (Figure 6.5).

Figure 6.4 Modes of HIV transmission in children (<15 years old) Malaysia: 2010-2016



Source: Surveillance Data, HIV/STI/Hepatitis C Sector, MoH Malaysia, 2016

Figure 6.5 Modes of HIV transmission in adolescent (15-19 years old) Malaysia: 2010-2016



Source: Surveillance Data, HIV/STI/Hepatitis C Sector, MoH Malaysia, 2016

Since 2011, the trend of ANC attendance among adolescents in Malaysia is declining. It is explained by an overall decline in adolescent population due to progressively declining total fertility rate (TFR) in the past decade. All adolescent pregnant women who attended antenatal services were screened for HIV and the observed HIV prevalence is less than 0.2% in the past 5 years (Table 6.1).

Table 6.1 Sero-prevalence of HIV among adolescent (15 – 19 years) in pregnancy

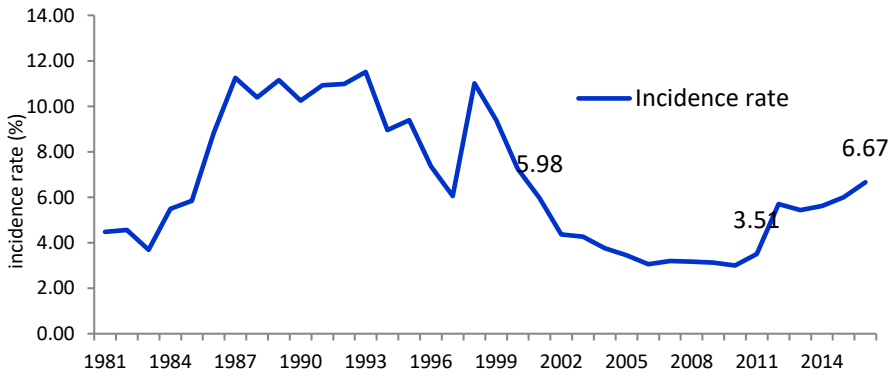
Year	2011	2012	2013	2014	2015	2016
No. of ANC attendance	18,186	18,376	17,148	16,115	13,485	12,180
No. screened for HIV	18,186	18,376	17,148	16,115	13,485	12,180
HIV positive	18	12	12	14	9	18
Prevalence of HIV among ANC ≤ 19 years old	0.10%	0.07%	0.07%	0.09%	0.07%	0.15%

Source: HIV/STI/Hepatitis C Sector, Disease Control Division & Adolescent Health Sector, Family Health Development Division, Ministry of Health, Malaysia.

6.3 Syphilis trends in Malaysia

Both acquired and congenital syphilis are notifiable by law in Malaysia (2). There was a rapid increase in the incidence of syphilis in the late 80s followed by a declining trend from 6.0 to 3.5 per 100,000 population between 2001 and 2011 (Figure 6.6). Majority of the syphilis patients are young adult males, in the 20-39 age group and it corresponds well with the increasing number of sexual mode of transmission of HIV

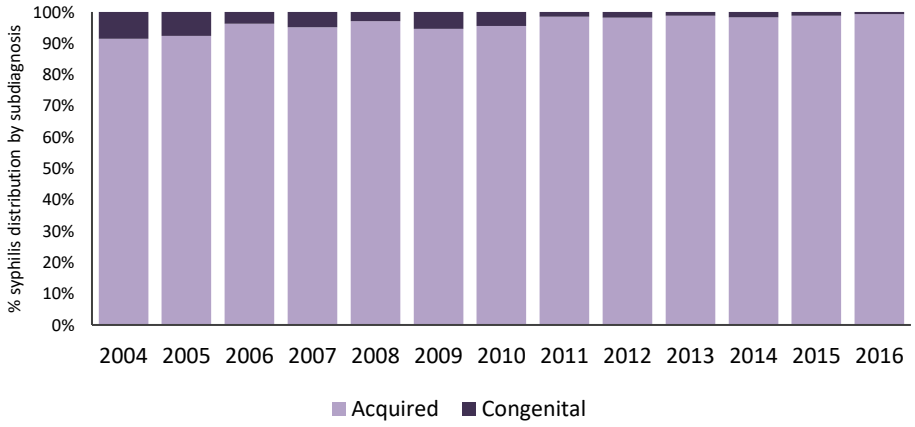
Figure 6.6 Incidence rate of Syphilis in Malaysia: 1981-2016



Source: Surveillance Data, Disease Control Division, MOH Malaysia 2016

Majority of these cases are the acquired subtype (Figure 6.7). In the last 10 years, the number of congenital syphilis diagnosed in Malaysia had been declining due to the better understanding of the definition as prescribed in Case Definitions for Infectious Diseases in Malaysia 2006 and latest 2016 and training among the personnel regarding the definition of “acquired” and “congenital” syphilis (3). The reduction in the number of congenital syphilis cases diagnosed is attributed to an early detection during antenatal screening and high treatment coverage among syphilis+ mothers (Figure 6.8).

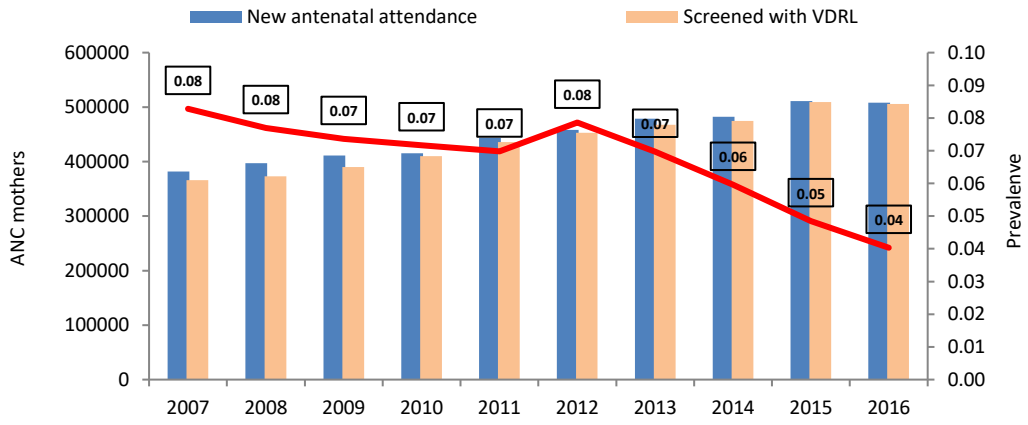
Figure 6.7 Distribution of Syphilis by subtype in Malaysia: 2004-2016



Source: Surveillance Data, Disease Control Division, MOH Malaysia 2016.

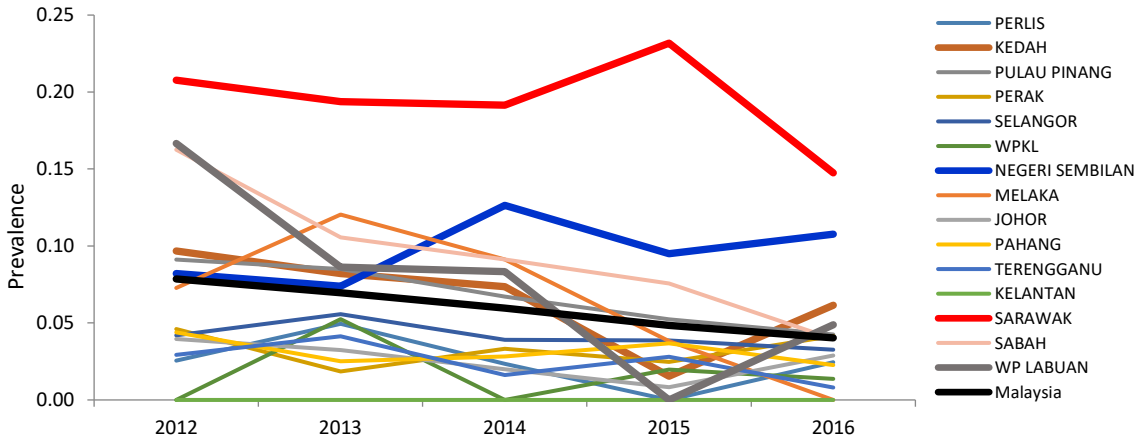
For more than 10 years, Malaysia has achieved almost 100% screening coverage for syphilis among ANC mothers based on programmatic data (Figure 6.8). The prevalence of syphilis among ANC mothers were declining from 0.08% in 2007 to 0.04% in 2016 (Figure 6.8). Despite reduction of syphilis prevalence among ANC mother for the country, three states have shown different trend. In 2016; Sarawak (0.15%), Negeri Sembilan (0.11%) and Kedah (0.06%) have shown an increasing trend of syphilis among ANC Mother (Figure 6.9).

Figure 6.8 Programmatic Data for Syphilis Screening among ANC Mothers and its trend.



Source: Surveillance Data, Disease Control Division, MOH Malaysia 2016

Figure 6.9 Prevalence of syphilis by Sub-national, Malaysia, 2012 - 2016



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CHAPTER 7

SURVEILLANCE, MONITORING AND EVALUATION OF PREVENTION OF MTCT TRANSMISSION OF HIV AND SYPHILIS PROGRAMME IN MALAYSIA

7.1 Introduction

The Ministry of Health Malaysia's (MOH) approach in eMTCT is based on the UNGASS' Declaration of Commitment, June 2001 and the World Health Organization's (WHO) four (4) ways of minimizing vertical transmission of HIV (1). Infected mothers are given the recommended Option B+ regime which has been in place as early as 2012 (2).

Some of the key elements which have been adopted by MOH to achieve and enhance the nation's eMTCT targets are outlined below: -

(a) MOH will maintain the provision of quality and comprehensive national PMTCT services in line with the WHO recommended four pronged strategies. MOH will continue to reach out to pregnant women, their partners and infants and key populations i.e. MSM, transgender, PWID and FSW.

(b) MOH will continue to strengthen community awareness of HIV to increase enrolment in the PMTCT programme and other related antenatal services. Some of these services will include family planning, sexual and reproductive health, voluntary confidential counselling and testing services, particularly among key populations.

(c) MOH will ensure the availability of PMTCT in all ANC facilities providing antenatal services including private health care facilities. This is to ensure that all HIV-infected pregnant women and their HIV-exposed infants receive ARV treatment and prophylaxis, together with infant feeding education and counselling.

7.2 Key activities, indicators and targets to achieve

As stated in the National Strategic Plan Ending AIDS 2016-2030 (NSPEA), the MOH has outlined some key goals/ targets to fast track our mission towards achieving Malaysia's eMTCT's targets / goals as stated below **(3).**

(a) Increasing testing coverage among women of reproductive age
(a) Reducing the loss to follow-up among HIV+ women at PPHIV clinics
(b) Reducing new HIV infections among women
(c) Reducing late booking among pregnant women
(d) Strengthening screening of partners of antenatal mothers
(e) Promoting adherence to treatment among HIV+ pregnant women
(f) Improving the repeat testing among HIV negative women during ANC
(g) Expanding of HIV testing women at private facilities

(h) Provision of syrup zidovudine to exposed infants
(i) Making Option B+ a must for all HIV+ antenatal mothers

These activities, indicators and targets have been carefully selected to measure the performance and outcomes of the programme and serve as guidance to our officers implementing eMTCT at the grass root level. The indicators / activities are selected to ensure that HIV+ antenatal mothers and their affected families will have access to high quality prevention, treatment, care and support services. In line with the UNAIDS Global Targets on Ending AIDS, the MOH has also incorporated the following indicators to reflect our nation's commitment (4).

(a) Impact indicators

(1) ≤ 50 new paediatric HIV cases (MTCT) per 100,000 live births
(2) ≤ 50 MTCT congenital syphilis cases per 100,000 live births
(3) MTCT rate of HIV < 2% in non-breastfeeding and <5% in breast feeding populations

(b) Process Indicators

(1) ANC coverage for one visit ≥ 95%
(2) Testing for (HIV & Syphilis) ≥ 95%
(3) ART coverage for HIV positive ANC mothers ≥ 95%
(4) Syphilis treatment for sero-positive mothers ≥ 95%

The incorporation of the above indicators and targets are being monitored closely at various levels of the public health system where they are discussed during technical and management review meetings at the district, state or national levels.

7.3 Data management

7.3.1 All health facilities (public and private) are required to notify all infectious diseases under CDC Act 1988 to the nearest District Health Office. Method of notification can be manual or online. Most public facilities are connected to the online system (e-notice) while others (private healthcare facilities) are using either online or manual notification methods. All data is managed centrally for easy monitoring and evaluation of the eMTCT outcomes. All public health facilities submit their report on a monthly basis to the District Health Office, while private healthcare facilities are not bound to any act/policy for PPTCT data submission. It was done voluntarily.

The data management of eMTCT in Malaysia encompasses a series of data collection, verification, analysis, storage, reporting and dissemination of information, focusing on the affected mothers, their exposed infants as well as their families **(5).** Besides managing the routine service monitoring system, officers are often requested to gather data and information through ad hoc surveys as and when necessary.

All registered cases of eMTCT (HIV and syphilis) must fulfil the Case Definitions of Infectious Diseases in Malaysia, 2016, Ministry of Health. Data collected from public and

private screening centres such as hospitals, health clinics, laboratories, prisons and Cure & Care centre are sent to the nearest District Health Office (DHO) monthly as illustrated in Figure 7.2 and as stipulated by the law. There is no difference in the methodology of notification and referrals, case investigations, training of staff between the private and public facilities. All confirmed diagnosed HIV cases notified to the nearest DHO will be verified, validated and registered into the National AIDS Registry (NAR). In summary, once diagnosed, all cases of HIV and syphilis among antenatal mothers will go to the same process of data management.

The data compiled will be verified and analysed at the District Health Office and later sent to the State Health Office and subsequently to the Disease Control Division, MOH in Putrajaya. (Figures 7.2 & 7.3). The MOH / State Health Departments will disseminate the information to all relevant key stakeholders.

Once notified, the submitted data will be reviewed for reliability and validity to ensure data quality is in line with the standards set by the MOH. Each electronic based system (e.g. National AIDS Registry (NAR) and the e-notice communicable disease information system has been designed in such a way to safeguard and protect the confidentiality of PLHIVs. E-notification is designed to capture all probable and confirmed cases while NAR only takes in confirm cases that are not yet registered in the system.

To ensure maximum confidentiality, only staff with passwords will be able to have access to the records. The data is only available to the staff at local levels i.e. staff in a certain location (e.g. District A) will not be able to access data in another location (District B). The data is only available at the District Health Office, and not available at the Hospital level.

Some of the key data collected about eMTCT include the following (6):

(a) Number of antenatal mothers screened for HIV & syphilis
(b) Number of antenatal mothers tested reactive in screening tests and confirmed HIV & syphilis
(c) Number of mothers receiving ART
(d) CD4 count of mother (Viral load data will soon be incorporated in near future)
(e) Mode of delivery of mother and birth outcome
(f) Number of babies getting PCR investigations, given prophylaxis and syrup zidovudine
(g) HIV and Syphilis status of male partners
(h) Feeding practices among HIV positive mothers

All partners of the HIV+ antenatal mother will be traced and screened for HIV. Contact tracing is mandatory under CDC Act 347 and will be carried out without delay. Once the HIV status of the partner known, partner will be enrolled into HIV care and treatment if positive. The implementation of partner/spousal test is state driven, and not regulated country-wide.

7.3.2 Line-listing of HIV+ and TPHA+ antenatal mothers

As part of the on-going improvement of data collection process for HIV+ and TPHA+ antenatal mothers, the MOH has developed a “line-listing” parameters (in the form of

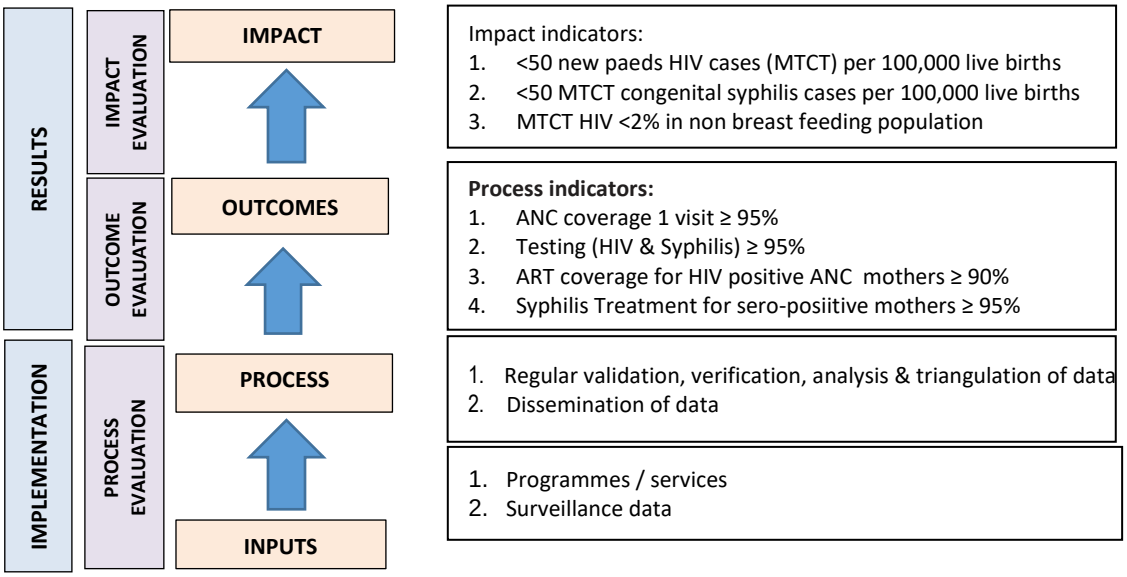
Excel spreadsheets) for these mothers. The spreadsheets have 63 parameters among which will comprise details that include:

(a) Socio-demographic data of mother, husband/partner and infant
(b) Health data of current pregnancy (date of booking, EDD)
(c) Mother's HIV status (date of confirmation, MOT and preventive measure)
(d) Mother's investigation status (date of HIV confirmation, CD4 counts before and during current pregnancy)
(e) Mother's treatment status
(f) Husband /partner HIV status, their confirmation date, MOT and preventive measure
(g) Infant's birth status, mode of delivery, feeding status, PCR tests dates and results, prophylaxis (AZT and CTX)

7.4 Monitoring and evaluation process

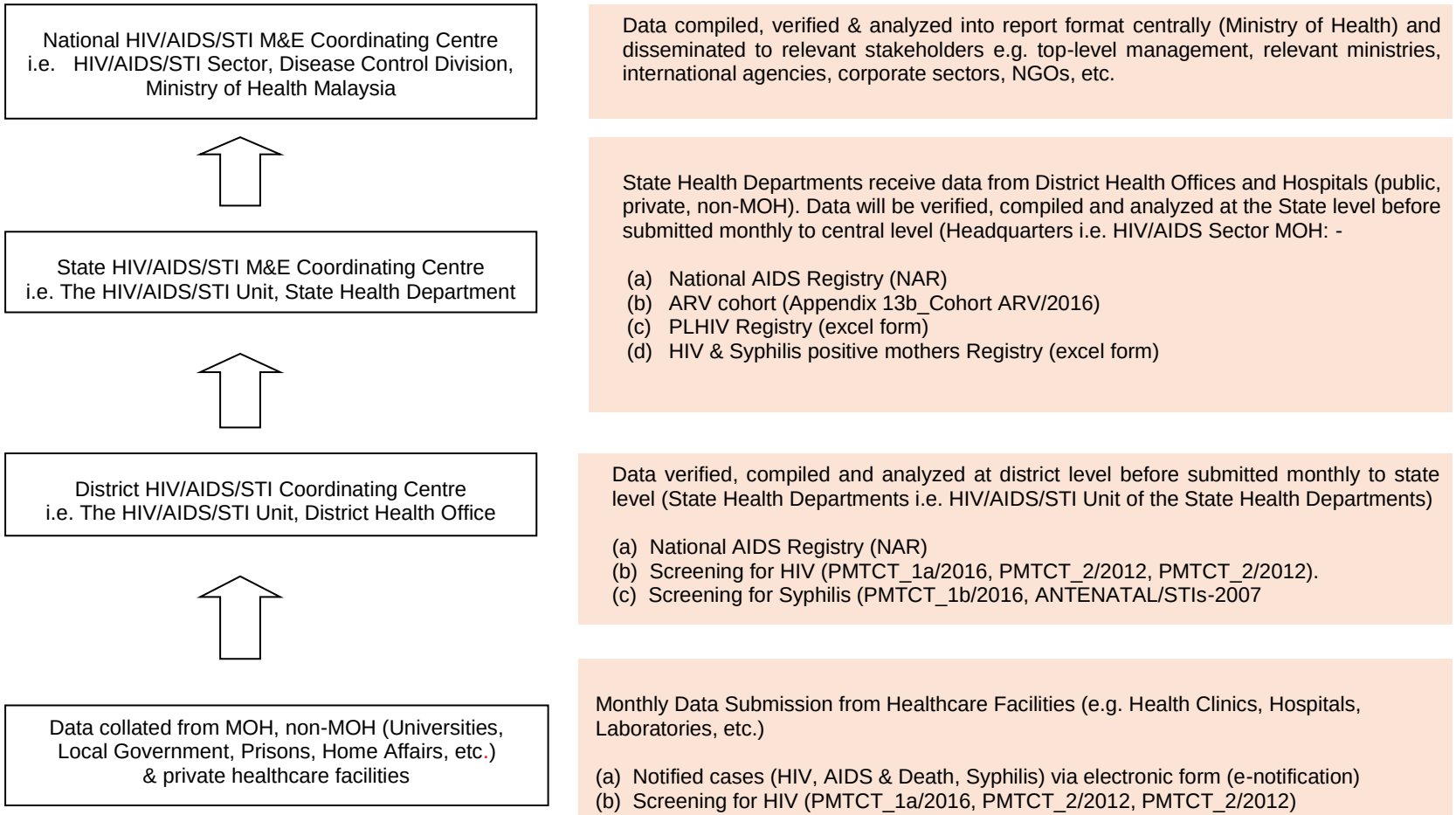
The monitoring and evaluation component of this programme will cover input, process, output and the impact as illustrated in Figure 7.1. These activities and indicators are regularly monitored, reported and utilized to measure the progress of the eMTCT programmes and activities, either at the local (DHO) / state and / or national levels.

Figure 7.1 Monitoring & evaluation framework for eMTCT programme: operational plan



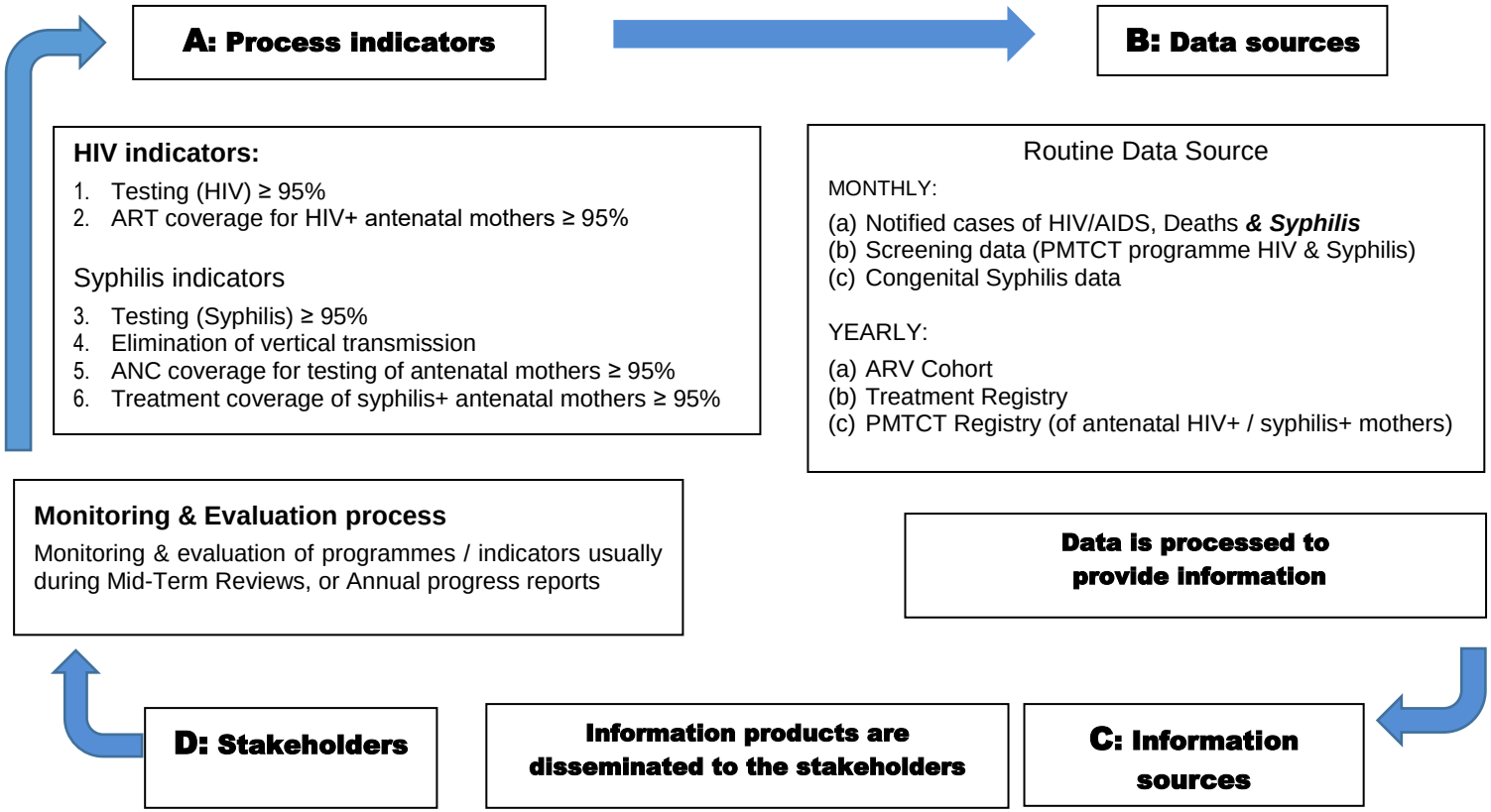
Source: HIV/STI/Hepatitis C Monitoring and Evaluation Framework, Malaysia, 2016 (unpublished)

Figure 7.2 Data system and reporting of data on eMTCT of HIV and syphilis



Source: HIV/STI/Hepatitis C Monitoring and Evaluation Framework, Malaysia, 2016 (unpublished)

Figure 7.3 Inter-relationship of key components of the eMTCT monitoring & evaluation systems (PMTCT Malaysia)



7.4.1 Monitoring and evaluation at state and district levels

District / Clinic level

Routine data will be collected using a standardized format in the form of spreadsheet consisting of pre-identified variables such as socio-demographic characteristics of mothers and partners, laboratory test results, treatment given, types of deliveries and prophylaxis given to exposed infant. The data is kept strictly confidential and will be reviewed periodically to evaluate the progress in the management of the affected individuals. Data is only available to those with specific password. The data available will be discussed periodically at the District / Clinic level to gauge the progress of the patients (mothers, spouses and exposed infants). The data collated will be sent to the State level (for the attention of State AIDS Officers), usually in the form of a spread sheet.

State level

The aggregated data (HIV & syphilis) will be sent periodically to the State AIDS Officers who will also monitor the progress of the mothers and exposed infants. Should there be transfer of patients from one state to another, it is usually done and monitored by the state AIDS officers. Every 3, 6, or yearly, the data at the state will be sent to the national level for further discussion and monitoring / evaluation process.

7.4.2 Monitoring and evaluation at the national level

The Monitoring & Evaluation (M&E) team, in MOH will monitor and evaluate the country's overall HIV/AIDS/STI's performance. Periodic performance reviews are conducted every six months with key stakeholders at all levels. Performance of each state will be scrutinised to ensure that targets are met according to standards set.

7.5 Annual progress report (refer also to Global AIDS Monitoring, Malaysia, 2017)

The HIV/STI Sector in MOH coordinates and facilitates the preparation of annual progress reports in line with Global AIDS Monitoring Report (GAM Report). Development of annual work plans will be discussed and finalised through national HIV programme performance reviews with the involvement of all key stakeholders. The annual progress report will be based on progress made in achieving the targets set for core indicators. This is carried out by analysing data collected in the centralized database. The report also includes analysis of the most recent surveillance data as well as other surveys to capture the changing and emerging epidemiological trends.

The HIV/AIDS Sector of the MOH, being the National AIDS Programme Secretariat, in close consultation with its partners, will prepare or revise the work plan for each coming year. In recent years, the data gathered, and the information documented is revised in accordance to the Global AIDS Monitoring surveillance system. All the information will be disseminated to our key stakeholders. This endorsed report can be downloaded from MOH website.

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CHAPTER 8

LABORATORY SERVICES AND NETWORK

8.1 Organisation and scope of laboratory services Related to eMTCT

Laboratory services are available in both, public and the private sector. Laboratory services in MOH hospitals are performed in *pathology* laboratories. Medical Development Division under the Medical Program of the MOH is responsible for all hospital laboratories whereas the Family Health Development Division is responsible for all primary care laboratories.

The MOH Malaysia has a network of public hospital and primary care laboratories to support diagnosis, case management, disease surveillance, prevention and control with a referral system between primary care laboratories and hospital laboratories (Figure 8.1). Hospital laboratories comprise of minor specialist, major specialist, state and tertiary laboratories (Table 8.1). Hospital Kuala Lumpur (HKL) and the Institute for Medical Research (IMR) function as national reference laboratories. This network of laboratories delivers comprehensive laboratory services for the nation. It also enables optimum use of resources. Screening and confirmatory tests for HIV and syphilis testing are conducted in laboratories that also perform other routine laboratory testing.

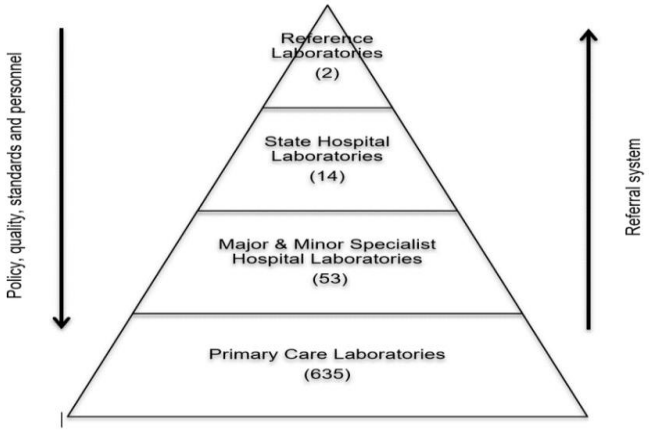
Similar laboratory network also exists within large and well-established private laboratories. Within these networks they have sample collection centres, laboratory screening, confirmatory and references centres. Collection centres may include general practice and hospitals. Examples of such private laboratories are Gribbles Pathology (M) Sdn. Bhd. and Pantai Premier Pathology Sdn. Bhd. Private laboratories can also participate in the public sector quality assurance system for a fee. Private laboratories follow national testing guideline and algorithms.

8.1.1 Laboratory infrastructure and scope of laboratory services at various levels of the health care system

Based on the WHO Laboratory Assessment Tool, laboratory services in Malaysia are classified into four levels as shown in Figure 8.1.

List of hospitals with laboratories under the 11th Malaysia Plan (2016-2020) is shown in Table 8.1. The network of pathology services ensures that Primary Health Care Laboratories are complemented by the nearest district hospital/minor/major specialist hospitals or state hospital laboratories. The State Pathologist usually based in the State Hospital Laboratory for HIV and Syphilis testing services within the state, the State Microbiologists (Pathologist and Science officer) works together in ensuring a quality service is being provided.

Figure 8.1 Tiers of Laboratory Services in Malaysia



** Note: Data up to April 2017

Sources: (1) Family Health Development Division, MOH and (2) Departmental Policy of Pathology Services, Medical Development Division MOH

Table 8.1 List of Hospitals under the 11th Malaysia Plan (2016-2020)

HKL+ State Hosp.	Major Specialist Hospitals	Minor Specialist Hospitals			Special Medical Institutions	Non-Specialist Hospitals		
14 (14)	30 (26)	36 (27)			18 (11)	59 (66)		
Kangar Alor Setar P.Pinang Ipoh Klang HKL Seremban Melaka J.Bahru Kuantan K.T'ganu K.Bahru QE Kuching	Sg.Petani Kulim Langkawi Sbg Jaya Taiping T. Intan Sri Manjung Kajang Sg.Buloh Selayang Ampang Serdang Shah Alam Putrajaya K. Pilah S.I. Pandan Muar B. Pahat Segamat Temerloh K. Krai Kemaman T.Merah Sandakan Tawau Keningau Sibu Miri Bintulu Petrajaya	Baling Kuala Nerang Sg Bakap B.Mertajam K.Batas Slim River K.Kangsar Grik Banting K Kubu Baru KSelangor *(Tg Karang)* P.Dickson Tampin Jempol	Jasin Kluang K. Tinggi Nusajaya Mersing Pontian K.Lipis Bentong Pekan Dungun Besut G Musang	Lahad Datu Labuan K Marudu Beaufort Sri Aman Sarikei Kapit Limbang Mukah Serian	IPR Bahagia Permai Mesra Sentosa PDN PKKN WCH Likas Rehab Cheras NCI WCH, KL Nat Forensic Center 6 Regional Blood Centres	Yan Jitra Sik Pendang Pdg Besar Balik Pulau Parit Buntar Batu Gajah Kampar Tapah Selama Sri Iskandar *(C Melintang)* Sg Siput S.Bernam Jelebu Rembau A.Gajah Kulai Tangkak Raub Jerantut Mdzm Shah Jengka Cameron H Rompin Bera	H. Trggu Setiu Machang Tumpat Pasir Mas Pasir Puteh Jeli Bachok Kudat Kota Belud Papar Ranau Tambunan Tenom Beluran Semporna Sipitang Kinabatangan Kunak K. Penyu Pitas Tuaran Lundu Saratok	Kanowit Marudi Lawas Bau Simunjan Betong Daro RCBM Dalat
Target: 49/20 resident specialty / subspecialties to be determined		Target: 10 resident specialty / subspecialties to be determined			Specific resident specialties	Visting specialist services		

Note:
Hospitals in pink refer to new hospitals to be developed.
Hospitals in red refer to hospitals that are upgraded from a minor to a major specialist hospital or from a district to a minor specialist hospital.
Numbers in closed brackets refers to the number of hospitals under the 10th Malaysia Plan (2011-2015)

8.1.2 Laboratory diagnostic services related to eMTCT of HIV and syphilis

Screening tests for HIV and syphilis are available in primary care laboratories and hospital laboratories providing antenatal care (ANC) services. Samples for supplementary and/or confirmatory tests are sent to referral or regional laboratories for testing.

8.1.2.1 Diagnosis of HIV

a) HIV Rapid Test Kit (HIV RTK) is the screening test done for samples from pregnant women attending the primary health care facilities and women in labour who have not been previously tested. HIV RTK is an immunochromatography test kit that allows women to receive their status on the same day of testing. (Table 8.3). This strategy provides HIV prompt access to pre-labour HV test result for women with unknown HIV antibody status.

b) Pregnant women who are tested positive by HIV RTK, venous blood will be collected and sent for further testing. The diagnosis of HIV can be made by serological immunoassay detecting either HIV-1/2 antibodies or HIV-1/2 antibody/antigen, supplemented with HIV-1/2 antibodies particle agglutination test. These tests are available at all minor specialist, major specialist and state hospitals. HIV-1/2 antibodies immunoblot (line immunoassay) and HIV-1 RNA PCR (Viral load) are done at the designated regional HIV testing centers. Whereas HIV-1 p24 antigen and HIV p24 antigen confirmation assays are only available at the reference laboratories and mandated for testing by laboratory that uses 4th generation immunoassay.

   HIV-1 RNA PCR (Qualitative) for early infant diagnosis and HIV drug resistance testing are offered at the reference laboratory (IMR) as well (Table 8.2).

8.1.2.2 Diagnosis for syphilis

Rapid Plasma Regain (RPR) is a non-treponemal screening test done for all pregnant women. It is available at all diagnostic laboratories. Those who screened positive, confirmation test by *Treponema pallidum* Haemagglutination/ particle agglutination (TPHA/TPPA) will be done at the major specialist, state hospitals and reference laboratories.

All the above-mentioned tests are also being offered at the private laboratories except HIV drug resistance. Generally, for serological tests (antigen and antibody detection), serum/plasma/whole blood is used, whereas for HIV-1 RNA PCR and HIV drug resistance, plasma collected in K2/K3 ethylenediamine tetra acetic acid (EDTA) tubes is used. Table 8.2 listed the HIV tests at laboratory services.

To ensure efficient service delivery, the organization shall ensure that all tests are done by a trained and competent personnel. Service is provided within the stipulated turnaround time as mentioned in Table 8.3. HIV viral load PCR turnaround time for routine baseline and ART treatment monitoring is 14-30 days. However, samples from

HIV positive pregnant women will be prioritized and tests will be performed the soonest possible.

Table 8.2 Diagnostic Laboratories for HIV and Syphilis Testing

Types of Laboratory	Reference Lab.	State Hospitals	Major Specialist Hospitals	Minor Specialist Hospitals	Primary Health Care Lab.	Private Lab.
HIV						
HIV RTK	X	√*	√*	√*	√	√
HIV ELISA (3^{rd} / 4^{th} generation immunoassay)	√	√	√	√	X	√
HIV particle agglutination (PA)	√	√	√	√	X	√
HIV p24 Antigen	√	X	X	X	X	√
HIV antigen confirmation	√	X	X	X	X	√
Immunoblot (Line Immunoassay)	√	√**	X	X	X	√
HIV RNA PCR (Viral Load)	√	√**	X	X	X	√
HIV RNA PCR (Qualitative)	√***	X	X	X	X	X
HIV drug resistance	√***	X	X	X	X	X
Syphilis						
Syphilis RPR	√	√	√	√	√	√
Syphilis TPHA/ TPPA	√	√	√	X	X	√

** RTK also done in most hospital labour rooms especially for un-booked cases with no prior test result or record*
*** Currently 6 states and 1 major specialist hospital function as regional HIV viral load testing centres.*
****Only available in IMR*

Source: Family Health Development Division, MOH & Departmental Policy of Pathology Services, Medical Development Division

8.2 Algorithms for HIV and syphilis diagnosis in adults and infants

The standard diagnostic testing for HIV infection in adults also applies to HIV testing of pregnant women. A reliable, accurate and reproducible result using uniform testing procedures is the most desirable outcome in the HIV testing laboratory. Accurate laboratory diagnosis of HIV infection relies on testing algorithms that maximize overall sensitivity and specificity by employing a sequence of tests in combination and applying decision rules for resolving discordant tests results.

8.2.1 Guidelines for diagnosis of HIV infection

In Malaysia, HIV testing strategy follows the national HIV testing algorithm that was developed in 2011, as shown in Figures 8.2 to 8.5 below. It is recommended that all accredited HIV rapid test kits marketed in Malaysia have ≥ 99.5% sensitivity and ≥ 99% specificity, to ensure the results are highly accurate and reliable.

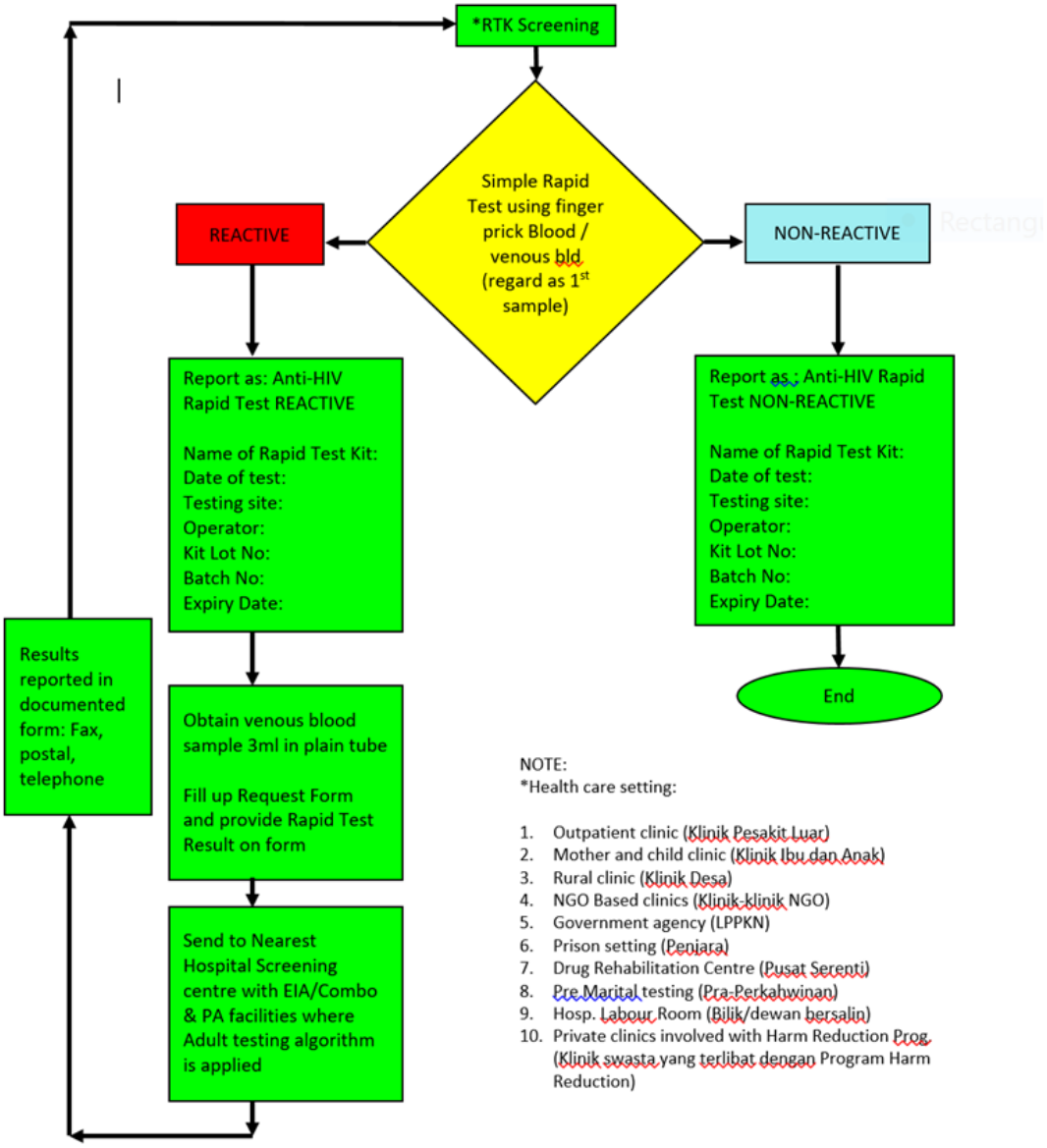
RTK strategy implemented as visual point-of-care tests that do not require any special equipment. These tests are simple, cheap and can be stored at ambient temperature. Figure 8.2 explains the diagnostic strategy using RTK.

Table 8.3 Turnaround time, diagnostic laboratory and personnel responsible for HIV and syphilis Testing

Type of Test	Laboratory Turnaround Time	Diagnostic Laboratory	Responsibility
HIV TEST (mother):			
a) Screening: RTK	10-15 minutes	Primary care laboratories	Medical laboratory technologist/assistant/ medical officer/ staff nurse/community nurse
b) Confirmation: • ELISA (3rd/4th gen.) • PA • HIV Ag • HIV Ag confirmation • Immunoblot • HIV RNA PCR	1-5 working days	Major or minor specialist hospital/ State hospital laboratory or regional HIV centres	Medical Laboratory Technologist / scientific officer/ microbiologist
c) Monitoring: • CD4 POCT	1 day	Primary care laboratories	Medical laboratory technologist / medical officer/ assistant medical officer/ staff nurse
• CD4/ CD8 ELISA	7 days	State hospital laboratory	Medical laboratory technologist / scientific officer/ microbiologist
• HIV 1 RNA quantitative RT PCR	14 - 30 days	Regional laboratory	Medical laboratory technologist / scientific officer/ microbiologist
• HIV-1 drug resistance genotyping assay	6 - 8 weeks	Reference laboratory (IMR virology)	Medical laboratory technologist / scientific officer/ microbiologist
HIV TEST (Early Infant Diagnosis):			
HIV 1 RNA RT PCR	1- 5 working days	Reference laboratory (IMR virology)	Microbiologist/ medical laboratory technologist
Syphilis Screening: RPR	1 day	Primary care laboratories Hospital laboratory	Microbiologist/ Medical Laboratory Technologist
Syphilis confirmation: TPHA/TPPA	1-5 working days	Hospital laboratory	Microbiologist/ MLT

Source: Family Health Development Division, MOH and Departmental Policy of Pathology Services, Medical Development Division

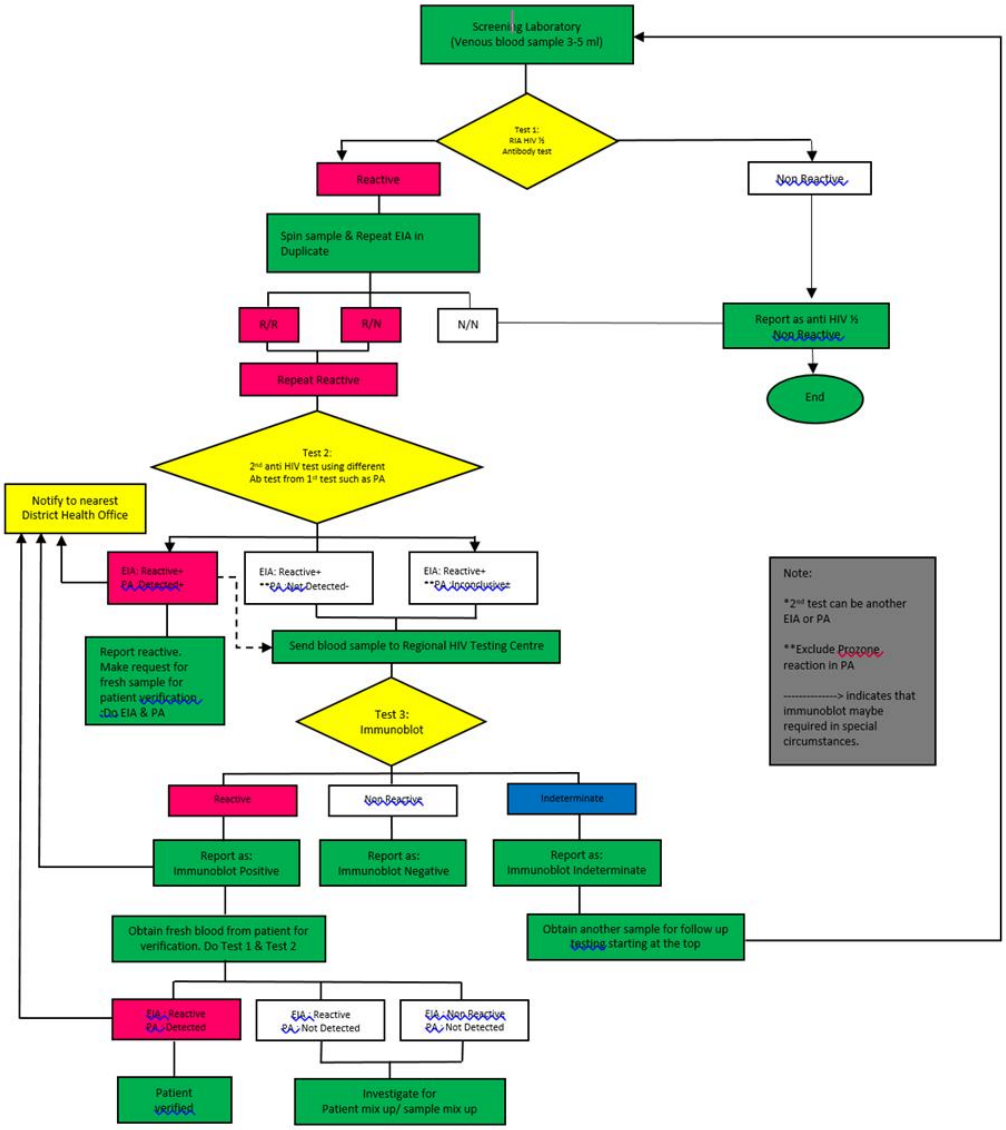
Figure 8.2. Algorithm for HIV Antibody Testing Using Single Rapid Test (1 RTK Strategy)



Source: Director General of Health Circular No.1/2011: Flow chart for screening and confirmatory tests for HIV. 2011

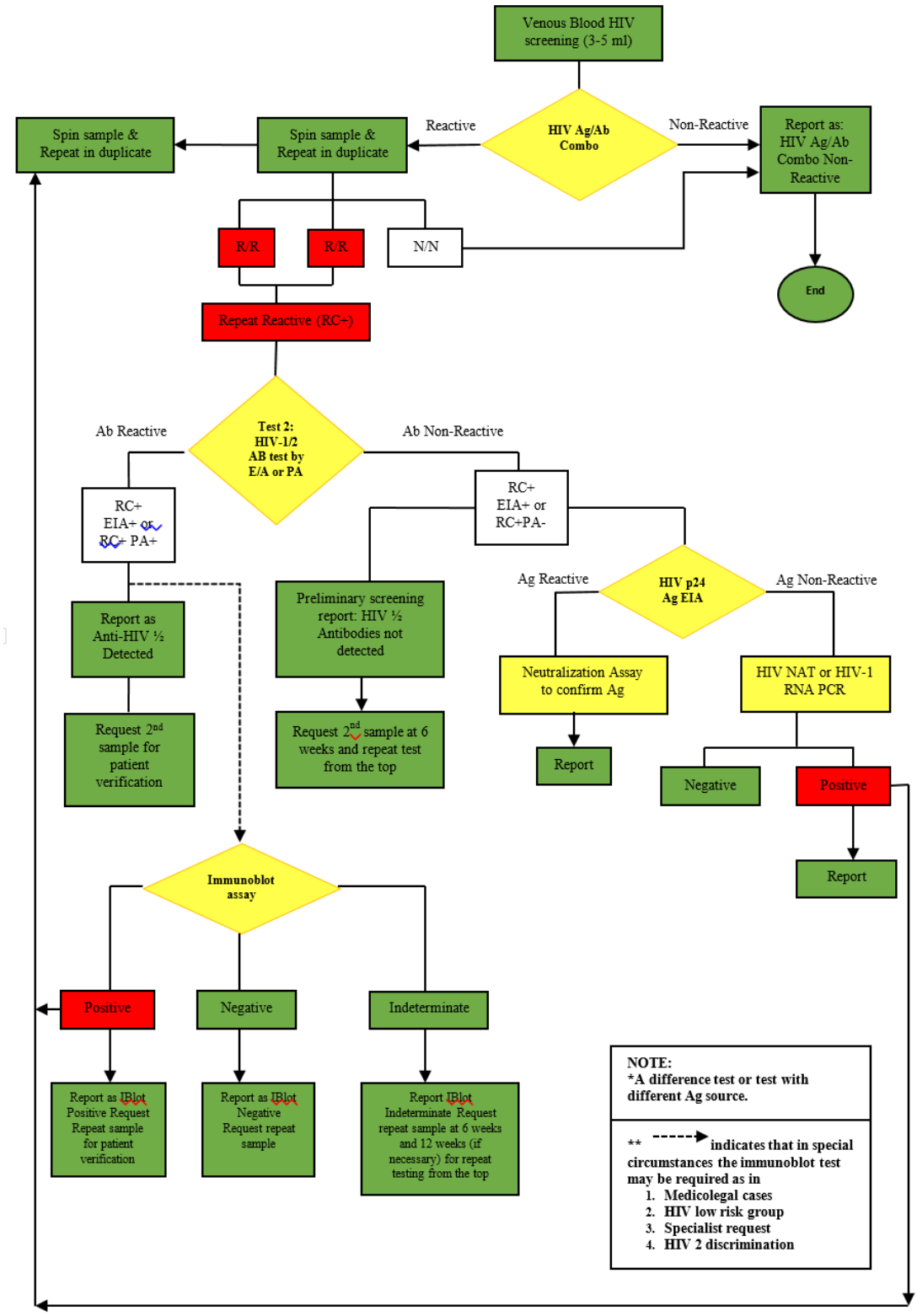
Figure 8.3 and 8.4 illustrates HIV diagnostic testing in adult for general populations. Two-test strategy is used for high risk individual (PWID, female sex worker, MSM). In addition, three-test strategy is generally performed for low risk individual (as determined by the test requestor), medicolegal cases, specialist request and for HIV-2 discrimination.

Figure 8.3 Algorithm for HIV Antibody Testing in Adults



Source: Director General of Health Circular No.1/2011: Flow chart for screening and confirmatory tests for HIV. 2011

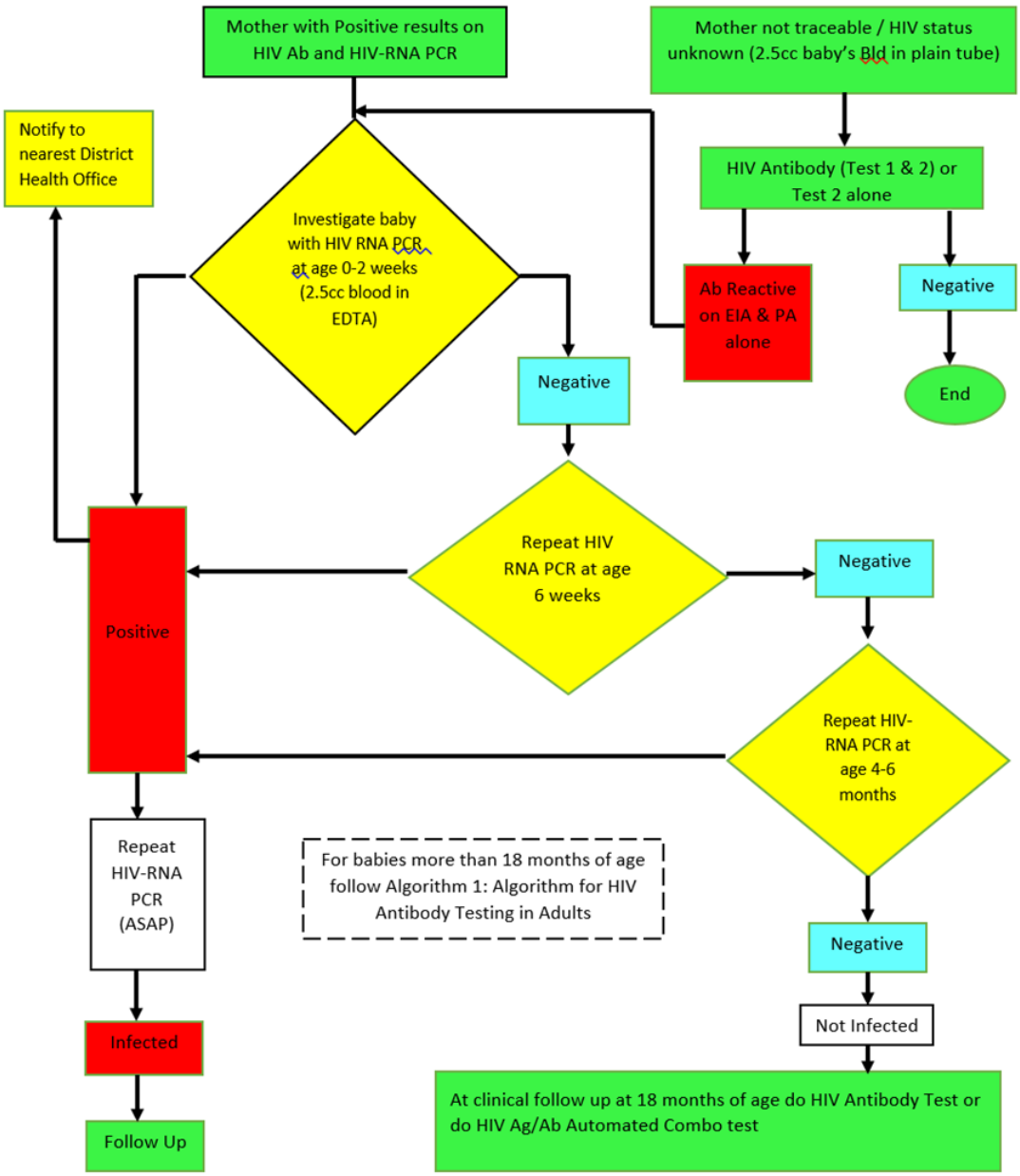
Figure 8.4 Algorithm for HIV Ag/Ab Automated Combo Test



Source: Director General of Health Circular No.1/2011: Flow chart for screening and confirmatory tests for HIV. 2011

This figure demonstrates the algorithm approach used for diagnosis in paediatric age group, aged less than 18 months. Ideally, three samples are collected at different age interval for confirmation of diagnosis.

Figure 8.5 Algorithm for diagnosis of HIV in paediatric age group, less than 18 months

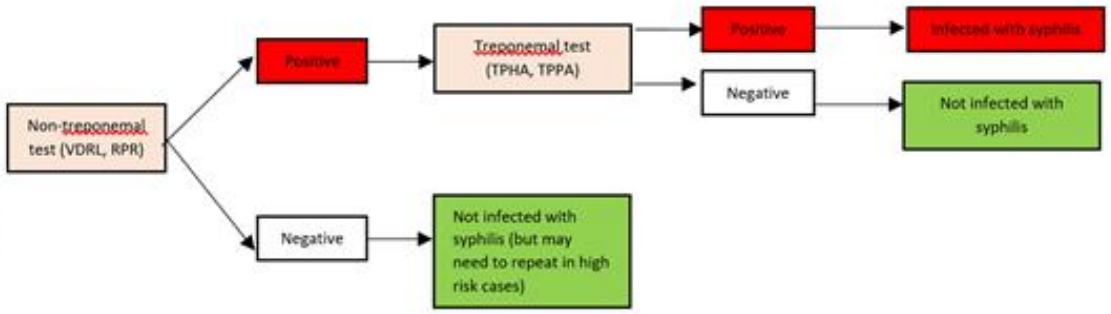


Source: Director General for Health Circular No.1/2011: Flow chart for screening and confirmatory tests for HIV. 2011

8.2.2 Guidelines for syphilis diagnosis

Diagnostic testing for syphilis begins with a non-treponemal assay (only RPR) followed by a treponemal assay (TPHA/TPPA). The testing strategy that is implemented in the laboratories is as shown in Figure 8.6.

Figure 8.6 Traditional strategy for syphilis screening



Source: WHO Bulletin of World Health Organisation 2004: Diagnostic Tools for Preventing and Managing Maternal and Congenital Syphilis

8.3 Ensuring quality of laboratory services

8.3.1 Quality management processes in accredited laboratories

Accurate, reliable and timeliness of laboratory test results are essential for diagnosis, treatment and monitoring of diseases. MS ISO 9001:2015 certification is mandatory for all laboratories. State and major specialist hospitals are instructed to be registered and be MS ISO 15189 accredited. Some hospital laboratories are also Malaysian Society for Quality in Health (MSQH) certified. MS ISO 15189 accreditation and MSQH certification is not mandatory as it involves payment to the local accreditation/certification body. Laboratory quality system is, therefore, implemented in laboratory facilities as a tool for assuring quality of laboratory services. To be accredited, these laboratories must participate in Laboratory Quality Assessment / Proficiency Testing for all tests included in the scope for accreditation.

Meanwhile, for primary care laboratories, a minimum standard quality has been developed together with Department of Standards Malaysia (DSM) to ensure these laboratories fulfil the minimum quality required. In addition, primary care laboratories are also moving towards MS ISO 15189 accreditation. In view of this, Family Health Development Division has initiated a pilot project involving one selected laboratory per state to go for this accreditation.

8.3.2 Quality management processes in non-accredited laboratories

Under ISO 9001:2015 certification most laboratories have a total quality management system in ensuring policies and procedures are in place for pre-analytical, analytical and post-analytical aspects of testing which include but not limited to specimen and reagent storage, result delivery, equipment maintenance and performance monitoring, staff training and competency assessment. Internal audit activities are carried out at regular schedule by local internal auditors or form external auditors from other facilities to ensure the documented policies and procedures are followed.

Since subscription to EQA program or inter laboratory comparison is not in place yet, these laboratories ensure quality by just having quality control procedure at a minimum using internal quality control material provided by the manufacturer. Standard operating procedure are available for all quality processes including work instruction to perform the tests. These documents are easily retrievable for reference in each laboratory by the relevant personnel.

Supervisory visits are coordinated by the state pathologists for laboratories without a resident pathologist or science officers to ensure a quality laboratory service is provided. The supervisory team members may include a pathologist, science officer and senior medical laboratory technologist. Each team has a list of designated laboratories to cover and needs to prepare annual supervisory visit schedule. In addition, supervisory visits are also carried out by the state and district medical laboratory technologists acting as primary healthcare laboratory coordinators. A check list loosely based on MS ISO 15189 elements comprising of management, personnel, equipment, pre-examination, examination, safety and post-examination is used to evaluate and recommendations for improvement are given.

In addition, the Family Health Development Division which is responsible for all primary care laboratories conducts regular technical and coordinating meetings. This includes national proficiency testing meeting which oversees the quality of the various EQA performance and National Pathology Services Coordinating Meeting with state pathologist and primary care officers from all states. In this meeting, quality performance and latest laboratory policies are discussed. Beside this, a national meeting with state and district primary medical laboratory coordinators is held annually.

8.3.3 Mechanisms for assessing laboratory proficiency and quality in HIV testing

Most hospital laboratories in Malaysia subscribe to External Quality Assurance (EQA) programme providers such as the Royal College of Pathologists of Australia (RCPA), Medical Laboratory Evaluation (MLE), American College Physicians (ACP) or National External Quality Assurance Scheme (NEQAS) provided by the National AIDS Reference Laboratory (NARL), Institute for Medical Research (IMR) Kuala Lumpur. Out of 45 hospital laboratories providing the HIV serology testing services, 42 (93.3%) laboratories have subscribed either one of the programmes. The overall laboratory performance for EQA programme was satisfactory. Meanwhile, 20 selected primary healthcare laboratories have participated in NEQAS and the overall laboratory performance was satisfactory (Table 8.4).

To ensure all hospital laboratories subscribe to an EQA programme, MOH Pathology Services is planning to organize a local EQA programme by providing internal quality control materials to each hospital in improving the quality of HIV testing in the country. More primary care laboratories will be participating in NEQAS in the near future. In addition, each laboratory ensures high quality HIV testing by having an internal control for each test kit used.

Table 8.4 Participation in External Quality Assurance Programme, Frequency and Service Provider for HIV testing

Scheme	Frequency per year	Service Provider
National External Quality Assurance Scheme (NEQAS) for HIV Serology	2	NARL, IMR Kuala Lumpur
Medical Laboratory Evaluation (MLE)	2	ACP
External Quality Assessment Scheme for HIV RNA Quantitative/ Viral Load*	2	RCPA/College of American Pathologists (CAP)
TREAT Asia Quality Assessment Scheme (TAQAS)	2	National Serology Reference Laboratory (NRL), Melbourne, Australia

Source: Medical Development Division, MOH Malaysia

8.3.4 Mechanisms for assessing laboratory proficiency and quality in syphilis testing

RPR test kits used for screening syphilis have inclusive internal positive and negative control. Most hospital laboratories subscribe to EQA programme provider while only selected primary care laboratories participate in EQA programme for syphilis RPR test. Confirmatory tests are done in hospital laboratories.

As part of the laboratory accreditation process, these laboratories must participate in an EQA programme or arrange inter–laboratory comparisons within their network to receive accreditation. To ensure all testing laboratories subscribe to an EQA programme, MOH Pathology Services is planning to organize a mechanism to supplement IMR (HIV serology) and National Public Health Laboratory (syphilis). For smaller laboratories, ensuring quality will be by inter-laboratory comparison. This will be discussed, planned and coordinated by the individual State Hospital Laboratory.

It is the responsibility of the individual laboratory to review the EQA results and disseminate to the relevant staff. If outlier is detected, it will be investigated, and a corrective action needs to be implemented, monitored and reported to the relevant authorities. Internal audit will ensure effective action has been taken to prevent recurrence.

Table 8.5 Participation in External Quality Assurance Programme, Frequency and Service Provider for Syphilis Testing

Scheme	Frequency per year	Service Provider
External Quality Assessment Scheme for RPR	4 3 2	RCPA MLE LABQAS

Note:
Laboratory Quality Assurance Scheme (LABQAS) by Malaysian Institute of Medical Laboratory Sciences (MIMLS) and College of Pathologist, Academy of Medicine Malaysia
Source: Medical Development Division, MOH, Malaysia

8.3.5 Participation and performance in External Quality Assurance Program.

HIV serology testing is offered in 45 hospital laboratories and 42 (93.3%) participated in the various EQA programme. All 7 regional HIV testing centres providing HIV RNA viral load test also subscribe to the EQA programme.

Syphilis screening test (RPR) only are offered in 49 hospital laboratories and out of this only 7 (14.3%) participate in RPR EQA programme A total of 51 hospital laboratories provide both screening and confirmatory test (RPR and TPPA) and 24 (47.1%) of these laboratories participate in an EQA program.

Meanwhile out of 635 primary healthcare laboratories offering syphilis screening, only 41 (6.5%) laboratories participated in an EQA programme since beginning 2017. A total of 20 (3.1%) primary health care laboratories participated in HIV RTK EQA program offered by IMR. Participation and performance in the various HIV and syphilis EQA programmes are shown in Tables 8.6 to 8.9.

For a non-conforming EQA or inter-laboratory comparison performance, investigation will be conducted to determine reason for the discordant result. The person in-charge of quality or section involved will repeat test on the same sample if there is adequate amount of sample for retesting. If recurrent discordant results are obtained or too many non-conforming results are in the subsequent cycle, the laboratory will review the test method and may consider change of test method or diagnostic kit. Usually a discussion with the designated technical person with the reagent supplier is conducted in determining the root cause if error is not operator dependent.

If a non-conformance is also detected either from day to day supervision by officers in charge or from an internal audit report or raised as a complaint by clients, a Shortfall in Quality (SIQ) form will be filled up. In this form the followings are documented:

1) Investigate and determine root cause of the problem (root cause analysis)
2) Troubleshooting activities
3) Provide solution or corrective and prevention actions
4) Monitor subsequent performance eg. EQA result

Table 8.6: Number of laboratories participating in EQAS programmes for HIV testing.

Number of participants		EQAS PROGRAMME					
	HIV Serology -RTK, ELISA (HIV 1/2 antibody, HIV 1/2 antibody/antigen), Particle agglutination test and line immunoassay (immunoblot)					HIV Molecular -HIV-1 RNA RT-PCR	
	RCPA & NEQAS	RCPA	NEQAS	MLE and NEQAS	CAP and NEQAS	RCPA	CAP
Hospital	14	2	25	1	1	6	1
Primary Health Clinic	NA	NA	20	NA	NA	NA	NA

Note: NA= Not Applicable

Table 8.7: Number of laboratories participating in EQAS programmes for Syphilis testing

Number of participants	EQAS PROGRAMME					
	Syphilis RPR	Syphilis RPR/TPPA	Syphilis RPR	Syphilis RPR/TPPA	Syphilis RPR/TPPA	Syphilis RPR/TPPA
	RCPA	RCPA	LABQAS	MLE	RIQAS	CAP
Hospital	3	19	4	3	1	1
Primary Health Clinic	NA	NA	41	NA	NA	NA

Table 8.8: Proportion (%) and number (n) of EQAS results that were acceptable for Hospitals, by types of EQAS programme and year

	RCPA	MLE	LABQAS	RIQAS	NEQAS	CAP
Syphilis (RPR and TPPA) (n) 2017	94.4% (17/18)	100% (3/3)	100% (4/4)	100% (1/1)	-	100% (1/1)
Syphilis (RPR and TPPA (n)2016	100% (18/18)	100% (3/3)	100% (4/4)	100% (1/1)	-	100% (1/1)
HIV EIA (n) 2017	92.9% (13/14)	-	-	-	100% (38/38)	-
HIV EIA (n) 2016	100% (14/14)	-	-	-	100% (37/37)	-
HIV Molecular 2016	83.3% (5/6)	-	-	-	-	100% (1/1)
HIV Molecular 2017	100% (6/6)	-	-	-	-	100% (1/1)
HIV POCT 2017	100% (1/1)	-	-		-	
HIV POCT 2016	100% (1/1)	-	-		-	
HIV EID 2017	100% (1/1)					

Table 8.9: Percentage (%) and number (n) of EQAS results that were acceptable for Primary Health Care Laboratories by EQAS program and year

	RCPA	LABQAS		NEQAS
Anti-HIV 2017	-	-	-	100% (20/20)
Syphilis RPR (n) 2017	-	-	-	97.6% (40/41)

An acceptable EQA performance is when the performance is above 90%.

8.4 Supply chain for HIV and syphilis testing

In Malaysia, HIV RTKs and CD4 for primary care laboratories are procured centrally by the Ministry of Health and distributed to the respective states to be supplied to the relevant clinics. Test kits for RPR are purchased at District Health Office level and distributed to the relevant health clinics as stipulated by the guidelines set by the headquarters.

Reagents for all other tests are procured by the respective institutions either through direct purchase, calling for multiple quotation for sums exceeding RM50,000 or tender process for very large volumes of test kits (If the purchase of certain items / reagents / test kits etc. is valued more than RM500,000, tender process will be called for (as stipulated by the government regulations).

On receipt of the test kits, each laboratory needs to perform acceptance test to ensure quality of the kit. Acceptance testing is varied according to the type of test and workload of the laboratory.

All new test kits in the market must be registered under the Medical Device Act 2012 (ACT 737) before it can be brought into Malaysia by the local vendors. The vendors also need to arrange for the kit evaluation before it can be marketed locally. A national committee headed by National MOH Pathology Services has been formed to coordinate such request from these vendors. The committee will determine the designated laboratories for the evaluation. These laboratories will either be Institute of Medical Research, National Public Health Laboratory or any MOH pathology department laboratories.

Kit evaluation using serum panel with known status will be based on concordance test or precision and accuracy test. This is conducted before any test is being introduced into the service. For example, IMR uses 100 HIV antibody-positive and 100 HIV antibody-negative panel for both pre- and post-market evaluation.

8.5 Training of personnel

(a) Personnel development training programmes are developed by each laboratory based on the requirements of its quality management systems (MS ISO 9001, MS ISO 15189).

Note:
MS ISO 9001 / 15189 is part of the quality management systems which has been adopted by Malaysia. MS ISO 15189 has been set to meet the requirements set for the Malaysian laboratory systems. The MS ISO 15189 has been adopted for laboratories in the country and used by the government or private laboratories

(b) Laboratory capacity building and training are provided by various public and private teaching institutions.

(c) Training courses and workshops organized by professional organizations, associations, universities and supplier of equipment.

(d) Training on the uses of POCT in Primary Health Care is given yearly to all categories of personnel involved. This includes laboratory and non-laboratory staffs

(e) Each accredited/ certified laboratory must show evidence of staff competency. It is also recommended for non-accredited/ certified laboratory to provide competency assessment for each personnel performing the test.

8.6 Data reporting system in health clinics (reference to eMTCT)

Primary care laboratories manage their data manually. Laboratory returns are sent from the Health Clinics to District Health Offices, State Health Departments and Headquarters in Putrajaya. There are 635 health clinics equipped with laboratories and 89 of them are connected with Teleprimary Care system, which in future is envisaged that all these primary care laboratories will be managed uniformly (i.e. “standardized” using a common laboratory information system for the whole country.

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CHAPTER 9

HUMAN RIGHTS, GENDER EQUALITY AND COMMUNITY ENGAGEMENT IN EMTCT OF HIV AND SYPHILIS IN MALAYSIA (WHERE POSSIBLE AND APPLICABLE, THIS CHAPTER WILL INCLUDE INITIATIVES MADE BY THE MINISTRY OF HEALTH MALAYSIA AND THE GOVERNMENT PERTAINING TO ISSUES ON THE POPULATION OF MIGRANTS AND FOREIGNERS)

The Malaysian Federal Constitution, Article 8 (equality) guarantees the rights to health by stating that all persons are equal before the law and entitled to equal protection under the law without any discrimination regardless of religion, race, descent, place of birth or gender. In line with this constitutional commitment, one of the strategic priorities of the Malaysian government is to ensure the enjoyment of the highest attainable standard of health as one of the fundamental rights of every citizen without distinction of race, religion, and political belief, economic or social condition. Based upon these principles, the Ministry of Health of Malaysia's is committed to enhancing the scope, quality and coverage of essential health services, including primary prevention of HIV and syphilis, early voluntary detection and accessible and affordable treatment for women living with HIV / syphilis and their families.

In addition, Malaysia has shown its commitment to human rights, gender equality and community engagement by developing national laws, policies and action plans and by ratifying various international human rights instruments. For example, although Malaysia is not a signatory to the International Convention on Economic, Social and Cultural Rights (ICESCR), it has ratified the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and the Convention on the Rights of the Child (CRC) which both enshrine the right to the highest attainable standard of health. CEDAW provides for the right to access health care services on a basis of equality of men and women (theoretically, including migrant workers). The country upholds the right of all individuals to sexual and reproductive health in line with CEDAW, and such services are available to those who seek care, irrespective of citizenship.

Relevant international commitments by Malaysia include the following:

(a) International consensus documents related to HIV and AIDS
- United Nations General Assembly Special Session on HIV and AIDS 2001 (Declaration of Commitment on HIV/AIDS)
- Political Declaration on HIV/AIDS 2006
- Political Declaration on HIV/AIDS: Intensifying our Efforts to Eliminate HIV/AIDS 2011
- ASEAN Commitments on HIV and AIDS 2007
- ASEAN Declaration of Commitment: Getting to Zero New Infections, Zero Discrimination, Zero AIDS-related Deaths 2011
- Millennium Development Goal 6: Combat HIV/AIDS, Malaria and other diseases (MDG 6)

- Sustainable Development Goals, including SDG3 on good health & well-being, SDG 5 on gender equality and SDG 16 on peace, justice & strong institutions.

(b) International human rights conventions:
- Universal Declaration of Human Rights 1948
- Convention on the Elimination of Discrimination against Women (CEDAW) 1979
- Convention on the Rights of the Child (CRC) 1989

As a Member State of the World Health Organization, the country has committed to various global and regional resolutions related to HIV/AIDS. This includes for example, resolutions by the WHO Regional Committee for the Western Pacific on Universal Health Coverage (2015) and on the Sustainable Development Goals (2016). At the global level, the 61st World Health Assembly adopted a Resolution on Migrant Health (WHA 61.17) in 2008, which recognizes increased health risks for groups of migrants and calls for the promotion of migrant-sensitive health policies and equitable access to health promotion, disease prevention, and care for migrants. In May 2017, the 70th World Health Assembly adopted a Resolution on Promoting the Health of Refugees and Migrants (WHA 70.15).

At the national level, a number of laws, policies and action plans have been developed. The *National Strategic Plan on Ending AIDS (NSPEA, 2016 – 2030)* details the strategies, action plans, budget and work mechanisms for realizing the Sustainable Development Goals (SDGs), and the country's commitment to the "Ending AIDS by 2030" target. Continuous efforts are being made to ensure the necessary resources, including sufficient human resources, technical expertise, budget allocations and work processes, are in place in order to implement the action plan to its fullest potential **(1).**

These steps at national and international levels undoubtedly reflect Malaysia's commitment towards the promotion, protection and fulfilment of human rights in the country, which includes efforts to enhance primary prevention of HIV and syphilis, early voluntary detection and access to affordable treatment for women living with HIV / syphilis and their families. Human rights, gender equality and community engagement remain core to the laws and policies enacted in the country.

9.1 Principles of Human Rights Endorsed by Malaysia

The MOH leadership in its pledge to promote universal access to health amongst its people has been commendable, particularly in ensuring efficient, sufficient and continued access to health care for all citizens of the country. To ensure the above pledge is kept, especially with respect to the rights of women and children in general, the Malaysian government has committed to and implements several significant international human rights instruments as mentioned below;

(a) Reaffirmation of the rights of women and children to health and health care. This reaffirmation is reflected in the number of pledges signed by the country towards protecting the rights of women and children.

Note: This chapter is devoted to the aspects of human rights, gender equality and community engagement issues in the implementation of eMTCT of HIV and syphilis in Malaysia. Amendments of constitutions, laws, regulations and policies take time and need to undergo processes endorsed by the government (including the Ministry of Health). Malaysia practices democracy and is governed by "the rule of law". Every individual and community in Malaysia is protected in the eyes of the law as enshrined in the Federal constitution.

(b) Women and their partners have the rights to proceed with their intended marriage irrespective of their HIV status.

Note: Other specific issues and strategies e.g. access to services for migrants, testing of HIV among adolescents under the age of 18 years old, sex workers, prevention of vertical transmission of HIV during pregnancy are being discussed in various policies and national plans within the framework of the Ministry of Health (as stipulated in the National Strategic Plan Ending AIDS Malaysia (NSPEA), 2016-2030. For example, the eMTCT programme is being emphasised in Strategy 2 of the NSPEA (i.e. Improving the quality and coverage of prevention programmes among key populations and eliminating mother-to-child transmission of HIV and syphilis) Issues on stigma and discrimination which is spelt out in Strategy 3 of NSPEA, have been dealt with via surveys, FGDs etc

(c) Women (during pregnancy and post-delivery) and their partners will continue to receive appropriate health care regardless of their social background and health status.

(d) Women and their partners have the right to determine the number of children they wish to have, irrespective of their HIV status. During counselling sessions, women who are HIV+ are counselled to use various types of contraception available in health clinics varying from the usage of oral contraceptives, condoms and hormonal injections.

(e) Women are represented in key decision-making bodies / committees.

The government also realizes that an enabling environment free from gender inequality, discrimination and violence is fundamental in reducing the vulnerability of women and girls to HIV/AIDS. Pledges, policies and frameworks have been put in place to maximize individuals' access to sexual and reproductive health services, including maternal health care, information, counselling and other HIV activities, regardless of their diverse backgrounds. For example, the MOH has outlined the framework of managing adolescents on STIs in the Management Guidelines of the Ministry of Health in Adolescent Health Clinics. Some of the policies, guidelines and frameworks were designed specifically for women living with HIV and their infants exposed to reduce mother-to-child transmission of HIV, as well as to ensure effective interventions for women living with HIV. Some of these pledges and declarations were made at conferences, conventions and seminars at various times over the last few decades.

9.2 Relevant laws, policies and guidelines implemented in Malaysia in reference to eMTCT

The Federal Constitution of Malaysia guarantees the right to health for all Malaysians. Access to health and medical care remains a priority area in the national development programme. This is being operationalized through the development of laws, policies and guidelines that promote and protect the rights of women and gender equality. Malaysia's initiatives to protect the rights of women and girls, particularly in the provision of health services, has contributed significantly to women's health and wellbeing, as demonstrated by significant improvements in health indicators. In Malaysia, everyone has the right to access health services, regardless of gender.

Below is a list of existing laws, policies and guidelines, which together provide an enabling environment to safeguard women's and children's rights to health in the country and to promote directly or indirectly gender equality (including in connection to the PMTCT programme):

9.2.1 Laws implemented in reference to eMTCT

The list provided below focuses on selected laws with particular relevance to the eMTCT of HIV and syphilis in Malaysia, as understood by the relevant authors of this chapter. Most of these laws make reference specifically to Malaysians. The issue of migrants accessing health care has been discussed in detail in other chapters (see delivery of services in Chapter 2 and other relevant chapters). In addition, the Ministry of Health has adopted policies (e.g. NSPEA) or guidelines (e.g. Guidelines of Adolescents Seeking Treatment for STI / HIV) providing information on the need for parental consent for those below 18 years. The medical officer who is treating a mother who is HIV+ (Malaysian or otherwise) is required to write a referral letter to the doctor of choice whom the patient prefers (either to a doctor in Malaysia or in the country of origin). In addition, a patient in Malaysia is also free to choose the preferred place of treatment anywhere in the country.

Therefore, these laws listed below will give an overview of the existing legal framework related to eMTCT.

(a) Marriage Laws

1) Under the Islamic Family Law (for Muslims), the minimum age for marriage for women is 16 years and for men 18.
2) Under the Law Reform (Marriage & Divorce) Act 1976 (Act 164), any marriage of non-Muslims purported to be solemnized in Malaysia shall be void if at the date of the marriage either party is under the age of eighteen years unless, for a female who has completed her sixteenth year, the solemnization of such marriage was authorized by a license granted by the Chief Minister.

(b) Provisions for Abortion

1) The Penal Code (Act 574) revised 1997, Chapter XVI, Article 312 permits termination of pregnancy by a medical practitioner registered under the Medical Act 1971 [Act 50] when the life or health of the woman is threatened.
2) Under the Fatwa (Muslim ruling) developed by the 26th *Muzzakarah* of the National Fatwa Committee in 1990 on termination of pregnancy, abortion is not encouraged for up to 40 days, permissible for up to 120 days and forbidden beyond that except to save the life of the mother or if there is foetal impairment.

(c) Domestic Violence Act 1994 (Act 521)

The objective of this law is to provide legal protection especially for women in situations of domestic violence and matters incidental thereto. It was amended in 2017 by Domestic Violence (Amendment) Act 2017 in an effort to strengthen protection of survivors of violence. In addition, the Sexual Offences against Children Act 2017 provides additional protection for children less than 18 years of age.

(d) Child (Amendment) Act 2016 (Act A1511)

This law was enacted to consolidate and amend the laws relating to the care, protection and rehabilitation of children and to provide for matters connected therewith and incidental thereto. Recognizing every child is entitled to protection and assistance in all circumstances without regard to distinction of any kind, such as race, colour, sex, language, religion, social origin or physical, mental or emotional disabilities or any other status (2). Chapter 2 of this Act outlines the roles and duties of parents, guardians and medical officers to provide medical examination to the child. This Act however, does not specifically mention on the steps to be taken for HIV or other STIs testing for clients below 18 years of age.

(e) Fees Act 1951 (Act 209)

This law was enacted for the provision of levy of fees and payments for licenses, permits and other matters to be leviable in subordinate courts and public offices. Every Malaysian will have equal access to quality healthcare. All fees for antenatal and postnatal care are exempted in government facilities. Whilst there is a government circular in 2016 which states that non-Malaysians need to pay for health services, it is also a policy of the Ministry of Health to exclude payments for non-Malaysians who are infected with certain infectious diseases like tuberculosis, dengue, malaria, syphilis and for non-Malaysian mothers who are HIV positive (Option B), including free ART prophylaxis and free formula milk (for 24 months) for exposed babies born to these mothers.

(f) Infectious Disease Act 1988 (Act 342)

This Act was enacted to consolidate laws pertaining to the prevention and control of infectious diseases and to provide for other matters connected therewith. Whilst it is mandatory for the medical practitioner to notify a list of infectious disease, this law also establishes the need to maintain confidentiality at all times (as stated in Part II (Administration) “an authorized officer shall maintain the confidentiality of all matters which come to his knowledge in the performance of his official duties under this Act and

shall not communicate any such matter to any person except for the purpose of carrying into effect the provisions of this Act").

9.2.2 Policies / Framework

(a) Eleventh Malaysia Plan, 2016-2020

The Government remains committed to achieving universal access to quality healthcare by continuing efforts to improve the fundamentals of the health system**(3)**. This means that everyone will have equal access to affordable and good quality healthcare services, whether delivered by public or private providers.

This aspiration will be realised through four strategies:

a. Enhancing targeted support, particularly for underserved communities
b. Improving system delivery for better health outcomes
c. Expanding capacity to increase accessibility of both healthcare facilities and personnel
d. Intensifying collaboration with private sector and NGOs to increase health awareness.

(b) National Policy on Women 1989

The main objectives of this policy are to ensure an equitable distribution of resources, information, opportunities and benefits of development for men and women. To ensure that women's participation in nation building is not taken lightly, the Ministry of Women, Family and Health Development (KPWKM) has successfully advocated for a minimum of 30% representation of women in decision-making positions in the public sector. **(4).**

(c) Adolescent Health Policies

In 2001, the National Adolescent Health Policy was developed and launched. In 2006, National Adolescent Health Plan 1997 was reviewed and incorporated into the National Adolescent Health Plan of Action (NAHPOA) 2006-2020. The National Adolescent Health Technical Committee was established to monitor the achievement and effectiveness of strategies, programs and activities in the National Adolescent Health Policy & Plan of Action.

One of the strategies of the NAHPOA is the provision of accessible and appropriate adolescent health care services encompassing a comprehensive range of health care with emphasis on preventive and promotive services for adolescents which are user friendly, gender sensitive and adjusted to adolescent health needs. Efforts were taken to strengthen the comprehensive adolescent friendly services in all districts/ health centres and selected hospitals in stages. One of the key priority areas under this strategy is sexual and reproductive health.

The introduction of the National Policy on Reproductive Health and Social Education and its Plan of Action in November 2009 further enhanced efforts and paved the way for increased access to reproductive health education, information and services for adolescents and youths, stressing on positive values as well as responsible behaviours. In 2011, efforts were made to integrate reproductive health and social education in the

National Service Training curriculum in 2011 which benefits more than 100,000 school leavers each year. In the same year, the Ministry of Education introduced reproductive health and social education (PEERS) in schools beginning with Year 1 students in primary schools. Among the content in this module are sexual reproductive health, skills, knowledge and behaviours.

(d) National Strategic Plan-Ending AIDS 2016 – 2030

One of the key strategies in the current Malaysia's NSPEA is to ensure access to HIV testing for all pregnant women accessing antenatal care. HIV positive mothers are given free ARV therapy, ART prophylaxis and free formula feeding given to HIV-exposed infants, and routine PCR tests are strictly observed. The programme also offers HIV testing and counselling for spouses. Beginning 2011, the government adopted Option B+ treatment for HIV infected mothers, and the HIV exposed infants are getting free replacement feeding for extended period of 2 years since 2012 (1). HIV infected pregnant women and the HIV exposed infants in prisons can also access treatment.

Note: an incarcerated woman who is HIV+ and pregnant is expected to be given the same antenatal care as any other expectant mothers. It is a standard practice for women in prisons to have antenatal check-ups and receive the same treatment from the Family Medicine Specialists, in-house medical officers, and they will be referred to the same joint care by the ID physicians and O&G specialists. These incarcerated women will receive the same ARV (option B+ or B) like any other expectant HIV+ mothers.

The NSPEA 2016-2030 clearly highlights the importance of respecting the rights of women who are HIV+ and their exposed infants as outlined in *Strategy 2 Improving the quality and coverage of prevention programmes among key populations* which mentions the PMTCT as one of the key programmes in the country (1). It emphasizes the need to enhance the PMTCT programme. Although it has been a standard practice for all mothers to receive a standard package of antenatal care in HCs, they have the choice to "opt out' from HIV screening should they wish to do so. Informed consent is required from the clients prior to any action, and mothers who agree to be screened are required to sign a consent form.

(e) Manual on HIV/AIDS in Islam 2010

Launched in 2010, the manual on HIV/AIDS in Islam has been developed specifically for Islamic Affairs officers' use at the state and district Islamic Religious Departments, Imam, Takmir teachers, holders of Islamic teaching credentials (mosque, surau and madrasah) and leaders of the Muslim communities to enable them to play a more effective role in the management of HIV/AIDS in Malaysia. It aims to provide a basic guidance to assist the Muslim leaders' involvement to increase the awareness and to harness the participation of the Muslim community in managing HIV/AIDS. The manual includes basic facts on HIV/AIDS, prevention, treatment, support, counselling, stigma and discrimination to enhance the understanding of Islamic leaders in preventing and controlling HIV/AIDS as well as strengthening the support for those infected and affected with HIV/AIDS.

(f) Code of Practice on Prevention and Management of HIV/AIDS at the Workplace 2001

In 2001, the Department of Occupational Safety and Health under the Ministry of Human Resources has formulated a Code of Practice on Prevention and Management of HIV/AIDS at the Workplace. Compliance is voluntary and places emphasis on the employer's responsibility to be non-judgmental and to have in place non-discriminatory policies for HIV-positive employees. The government is working closely with Malaysian AIDS Foundation to legislate the HIV and AIDS in Workplace Policy by 2020. Plans are underway to make it a compulsory regulation for all corporate companies to abide.

(g) One-Stop Crises Centres (OSCC) 1996

These centres have been set up in emergency departments of all government hospitals to support survivors of violence, domestic violence and sexual assaults (5). Support in terms of counselling, lodging police reports, medical examination, referral to shelter homes and free legal aid bureau can be obtained by survivors at these OSCC. At the OSCS, medical examination and police reports can all be made in one place, and medical services at such places (OSCC) are free for survivors of domestic and sexual violence. Reports on cases of violence are developed and can be made available at these centres and also at the Women's, Family and Community Development Ministry.

9.2.3 Guidelines / Standard Operating Procedures (specifically in reference to eMTCT Malaysia)

(a) Management of HIV Infection in Children (2008)
(b) Management of HIV Infection in Pregnant Mother (2008)
(c) Guidelines for the Management of Adult HIV Infection with Antiretroviral Therapy, (2011)
(d) Consensus Guidelines on Antiretroviral Therapy (2014)
(e) Model of Good Care for HIV among Pregnant Women and New-born (2015)
(f) Guidelines of Adolescents Seeking Treatment for STI / HIV (2012)
(g) The Malaysian guidelines in the treatment of Sexually Transmitted Infections (reference to syphilis and related management) 3rd Edition (2015)
(h) Paediatric protocols for Malaysian for Hospitals 3rd Edition (in reference to syphilis and related management) (2012)
(i) National Antibiotic Guideline 2nd edition (2014)

The above guidelines were specifically written over the years with the objective of assisting clinicians to make evidence-based decisions regarding the management of pregnant HIV+ women and their exposed infants. Some of these guidelines were produced with the inputs of various professional bodies as well as HIV+ women themselves.

The above-mentioned laws, policies, frameworks and guidelines, recognize the importance of responding to and caring for HIV+ women. Some of the laws focus on women in general, whilst other policy frameworks and consensus guidelines are explicit on gender equality and sensitivity to women, their exposed children and their partners in aspects of HIV prevention, treatment and care.

9.3 Protecting the rights of PLHIV: The roles of commissions, task forces, committees, organisations and human rights groups in Malaysia

Various committees have been formed to promote human rights and gender equality involving vulnerable key populations. The formation of these committees indicates the strong political commitment and leadership at the highest level of the Malaysian government. Specifically, in relation to the HIV epidemic, a key milestone was the formation of National AIDS Task Force in 1985, which was replaced by the National Committee on AIDS in 1993, an inter-sectoral committee comprising of multi-sectoral agencies and civil society. Whilst there are commissions which have been set up by the government, there are also many other independent NGOs advocating for the rights of individuals.

(a) The Human Rights Commission of Malaysia (SUHAKAM) is an independent commission set up by the government to oversee issues related to human rights in Malaysia. This institution was established under the Human Rights Commission of Malaysia Act 1999 (Act 597) and acts as a platform to discuss issues affecting the states, central agencies and other individual matters which are of current interest by engagement with key government agencies, individuals, and NGOs.

(b) Various committees have also been set up by government agencies to address concerns by HIV+ individuals, including women and children. In order to make inclusive decisions on pertinent issues facing HIV+ individuals, including women and children, government agencies have set up task forces and committees which meet regularly.

(i) Women's Task Force on HIV/AIDS
(ii) The National Harm Reduction Committee
(iii) The National Coordinating Mechanism of Malaysia (CCM Malaysia)

Note: The participation of youths is strongly encouraged, such that for CCM Malaysia, there is a seat for youth's representative. The Ministry of Health also encourages youth participation in the prevention of HIV/AIDS programmes, which is clearly outlined in ProSTAR (a programme to encourage youths to be involved in HIV/AIDS activities)

(c) There are many organisations working independently to promote issues related to the rights of women and children. These organisations have been actively promoting and protecting human rights issues in the country for many years.

(i) The Malaysian AIDS Council
(ii) The National Council of Women's Organisations (NCWO),
(iii) All Women's Action Society (AWAM),
(iv) Women's Aid Organisation (WAO)
(v) SEED Foundation,
(vi) Tenaganita

Their core activities generally relate to the overall promotion and protection of women's rights, or in some cases protecting the rights of HIV+ individuals or families

on common grounds such as access to treatment and care, stigma and discrimination. The inception of MAC in 1992 as the umbrella organization for more than 50 HIV/AIDS organisations is a hallmark of progress for PLHIV in Malaysia.

Over the last 5 years, some groups have been actively advocating for the specific rights of HIV+ individuals especially in relation to treatment (antiretroviral drug pricing, Hepatitis C treatment). These issues were brought to the attention of relevant authorities and deliberated during informal roundtable discussions either within or outside the country.

Some examples of best practices by organisations / NGOs for the promotion of eMTCT in Malaysia

(a) *PEWAHIM*

This shelter home is situated in the state of Selangor and is run by a PLHIV woman who is actively involved in HIV work. This shelter home has been running for about 3-4 years and has sheltered unmarried girls mainly, who were referred by hospitals, and the community. These women and girls are HIV+. Puan Norella, the woman who runs this shelter home herself has been advocating the rights of HIV+ women for many years and is currently sitting as one of the committee members in CCM Malaysia.

(b) *Rumah Solehah (The Solehah Shelter Home)*

Rumah Solehah is a halfway house for women, children and orphans made vulnerable by HIV/AIDS. It was established by the Islamic Medical Association of Malaysia (PPIM) to provide healthcare and medical treatment, as well as psychosocial support for the residents. Located at the periphery of Kuala Lumpur, this shelter home has been a safe haven for HIV+ women and their affected children for many years. Rumah Solehah has been receiving referrals from KL Hospital for many years now, and still in operation.

(c) DIC Pahang

DIC Pahang is one of the partner organisations of MAC, and to date has 3 major shelter homes for PWID, women & children, and a transition place for those PLHIV who have been discharged from hospitals.

(d) *Tenaganita*

This NGO has been championing the rights of migrant workers for many years, and in particular the rights of workers in the plantation sectors as well as the rights of foreign domestic helpers in the country.

Outcomes of these best practices:

Below is an example of how one writer wrote on the website regarding her visit to Rumah Solehah:

We had the pleasure of attending a field visit organized by Women Deliver and sponsored by Malaysian Ministry of Women, Family and Community Development and the Ministry of Health. We visited Rumah Solehah, a support and medical center for women and children living with HIV/AIDS. The organization works under the umbrella of the Islamic Medical Association of Malaysia, and provides a variety of medical and psycho-social services to infected and affected women and children. Rumah Solehah was founded in 1998, and employs six staff members as well as volunteers. The organization works with a variety of infected groups, including sex workers and drug users; women infected by their spouses; and infected mothers and children who are either infected or affected by HIV. They run two separate homes, one for women, which has facilities to host five women at a time, and another for children which has space for up to ten children.

The approach of Rumah Solehah is multi-pronged, and targets both the physical and emotional well-being of the women and children. For the women who come to the organization, Rumah Solehah offers support in building the women's self-esteem, supporting their communication skills and developing their vocational skills, while also monitoring their health. The women stay in the house for a minimum of three months and a maximum of 12 months, and come to Rumah Solelah through referrals from doctors and HIV specialists throughout Malaysia. Rumah Solehah is one of 45 Malaysian NGOs affiliated with the Malaysian AIDS council, and they work closely with many other partners through periodical meetings and seminars ……"

Rumah Solehah is just one example of how Malaysia is leading the way in maternal care. By offering well-rounded, high quality and culturally relevant care to patients, not only are they improving the lives of women and children affected by HIV/AIDS, but the cycle of former patients who continue to volunteer with the organization is a testament to their effectiveness.

9.4 Promotion and protection of human rights, gender equality and community participation in eMTCT of HIV & syphilis

Below are examples of the steps and action taken by the Ministry of Health Malaysia and in collaboration with the community & civil society protecting the rights of individuals:

9.4.1 Standard operating procedures (SOPs) pertaining to human rights issues, and gender equality

Currently there is no existing specific law on HIV/AIDS and other STIs in relation to discrimination towards PHLIVs. However, realizing its importance, the MOH continues to participate in and advocates through various committees and meetings pertaining to PLHIVs. Some of the standards that MOH have been championing for are:

(a) Informed consent is required for all patients going for HIV testing. Voluntary and confidential HIV testing (VCT) and Provider Initiated Testing and Counselling (PITC) are performed in public healthcare facilities (HCs and Hospitals). Before any HIV testing is done, women accessing antenatal care are required to sign a consent form. Parental consent is required for minors. However, interventions are given based on the principal of harm reduction and in the best interest of the child. The rights of the child in need of medical examination or treatment are spelt out in Chapter 2 of this Act. The responsibility of consent of those teenagers below 18 years of age usually rests with the husband. During emergency, this Act specifies that should the child needs hospitalisation, a protector or police officer may authorise the child to be hospitalised.

(b) All HIV+ women are counselled on their status and the impact on pregnancy. Accurate information, including the range of contraceptive options is given to enable them to make informed choices. The decision to bear children or use contraceptives is solely up to the individual woman and her partner.

(c) There is no compulsory HIV testing for pre-employment physical examination for civil servants. In addition, there is a Code of Practice on Prevention and Management of HIV/AIDS at the Workplace that is relevant to all workplaces (public and private including foreign companies). While compliance is voluntary, the code places emphasis on the employer's responsibility to be non-judgmental and to have in place non-discriminatory policies for HIV-positive employees. The Ministry of Human Resource and the Malaysian AIDS Foundation have drafted a policy on “HIV/AIDS in the workplace” which would be tabled in 2019/2020 to address among other things stigma and discrimination in the workplace (related to HIV/AIDS). Efforts are also being taken to educate companies to not mandate testing.

(d) For Muslim couples, HIV status is not a legal consideration for annulment of a marriage to be annulled. Pre-marital HIV testing is strongly recommended for non-Muslim couples, but it is not a requirement.

(e) All patients accessing care must be treated equally without any form of stigma and discrimination. The MOH welcomes all patients regardless of their HIV status, those who feel that they are being stigmatized or discriminated are free to lodge complaints against any staff member or institution and the case will be investigated.

9.4.2 Specific actions and steps taken by the Ministry of Health Malaysia to address the issue of HIV/AIDS stigma and discrimination in healthcare facilities

There are various avenues/mechanisms in place to address matters pertaining to violations of human rights, stigma and discrimination against PLHIVs, which can be addressed either formally or informally.

Some examples of mechanisms and steps taken by the Ministry of Health (and the community) to minimise the impact of stigma and discrimination in health care facilities include the following:

(a) Formal mechanisms

Those who feel that they are being stigmatized or discriminated against can lodge official complaints through various channels (the MOH complaints' bureau hotline, emails, letters, etc.). Individual letters can be sent to the top management of MoH, which are addressed as soon as possible (within a certain time frame).

So far, there have been no cases pertaining to stigma, discrimination, human rights issues, and/or gender issues which have been brought to court. There have also been no specific records or documented reports of human rights violations (2014, 2015, 2016 and 2017) related to eMTCT of HIV and syphilis in Malaysia. In addition, there are some relevant committees which PLHIVs can also access to lodge formal complaints, including the following committees:

(i) National Harm Reduction Task Force
(ii) Country Coordinating Mechanism Malaysia (CCM)
(iii) National Task Force on Women and AIDS

These committees (based on their terms of reference) are given responsibilities to promote and protect the rights of PLHIVs, on top of monitoring the complaints, and coordinating solutions for PLHIVs. Currently, there is no proposal to draft specific laws pertaining to the rights of HIV+ individuals.

(b) Informal mechanisms

All PLHIVs are free to voice their dissatisfaction with policies, guidelines, SOPs, to any of the MOH health staff. These informal complaints can be lodged through social media (e.g. Facebook) and newspapers.

(c) Survey on stigma and discrimination in 2011

The 2011 Survey on Stigmatisation and Discrimination focused on key populations in Malaysia i.e. People Living with or affected by HIV/AIDS and the general public in Malaysia. The study was carried out using qualitative Focus Group Discussions (FGD). It found that most participants had an adequate knowledge about HIV/AIDS. However, having adequate knowledge about HIV/AIDS was not associated with HIV/AIDS-related stigma or discriminatory attitudes. Despite the satisfactory knowledge, discriminatory attitudes were displayed by most participants, showing a disturbing degree of unease with HIV-infected persons. This survey did not touch on the sexual and reproductive health of those interviewed.

(d) Stigma Index Assessment in 2014

A Stigma Index Assessment was incorporated into the Integrated Bio-Behavioural Survey (IBBS). The study observed notably high level of internalised stigma among KPs in Malaysia. Overall, 56% felt ashamed, 47.3% felt guilty and 47% blamed themselves because of their behaviour and appearance. In contrast to internal stigma, the majority of KPs did not significantly experience stigma and discrimination in family and

community interactions, as only 2% to 27% reported being excluded from social gatherings, abandoned by a spouse, isolated in the household, or no longer / less visited by family and friends. There have been no formal studies to assess the level of stigma experienced by HIV+ patients in health care settings yet. Plans are underway for this to take place.

(e) Survey on stigma and discrimination by HCW in 2018

The survey on stigma and discrimination was conducted on 2018. This survey was carried out using online survey to the general population and out of which, approximately 48% are HCW. The survey found that most HCW had an adequate knowledge on HIV/AIDS transmission. Thus, this satisfactory knowledge is reflected positively on their HIV/AIDS-related stigma and discriminatory attitudes towards the PLHIV. Among HCW, 85.6% believed that all children despite of their HIV status should be allowed study in the same school and not being discriminated. While 77.7% of them would buy groceries and vegetables from PLHIV vendor. This survey exhibited that provision of adequate knowledge and education about HIV/AIDS among the HCW appears to contribute to less discriminatory practices and attitudes towards the PLHIV in general. However, this survey did not specifically ask the practices regarding informed consent, testing, and disclosure; treatment and care of patients with HIV/AIDS; and attitudes and beliefs about treatment and care of patients with HIV/AIDS.

(f) Other key actions to address the issue of stigma and discrimination taken by the Ministry of Health

The MOH has taken concrete steps to address the issue on "stigma and discrimination" as spelt out in strategic number 3 of the NSPEA document i.e. *Reduction of Stigma and Discrimination.* By addressing this issue in the current NSPEA, the MOH is committed to engage civil society, corporate bodies and the community to engage in continuous/ healthy discussions and take steps to minimise the impact on the lives of mothers, children and those affected by HIV. Continuous training for the staff of the MOH (on stigma and discrimination) is also being outlined in this current strategy.

(1) Focus Group Discussion in 2017 amongst HIV+ women in Kuantan, Pahang

Note: This is a qualitative study to explore the perceptions and feelings of HIV+ women who have gone through the eMTCT process. Since this is an FGD, thus, the number of participants is relatively small i.e. 5 (five). Pahang was chosen because of the close relationship the AIDS Officers have with the HIV+ women, thereby making the discussions much easier (in a more relaxed and conducive environment).

Objectives of the above FGD:

A focus group discussion (comprising of 5 participants) was conducted in Kuantan, Pahang on 14 March 2017 to explore the perception of HIV+ mothers regarding the services received during their visits to antenatal check-ups. This FGD also explored the perception of the health care providers working at the HCs. The aim of the discussion was to focus on issues related to HIV/AIDS such as stigma and discrimination. The discussions lasted approximately 1 hour and were audio-taped.

Methodology:
All of the women who were interviewed had gone through the eMTCT programme and were interviewed after delivery (post-partum mothers). Prior to the FGD, questionnaires were structured initially with the basic knowledge on HIV/AIDS, its transmission and methods of prevention. Participants were encouraged to discuss issues pertaining to HIV/AIDS related-stigma and discrimination issues. The health care providers were also encouraged to discuss their perception towards PLHIVs in general. All of the discussion was conducted in Malay (Bahasa Malaysia) and translated verbatim to English.

Main findings:
Most of the participants felt ashamed, depressed with regard to their HIV status. The majority also expressed the desire to keep their HIV status a secret from family members and friends. Two of the participants would consider terminating their pregnancy if they were to get pregnant again. Four of the participants received positive feedbacks from their health care providers throughout their pregnancies. They also felt that the treatment that they got from the health care providers was much better compared to previous occasions. Only 1 mother felt being stigmatised and discriminated by the healthcare providers.

Note: Whilst it is important to note that majority of the mothers (4 out 5) did not have negative experience, more in-depth interviews need to be done to gauge and explore the level of stigma and discrimination as experienced by one particular mother who mentioned otherwise.

Most of those interviewed received HIV/AIDS information from traditional sources like radio, television, booklets, the medical personnel and NGOs. Majority of them mentioned that more needs to be done to address issues pertaining to stigma and discrimination towards PLHIVs.

Various purposive sampled surveys have shown a relatively high level of knowledge on HIV and its modes of transmission among Malaysians. The fact that HIV is relatively confined, at present, to selected high-risk groups and with harm reduction and prevention programmes targeted to this concentrated epidemic, has shown a positive response towards change.

(2) Development of specific module on *"Effective communication for environmental officers"*

As outlined earlier in page 24, chapter 2 (training of staff on eMTCT) this module is its final stages of documentation. The main objective of this module is to sensitise the health officers who normally do investigative work involving PLHIVs. Part of this module will address issues on how officers should behave, counsel and communicate effectively especially when they face HIV/AIDS-related issues among PLHIV (which include HIV+ mothers accessing antenatal care)

(3) *Sexually Transmitted Infection (STI) Client Friendly Clinics*

In order to encourage the KPs access appropriate treatment and care services, MOH introduced the Sexually Transmitted Infection (STI) friendly clinics with the cooperation of the Malaysian AIDS council. These clinics were specifically designed to focus on testing and management of STIs and HIV. The STI friendly clinic is unique in its approach of engaging government healthcare workers to provide quality medical care in a safe, friendly and stigma free environment for the KPs. These clinics strive to ensure early identification, treatment adherence and regular testing among KPs with an enabling environment regardless of their sexual orientation, sex and gender identities. This approach is exemplary in addressing poor engagement of KPs at risk for HIV/STI infection in treatment and care services.

Twenty-two (22) health clinics were chosen to create an "enabling environment" for key populations to seek appropriate health care management in health clinics. To promote accessibility, these clinics do not limit any particular day or number of patients for key populations to seek treatment. For example, in Cheras Health Clinic, the clinics provide special rooms, and clients do not need to register in the main area but are shown directly to the special area where key populations feel more comfortable. The staff of the respective clinics were sensitised on issues faced by key populations who might have faced previous unpleasant experiences when seeking health care. Existing clinic staffs were given trainings to sensitize them to HIV/AIDS-related issues. Where possible, new staff who had undergone a 6-month training course on HIV/AIDS counselling were placed in these clinics to meet needs of key populations. NGOs were also introduced to the staff of these clinics so there is rapport among all those concerned to strengthen access by clients to such clinics (thus, the term "friendly" is coined here). Information on STI Client Friendly Clinics is also provided n the subsequent chapter.

(4) Stakeholders' meetings between the Ministry of Health and the civil society / NGOs (inclusive of Round Table Discussion with the religious authorities)

Frequent discussions have been held between the Ministry of Health and other key relevant stakeholders to address issues of stigma and discrimination (Refer to 8.5.2 and 8.5.4)

9.5 Community involvement in eMTCT programme in Malaysia

9.5.1 Malaysian AIDS Council and its initiatives

The Ministry of Health recognises the pivotal role of civil society and communities in complementing the Government's efforts to effectively respond to the HIV/AIDS epidemic through prevention, treatment, care and support activities.

The Malaysian AIDS Council (MAC) is an umbrella body consisting of 46 partner organizations (NGOs). It main function among others is coordinate programmes and activities on HIV/AIDs and STIs at the grassroots levels. MAC was formally formed in 1992, and ever since its inception, MAC has presented meaningful opportunities for greater involvement of the community and its actors to be part of the national response on HIV/AIDS. Funding of projects contributed by the Ministry of Health, Global Fund, and other international and local agencies is channelled mainly via MAC.

MAC plays a key role in coordinating projects and activities, and supporting fund raising amongst the civil society organizations working for key affected populations as it has direct communication channels to those in need of help, counselling, financial support, and for PLHIVs, mothers / families affected by HIV/AIDS, etc.)

The inclusion of MAC as a committee member by MOH with regards to issues related to HIV/AIDS/STI at the national level has harmonised the various actions and responses by civil society organisations in a more effective and coordinated manner. Through this inclusion, MAC has demonstrated that meaningful involvement of community actors at the national level can contribute to a balanced mix of interventions that maximises the use of resources, minimises duplication of efforts and contributes effectively to improve health outcomes (6).

Through collaborative efforts, various training programmes and activities to be carried out by civil society / NGOs are being coordinated by MAC. Some of the current collaborative efforts include the following:

(a) Disbursement of funds funded by MOH and GF
(b) Monitoring and evaluation of projects funded by MOH / GF
(c) Community Based testing among the key populations
(d) Treatment Adherence Peer Support (TAPS) for the NGOs
(e) Case Management Workers projects
(f) Coordinating the regional GF grant projects e.g. SHIFT project
(g) IBBS project Malaysia 2017

Note: At the moment, projects / activities which are linked to eMTCT include continuum of care of PLHIVs in shelter homes, and involvement of women PLHIV in the CCM Malaysia meeting.

9.5.2 Country Coordinating Mechanism (CCM)

Currently, this committee is chaired by the Deputy Minister of Health. This committee comprises of representatives from various government agencies, corporate sectors, civil society and key populations. Besides discussing issues pertaining to disbursements of funds to projects funded by MOH and GF, this committee is also tasked to raise issues concerning PLHIVs. Issues concerning PLHIVs are being brought out by the community themselves and will be channelled to various other committees / agencies if need be.

Note: At the moment, there are representations of PLHIV (woman), TG, PWID, sex workers.

9.5.3 Key stakeholders' meetings

At the state levels (sub-national units), stakeholders meeting is conducted by state AIDS officers with MAC and their partner organisations to obtain updates and progress reports on harm reduction and other preventive activities and programmes with the objective to reach out to more key populations. Such meetings are held regularly usually 6-monthly and are usually chaired by the Director or Deputy Directors of the state health departments.

At the national level, various committees are formed and presided by MOH senior management (e.g. Deputy Minister of Health, Deputy Director-General of Health and Director of Medical Division). These meetings are held usually six-monthly or annually (e.g. the Harm Reduction Task Force meetings, CCM Meetings)

(a) Round Table Discussion between Government and NGO's

These "closed door sessions" are usually held at the request of non-Health sectors together with other relevant agencies and civil society. One of the latest round table discussions include discussions with the Islamic Religious Department and WHO on PrEP studies to be conducted in Malaysia.

(b) Migrant population and accessibility to the health care facilities in Malaysia – the involvement of the Ministry of Health, NGOs and the international organisations to address their needs in health care

Malaysia does not discriminate against any person who seeks general health care, in either public or private facilities. The migrant populations in the country have the right to health care as any other citizen in the country. There are no specific provisions to facilitate migrant populations to have direct access to health care facilities in Malaysia. Migrant workers who choose to seek treatment at any Ministry of Health facility are subject to the Ministry's medical fee schedule.

One of the biggest challenges faced by the MOH in meeting the health care needs of the migrant population relates to the large number of migrants in the country. There are 2.5 million registered immigrants in Malaysia and likely over 1.2 million undocumented immigrants, making up 15% of Malaysia's workforce in 2014. Thus, on many occasions it is a challenge for authorities to provide comprehensive social and health services for migrants.

However, the migrant population in Malaysia has not been denied access to medical care (including antenatal care services). Below are some of the steps taken by various international bodies, NGOs and the MOH to provide services to the migrant population:

(i) A number of NGOs and international bodies (e.g. UNHCR) have been responding to the health care needs of migrant populations before they are resettled to a third country. One of the leading NGOs in the country which has a long history working with the migrants is *Tenaganita.* This organisation has been championing the rights of migrant populations in estates, construction sites and service industries. Besides *Tenaganita,* there are also other NGOs which provide medical assistance to migrant

populations, such as the Red Crescent Society, the Outreach programmes of the Islamic Youth Movement of Malaysia (ABIM), etc.

(ii) The partner organisations of MAC have outreach programmes to reach out to female sex workers (including foreigners) who may need antenatal care services. The exact numbers of foreign pregnant women and mothers currently reached by antenatal care is unknown.

(iii) Migrants with UNHCR cards are entitled to a 50% discount on all public health care fees in the country.

(iv) There are now plans to introduce compulsory health insurance schemes for the migrant workers in the country, to facilitate meeting their health care needs whilst they are in Malaysia.

Note: (a) The numbers of migrants are currently being recorded by the Immigration Department. The number of UNCHR cards issued is being handled by UNHCR and the Immigration / Ministry of Home Affairs. (b) The employers of foreign workers are duty bound to ensure that foreign workers under their care are covered by private insurance for migrant workers. This is neither a national policy nor compulsory at the moment.

(c) Collaboration with the religious sectors

The MoH has a long history working with the religious authorities on health issues for many years. Various pertinent issues on eMTCT have been discussed with the Islamic religious authorities at the state and national levels, to facilitate activities and programmes on HIV/AIDS in the country. Some of the recent activities that have been implemented include the following

(i) Pre-marital screening on HIV,
(ii) Manual of HIV/AIDS in Islam,
(iii) Document on HIV & Islam – Responsible religious response to HIV/AIDS in Malaysia,
(iv) Round Table Discussion on HIV/AIDS issues,
(v) International Conference on HIV/AIDS in 2015.

We are expecting more collaborative work with various religious agencies on HIV/AIDS-related issues in future.

9.5.4 Production of relevant manuals / SOPs by the community and non-health sectors

Below are key manuals on PMTCT produced by the non-health sectors:

(a) Manual on HIV/AIDS in ISLAM

The HIV & Islam Manual is used to institutionalise HIV and AIDS education into the formal training of religious leaders. Initiatives to develop the content of the Manual were jointly undertaken by the Department of Islamic Development Malaysia (JAKIM) and the Ministry of Health, with Malaysian AIDS Council (MAC) assuming an advisory role. The

Manual discusses Islamic principles of HIV prevention, management of HIV in Islamic rituals, and most notably the religion's intolerance for stigma and discrimination(6) **(7)**

(b) HIV and AIDS in the workplace

The Code of Practice on the Prevention and Management of HIV/AIDS in the Workplace was prepared by the Human Resources Ministry in collaboration with representatives from various government agencies, NGOs and international organisations. The purpose of this code of practice was to reduce the spread of HIV/ AIDS and assist employers and employees in managing issues related to HIV/AIDS in the workplace. This programme is implemented to create a workplace with a high level of awareness about the spread of HIV/AIDS and to reduce the risk of employees contracting the disease. Workplace implementing the Code of Practice will be viewed by clients in a positive light as the workplace does not practice discrimination against people living with HIV/AIDS.

(c) Management of HIV/AIDS in Prisons' Settings

Realising the importance of adopting universal access to ARV treatment as part of the national strategy for the prevention and control of HIV/AIDS, a major decision was made in October 2007 to extend such treatments to all prisoners with HIV/AIDS in the country. This breakthrough decision was made at the cabinet meeting on HIV/AIDS chaired by the Deputy Prime Minister. There is now a comprehensive package of HIV care in prisons which include counselling, testing, ARV treatment and treatment for other HIV related opportunistic infections as well as the involvement of infectious disease physicians and family medicine specialists in their care. This is also in line with the National Strategic Plan for ending AIDS 2016-2030, namely the provision of treatment, care and support to HIV infected individuals without discrimination against HIV infected prisoners. In addition, HIV/AIDS education and training of staff involved in the management of prisoners with HIV/AIDS have also been introduced in a plan drawn up by the Ministry of Health and the Prisons Department. They are introduced to preventive measures, counselling and drug dependence treatment and rehabilitation. A manual on Management of HIV/AIDS in the Prisons' Settings has also been jointly developed between the Ministry of Health and the Prisons Department in 2001.

(d) Adolescent Health Policies

Adolescent health issues are addressed by different government agencies, private sectors and NGOs. The major agencies are the Ministry of Health, Ministry of Education, Ministry of Youth and Sports, Ministry of Women, Family and Community Development, Malaysian Islamic Development Department, Federation of Family Planning Association Malaysia, Malaysian Medical Association, Malaysian Association for Adolescent Health, Malaysian Mental Health Association and Malaysian AIDS Council.

Under the National Adolescent Health Plan of Action (NAHPOA) 2006-2020, sexual and reproductive health services were provided to all adolescents in all primary and secondary healthcare facilities nationwide. With this kind of access, a total of 11,024 new antenatal cases among 10 to 19 years old have been registered at the Ministry of Health primary care facilities in 2017, of which 3,694 (33.5%) were unmarried.

The Government of Malaysia has also established six youth-friendly adolescent centres known as kafe@TEEN to increase access to reproductive health information and

services for young people aged 13 to 24 years, accordingly to provisions of the National Policy on Reproductive Health and Social Education and its Plan of Action 2009. These centres offer a wide range of services such as reproductive health information and education, skills building programmes, reproductive health services as well as counselling and recreational activities.

(d) The AIDS Charter

This charter sets a basic framework of shared rights and responsibilities which was launched during the early stage of MAC's formation in the early 90's. Some of the highlights which have been outlined in this Charter include the following: -

(i) Recognising the imperative necessity for concerted action by all Malaysians to halt the spread of HIV.

(ii) Recognising the paramount importance of HIV/AIDS awareness and knowledge among all sectors of the population.

(iii) Recognising that no programme of awareness, education and knowledge can fully succeed in Malaysia without incorporating and integrating the shared religious and ethical values of multi-ethnic Malaysia.

(iv) Recognising that there is wide-spread discrimination and prejudice against persons living with HIV/AIDS, and their partners, families and caregivers.

(v) Recognising that the escalating HIV/AIDS epidemic will have an adverse impact on the socio-economic development of the nation, thus endangering the achievement of Malaysia's Development Policy as enshrined in Vision 2020 **(8).**

9.6 Capacity building for service providers

MOH continues to develop policies and standards to improve healthcare services (including PMTCT services), to keep pace with developments in technology and to be in line with current guidelines of international organisations. Numerous capacity building activities for healthcare service providers, including for the public sector, private sector, corporate bodies, and NGOs / civil society, have also been undertaken to continuously improve the overall services being rendered to the public.

Some of the main activities being conducted and under consideration include the following:

(a) Development of policies, guidelines, handbooks and other IEC materials. These materials are produced to increase knowledge and awareness of MOH staff, the public and civil society. Materials produced for civil society, corporate bodies and non-health sectors are usually produced in collaboration with MAC or other NGOs.

(b) In recent years, it has been a standard practice for the HIV AIDS Sector, MOH to conduct workshops, training and roundtable discussions with MAC and other partners in health, in recognition of the fact that good health outcomes are

usually achieved through consensus and collaboration across sectors towards programme effectiveness.

(c) In order to improve the skills and knowledge of MOH health staff, echo-trainings, workshops and discussions are conducted periodically at the state and district levels for efficient delivery of services to the public. Some of the activities, programmes, trainings and workshops are as follows:

(i) Workshops on PMTCT programmes
(ii) Workshops on HIV testing & counselling
(iii) Community Based Testing (CBT)
(iv) Women & HIV / AIDS

(d) As part of the monitoring and evaluation process, supervisory visits are conducted periodically using a multi-sectoral approach, i.e. supervisory visits by relevant stakeholders. For example, in 2016, two supervisory visits were jointly conducted by the MOH and MAC to project sites which received funds from the MOH and GF. These visits were conducted as part of our social responsibility to look at the providers' competence in delivering services to KPs.

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CHAPTER 10

SUSTAINING THE SUCCESS OF EMTCT OF HIV AND SYPHILIS PROGRAMME IN MALAYSIA

The Ministry of Health Malaysia is confident of sustaining the success of *Elimination of Mother-to-Child Transmission Programme (eMTCT*) of HIV and syphilis in Malaysia. Due to strong political commitment from the government, a multi-sectoral partnership with involvement of multiple stakeholders, we believe the achievement of the eMTCT programme will be sustained in years to come. The support and involvement of various non-health key partners are indeed crucial.

Universal voluntary testing for HIV and syphilis, provision of antiretrovirals and formula milk for pregnant women has been integrated into antenatal care services in Malaysia for many years. Over the past 5 years, we have noted that our vertical transmission rate of HIV is persistently below 2% and the congenital syphilis rate has been on a steadily declining trend (1).

10.1 Factors contributing to the success of eMTCT of HIV and syphilis in Malaysia

There are many factors which have contributed to the success of the eMTCT project in Malaysia. Malaysia stands out with its high-level commitment to maternal child health, the multi-sectoral partnership and stakeholder engagement funded nearly entirely by national resources which allows other diseases control programmes such as HIV and syphilis be fully integrated into the maternal child health platform.

We have learnt and applied various strategic frameworks that cover a wide range of issues ranging from socio-cultural, epidemiological, medical and ultimately to antenatal care. We have also adapted approaches from regions around the world to suit our local situation. Malaysia has firmly taken an integrated, rights-based approach to diagnosis and treatment for HIV and syphilis. Malaysia has as well as established multi-sectoral collaboration with y government and non-government agencies around the region and globally.

10.1.1 Leadership and commitment of the government, NGOs/civil society and other key stakeholders - Multisectoral approach

The multi-sectoral approach in health taken by the Malaysian government is the key driver to the success of many health-related programmes and activities in this country, including the eMTCT programme. The involvement of key ministries (from the relevant government stakeholders), civil society, non-government organisations and international representatives at various committees, task forces, reflect the high level of commitment by various stakeholders to combat vertical transmission of HIV/AIDS/syphilis in the country.

The MOH does not act alone; there are many examples that reflect the existence of partnerships with other stakeholders when it comes to matters of national interest. For example, with reference to eMTCT programme and activities, the MOH has co-published national guidelines and standard operating procedures with other partners, namely:

(a) Malaysian Society for HIV Medicine
(b) Malaysian Paediatrics Association
(c) Dermatology Society of Malaysia
(d) Academy of Medicine of Malaysia
(e) Malaysian AIDS Council

This smart partnership approach is expected to be sustained in the years to come.

10.1.2 EMTCT - an example of integrating of common approaches, strategies and practices into common action

The prevention and control of STIs in Malaysia has been integrated into the HIV/AIDS programmes for many years. Thus, programmes for STIs have also been incorporated into the HIV/AIDS programmes. The integration of STIs/HIV/AIDS and the MCH services in Malaysia is clearly a fine example of how the mission of eliminating dual infections into a common EMTCT programme can be made a success by integrating the services into the maternal child health platform.

10.1.3 Sound financial support from the Malaysian government and other key stakeholders

The HIV/AIDS and STIs prevention and control programmes in Malaysia (which includes the eMTCT project) receives funding of more than RM200,000,000 (USD48.78 million) annually. Malaysia has a self-sustaining funds for eMTCT as the budget for this important activity / programme comes mainly from the government. On average, only 5% of the country's HIV/AIDS & STI annual budget comes from international donors.

Malaysia is confident that funding of HIV/AIDS/STI projects will continue to be on the Government's agenda (1). The MCH services will most certainly remain one of the main health priorities in the country, as reflected by the enhancement of primary health care services in many of our nation's health care reviews. Thus, we are equally confident that these health care reviews will ultimately benefit key beneficiaries i.e. HIV positive and syphilis positive mothers and their families.

10.1.4 Strength of the Malaysian maternal-child health (MCH) care services

The health clinics will continue to provide high quality services which will no doubt benefit both the HIV and syphilis positive women, their exposed infants, partners and families. The HIV and syphilis infected mothers will continue to have access to the continuum of care and support for many years to come, be it from the state or the community.

The eMTCT project in Malaysia is an integrated programme with linkages into the existing maternal and child health services, and where appropriate, into primary health care, family planning and sexual and reproductive health services. We believe these linkages will continue to be strengthened. The strength of our primary health care system has been cited as one of the successful models for developing countries as reflected below:

(a) Human resources

There are 329 Family Medicine Specialist (FMS) serving in 257 HCs all over the country. This ensures that 26% of government health clinics in Malaysia are staffed by trained personnel with clinical specialist care training. Over the next 5-10 years, we are confident that there will be an incremental increase in the number of such specialists serving our health clinics. (Tables 3.1 and 3.2). In addition, currently, there are 11,122 nurses, 1,896 MLTs, and 2,140 pharmacists serving the health clinics. We are also confident that training of personnel will be greatly enhanced in the years to come, matching the skills and expertise of other developed nations.

(b) Infrastructure

As of 31st December 2015, the number of health clinics in the country stands at 1,061 (including Maternal and Child Health Clinics). In addition, there are 1,808 Community Clinics and 334 *Klinik 1Malaysia (1Malaysia clinics)*. As mentioned in Chapter 3, 1Malaysia clinics are health clinics which are mainly placed in the urban areas, with the aim to provide the urban poor with basic health care services (2). Due to the extensive network of health infrastructure available in both urban and rural areas, the population of Malaysia has good access to health services especially for MCH. In fact MCH services were the first services provided in primary health care centres and have been gradually expanded over the past years. The MOH will continuously improve the quality of services that we are rendering to the public, which is inclusive of the eMTCT programme.

(c) Treatment coverage for HIV positive mothers, child and partners

The treatment coverage of HIV positive pregnant women during antenatal remains consistently above 95% over the last 3 years (1). HAART is provided free for all Malaysians, and 50% discount is given to UNHCR card holders.

While government employees are eligible for free medical and dental treatment in government hospitals, they can avail themselves of private health insurance for which they pay out-of-pocket. For employees in the private sector, the majority of them are insured through private health insurance as part of employee benefits. Other social security contributions by employers and employees for health benefits are the Social Security Organisation and the Employees Provident Fund. Foreign workers are also covered under a private health insurance scheme for healthcare in public hospitals. For HIV / AIDS patients, treatment coverage for HIV AIDS and STI treatment is best reflected in situations as described below: -

(i) First line regimen is given free of charge to HIV/AIDS patients, whilst the second line regimen is heavily subsidised by the government.

(ii) All UNHCR card holders are given a 50% discount on treatment in outpatient departments of government hospitals (inclusive of HIV/AIDS treatment). The issuance of the UNHCR card is strictly being monitored by UNHCR which has an office in Kuala Lumpur and works very closely with the Immigration (Home Affairs Ministry) Department.

(iii) The Malaysian AIDS Council has also initiated the Paediatric AIDS Fund to cater to the needs of HIV positive children who cannot pay (certain criteria need to be met before MAC releases funds for the purchase of the second line regimen e.g. Orphans, children of single mothers, children placed in shelter homes, patients without a stable income, etc. are some of the criteria being used). It is estimated that the number of patients on the second line regimen is less than 5% of the total patients receiving ART. Currently, MAF (Malaysian AIDS Foundation) has initiated and collaborated though the smart partnerships programme with Sime Darby Foundation to subsidise second line treatment for about 70 patients.

(iv) Four state religious departments have provisions under their Islamic Enactment Act to support the HIV AIDS patients through special payment schemes using the tithe contributions *("zakat").*

Refer to Appendix 7 for other benefits packages for PLHIV.

10.1.5 Strength of our surveillance system

(a) *e-notice,* the National AIDS Registry and the CDCIS for communicable diseases (syphilis)

About 10% of government health clinics are connected to an online *e-notice* surveillance system that requires mandatory notification of communicable diseases including HIV/AIDS/syphilis (the Tele primary Care system). This surveillance system is expected to expand. This online surveillance system allows data to be viewed centrally in the Ministry of Health and assists District Health Offices and the State Health Departments to monitor and evaluate the impact of HIV/STI programmes. As for the process indicator (antenatal coverage), every state is required to report to MOH, and this includes data collection from the private sectors (clinics and hospital) as well. The extensive network of our surveillance system shows that data captured through our health system on the eMTCT programme is very reliable, thus minimising loss of patients' information.

(b) Follow-up of exposed infants (HIV and syphilis) and their families

There are still some areas which need improvement e.g. the surveillance data on congenital syphilis and follow-up of exposed infants until they are of certain age (e.g. < 13 years old). Currently, mothers who are HIV / syphilis positive and their exposed infants are followed up until the children reach the age of 2 years. There is a need to update clinical practice guidelines for these exposed infants and their families. For example, the follow-ups of these infants need to be streamlined between the clinical counterparts (who usually follow up on these exposed infants) and the family medicine

specialists (FMS) based in health clinics. It would be ideal if the parents of the exposed infants are counselled from time to time, and especially so for babies who are detected to be positive. We hope to strengthen documentation of the follow up of cohorts of those diagnosed with congenital syphilis and HIV-exposed infants as the treatment for these children are prolonged and follow up can be lifelong.

(c) Continuous development of creative ideas and innovations in the surveillance system e.g. investigation format for congenital syphilis and surveillance of stillbirths in the country

Various innovations and creative ideas need to be in place to make our surveillance system robust. Some of the newer interventions include the development of an investigation format for congenital syphilis and surveillance of the causes of stillbirths in the country by the Family Health Development Division.

10.1.6 Strong support from the non-health agencies and civil society

The Ministry of Malaysia has continuously recognised the importance of community participation in ensuring the success of our programmes and activities. Thus, to ensure that this partnership is maintained, MOH will take the following actions:

(a) Participation of Malaysian AIDS Council in ensuring the continuum of care of mothers and children who are HIV positive

Malaysian AIDS Council has been one of our key partners in the prevention and control of HIV/AIDS & STIs since its establishment in 1992. To date, the MOH has allocated almost RM90,000,000 (USD21,951,220) to fund projects by the NGOs/civil society. In 2016, the Ministry of Health approved RM7,000,000 (USD1,707,320) for HIV/AIDS & STI prevention and control programmes to be channelled to MAC, out of which almost RM1,000,000 (USD243,902) was approved for shelter homes for the placement of HIV positive patients, including mothers and their children. We are confident that this support will be continued and enhanced in the years to come.

(b) Participation of women living with HIV+ at the national level committees

Currently, 25% of the seats in Malaysia's Country Coordinating Mechanism Committee (CCM Malaysia) are allocated to civil society, including two seats for representatives for women living with HIV and female sex workers (3). The inclusion of women with HIV exemplifies smart partnerships between the government and NGOs to ensure that the voices of the women living with HIV are heard.

(c) Involvement of non-health sectors for the well-being of HIV positive women and their families

The MOH is confident that the involvement of the private sector and religious authorities will continue to be sustained in future as reflected by the various activities and programmes to support women living with HIV and PLHIVs in general. The projects currently being carried out include the disbursement of funds to PLHIV shelter homes, subsidies for the procurement of second line ART regimen, special incentive schemes for the procurement of ART for children, etc.

10.2 Causes of new perinatal HIV and congenital syphilis infection

10.2.1 Vulnerable and high-risk population groups presenting late during labour or delivery

The MOH realises that there are still pregnant women who either present late at antenatal check-ups, showing up only during labour or who have poor adherence to HAART. The number of pregnant women who are considered as a “late booking” (e.g. arriving in labour rooms without antenatal cards or HIV screening) is estimated to be around 3-5% of all antenatal deliveries in a year). We need to further evaluate this issue e.g. further studies / surveys are needed to ascertain the determinant factors that triggering late booking and to identify interventions to address these factors.

Based on some informal feedbacks that we have received, we do realise that stigma and discrimination against women by a few health service providers may be one of the reasons for late presentation and non-compliance.

As one of our proposed interventions to minimise this issue, the MOH is developing a national guideline to counter stigma and discrimination, especially among key populations, in collaboration with our civil society partners. We are confident that this initiative will be fruitful in the years to come.

10.2.2 Accessibility

Accessibility to health care facilities is not a major issue in Malaysia. However, we also acknowledge there are segments of population in this country who might have some difficulties in accessing health care e.g. immigrants, indigenous populations in some parts of the country and key populations. We need to support more NGOs to provide health services to these vulnerable populations e.g. reaching out more through home visits, having more outreach programmes, and initiating special financial schemes. Some of these initiatives and incentives have been addressed by charitable organisations and religious bodies.

10.2.3 Follow up during post-natal care

Early infant diagnosis services are still highly centralised and loss to follow-up during post-natal period are still occurs. Improvements in early detection and management of HIV infected women and their infants have resulted in reduction of the incidence of HIV infection/congenital syphilis in children. There is a need for closer collaboration between the health clinics and paediatric clinics for improved coordination of follow-up of these exposed infants, so that loss to follow-up will not be an issue.

10.3 Strategies for the sustainability of eMTCT of HIV and syphilis programme in Malaysia

10.3.1 Surveillance systems strengthening (exposed infants)

The gaps found in the data validation exercise should be corrected and minimised to ensure that exposed infants are not lost to follow-up. Some of the gaps that were identified include lost to follow-up of pregnant women accessing antenatal care and exposed infants, lack of communication between the hospital and health staff in terms of managing HIV and/or syphilis positive mothers, lack of knowledge regarding the status of exposed infants especially among the HC staff.

To minimise such occurrences, the following areas need strengthening as follows: -

(a) Strengthening the surveillance of eMTCT of HIV and syphilis at the state level and in health delivery centres (government and private)

To assist in eMTCT programming and to ensure it succeeds, it is pertinent that MOH ensures all health care providers are well versed with data management, this ensuring all key stakeholders are well informed that indicators/targets are kept on track. The launching of the Malaysian Health Data Warehouse, a one-stop centre for health-related data gathered from public and private hospitals, by the Ministry of Health in April 2017 and the continuing development of the electronic medical records in hospitals and primary care clinics will strengthen the surveillance system, including for eMTCT, in the coming years. At the moment, the MOH should also be looking at the surveillance systems beyond government sectors to enhance prompt actions and interventions. Efforts will be made to strengthen the e-notification system to link congenital syphilis to the Congenital Syphilis Registry including revision of case definition for congenital syphilis. Also, strengthening existing stillbirth surveillance to include syphilis as causal factors.

Reporting of data by the private hospitals/facilities will be strengthened. In depth analysis will also be carried out on each case of mother-to-child transmission of HIV and congenital syphilis in the different population groups to improve programme management.

Policies and regulations on HIV and syphilis testing in the private laboratories will be reviewed, assessed and monitored regularly in line with WHO laboratory guidance to strengthen national laboratory quality management.

(b) Encouraging male partners involvement in eMTCT

Terengganu, Kedah, Penang and Sabah are examples of the states in Malaysia which have started voluntary male partner HIV testing (male partner HIV and syphilis testing is not part of the standard package for HIV testing for mothers accessing antenatal care in Malaysia, thus, the pre-test counselling sessions for male partners may differ from one facility to another). It is estimated that the uptake of the male partners' HIV voluntary testing is around 25–40% (4). We strongly believe that this initiative should be encouraged so that interventions

e.g. standard treatment, care, support could be initiated as soon as the diagnosis is confirmed. Standard practice guidelines (SOP) for voluntary HIV and syphilis testing for male partners of mothers accessing antenatal care should also be encouraged and initiated.

In addition, a next step is also to increase the uptake of syphilis voluntary screening among male partners of mothers who are TPHA+.

10.3.2 Strengthen the accessibility "vulnerable populations" to HIV and other STIs (e.g. syphilis) to health facilities

The HIV epidemic remains a "concentrated" epidemic in Malaysia. The majority of those infected with HIV and STIs are usually associated with vulnerable populations groups (PWID, MSM, TG and sex workers). Strong linkages between these vulnerable populations and the health sector need to be maintained so that they are not marginalised even further. The *"STI Client Friendly Clinics Concept"* which has been introduced in 22 Health Clinics is an example of how NGOs could encourage key populations to seek care and get appropriate treatment and care by well trained personnel (5).

Note:
22 Health Clinics all over Malaysia have been chosen to be in this project. The Health Care providers (FMS, doctors, nurses, medical assistants, health inspectors) were specifically trained to be in contact with NGOs/civil society organisations. These NGOs will act as a "bridging component" between the clients and the health care providers. The NGOs will encourage the key populations (PWIDs, MSM, sex workers, transgenders) to seek appropriate care (for STIs and HIV) at the health clinics. These NGOs will bring in the key populations for the first time to these clinics where they (key populations) will be in an environment which is deemed not to be "hostile" towards them (enabling environment which does not discriminate against the clients' sexual preferences or gender identities).

10.3.3 Participation of key populations in eMTCT

We take note that in order for eMTCT to be successful, participation from key and vulnerable populations is crucial. The eMTCT programme needs to be responsive to the needs of the community, including vulnerable and key populations. Key populations should also be encouraged to voice their grievances if any and voice their opinions on how service delivery could be improved to better serve them.

(a) Service delivery concerns

To ensure quality service delivery at both public and private, a revised guideline for prevention of mother to child transmission of HIV and syphilis is crucial. This would include all aspects of intervention (mother, infant and partner).

The MOH has developed a system for the public to air their dissatisfaction (6). This system, called SisPAA KKM, records grievances, especially those related to service delivery at clinic/outpatient/in-patient levels, and ensures that they are dealt appropriately. This system allows the Heads of Departments to take immediate remedial actions. It is coordinated by the Headquarters in Putrajaya. We are also confident that the on-going process of sensitising health care staff

on the needs of vulnerable populations will continue to be at the top of the MCH agenda for many more years. Likewise, regular efforts to review policies and practices to address issues of stigma and discrimination will be continued.

Ongoing community empowerment programmes will be strengthened particularly among vulnerable women to raise awareness on HIV and Gender-based Violence (GBV), and to reduce stigma and discrimination.

Special efforts will be made to review access to HIV testing and treatment including other SRH services for older adolescents (below 18 years) without requiring parental or guardian or husband consent.

Note: At the moment, there is no study or in-depth analysis done with regard to the complaints of non-Malaysians (especially on HIV/AIDS issues or the eMTCT programme).

(b) Engaging community leaders among the migrant population

We need to ensure that HIV and/or syphilis positive pregnant women among the migrant population have access to HIV/STI-related services, which includes the eMTCT programmes. Community leaders among these migrants need to be engaged in order to facilitate a better understanding between the healthcare providers and the needs of those affected in these communities.

10.3.4 Self-sustaining health system

The Malaysian government has commissioned a review of its health system with a view to support health system strengthening to address the issue of sustainability of the system in the face of current challenges of the double burden of disease and escalating health care cost. The situational analysis has been completed and the review is at the stage of testing interventions. With these efforts, Malaysia hopes to continue to be self-sustaining in facing the burden of diseases, including communicable diseases, and specifically for eMTCT for HIV and Syphilis.

With the enhanced PHC initiative planned for implementation in July 2017, over the next 5-10 years, we are confident PHC services will increase in coverage and quality with investments in infrastructure upgrading and human resource competencies, specifically in preventing HIV and syphilis and responding to mothers with HIV and syphilis in primary care. A strong health system and Malaysia's self-reliance on production of human resource for health are crucial in sustaining eMTCT of HIV and syphilis.

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ESTIMATING PREGNANT WOMEN

Malaysia has HIV surveillance system in place before the first HIV case was reported. All HIV, AIDS and HIV/AIDS related deaths cases are notified to this system under Malaysia CDC Act. The reporting sources include government and private health facilities through HIV screening at drug rehabilitation centres, prisons, blood donor, ANC, STI, Hepatitis and TB cases as well as for all PLHIV contacts. It was estimated that 95% of PLHIV in this country have been tested and know their status.

This triangulation exercise is conducted to validate the antenatal coverage in Malaysia for 2015 and 2016. Data for this triangulation exercise was sourced from various related agencies including UNDP, Department of Statistics Malaysia (for vital statistics data), Home Ministry (for immigration data), Malaysia AIDS Council (for surveys and programme data among key population), Amnesty International (for migrant data) and Ministry of Health programmatic data from multiple divisions.

Methodology

Two main crucial data were calculated during triangulation; namely estimated total pregnancy and possible missing PLHIV pregnant mother from antenatal care.

(a) Estimated total pregnancy was calculated by summation of reported live births, stillbirths and abortions in 2015 and 2016. These numbers are required to be reported by all health facilities to Health Information Centre (HIC).

(b) We have also calculated the number of possible missing PLHIV pregnant mother from antenatal care. There are 3 possible groups of women missing out antenatal care namely female PWID, teenage pregnant mother and female sex worker (FSW). These data were triangulated using short surveys from MAC, findings from IBBS 2014 and programmatic data from MOH.

Summary findings

(a) Having triangulated the data above, we found out that the results were compatible with programmatic data with new estimated pregnant women of 557,740 and 544,661 in 2015 and 2016. Using this estimated pregnant woman as denominator, we derived the antenatal coverage of 95.6% and 96.7% for 2015 and 2016.

(b) The number of missing PLHIV pregnant mothers from attending ANC were minimum, 8 cases in 2015 and 10 in 2016. These numbers were then added to the total PLHIV pregnant mother cases in programmatic data. This adjusted programme number that reflects the population level data of PLHIV pregnant mother was used as the adjusted and triangulated denominator for ART coverage calculation.

Estimated PLHIV pregnant women not receiving antenatal care based on data triangulation

	2015	2016	2017[g]
Female PWID			
Estimated size of female PWID[a]	3,400	3,400	2,300
HIV prevalence[b]	3.8%	3.2%	2.5%
Estimated number of HIV+	129	109	58
Estimated number of pregnant female PLHIV PWID[c]	0	0	0
Number of PLHIV pregnant PWID reached by NGO to access antenatal care[d]	0	0	0
Number of pregnant female PLHIV PWID not receiving antenatal care	**0**	**0**	**0**
Teenage pregnancy			
Estimated pregnancy among teenage (15-19)	18,434	17,811	17,110
Percentage of HIV+ among teenage girls	0.08%	0.13%	0.11%
Estimated number of HIV+	14	22	19
Number identified from ANC (from line listing PMTCT)	9	18	16
Number of HIV+ teenage mother (15-19) not receiving antenatal care	**5**	**5**	**3**
(c) Female Sex Worker (FSW)			
Estimated population size of FSW	21,000	21,000	21,000
HIV prevalence of FSW (IBBS 2014)	4.8%	5.0%	5.3%
Estimated number of FSW (18-49) (IBBS 2014)	17,535	17,535	16,905
Estimated number of pregnant FSW (18-49)[e]	81	81	78
Estimated number of pregnant FSW PLHIV (18-49)	4	4	4
Number pregnant FSW PLHIV reached by NGO to access antenatal care[f]	1	1	3
Number of PLHIV pregnant FSW not receiving antenatal care	**3**	**3**	**1**
Total number HIV pregnant women not receiving antenatal care	**8**	**8**	**4**

[a]*Female PWID is recorded around 2% of male PWID from NGO database*
[b]*We used FSW HIV prevalence as proxy in the absence of representative female PWID data from surveys and IBBS*
[c]*Pregnancy rate of female PWID is taken as 0.2% based on M&E from NGO (SyrEx2)*
[d]*Assuming pregnant rate for PWID is similar to that of FSW*
[e]*Pregnancy rate among FSW was found to be 0.46% from quick survey involving outreach worker providing service to FSW*
[f]*Percent pregnant FSW accessing antenatal care was 20% based on short survey involving outreach worker providing service to FSW*
[g]*2017 data is to show the trend, not as part of the validation*

Summary of PMTCT Results 2015-2016, SPECTRUM v5.63

	2015	2016	2017[a]
PMTCT coverage	**96%**	**97%**	**98%**
PMTCT coverage of more efficacious regimens	96%	97%	98%
MTCT rate at 6 weeks	2.46	1.99	1.74
Final transmission rate including breastfeeding period	**2.46**	**1.99**	**1.74**
Number of HIV+ breastfeeding women at 3 months	0	0	0
Number of HIV+ breastfeeding women at 12 months	0	0	0
Number of new child infections due to mother-to-child transmission			
Total	8	6	6
Male	4	3	3
Female	4	3	3
Treatment coverage for HIV+ pregnant women	**96%**	**97%**	**98%**
Number of infants diagnosed with HIV	8	6	6

[a]2017 data is to show the trend, not as part of the validation

Appendix 3

Study on non-MOH Hospitals (conducted in Klang Valley for the states of Selangor, Kuala Lumpur & Negeri Sembilan)

The HIV/AIDS/STI Sector of the MOH conducted a survey in May 2017 to determine the extent of PMTCT coverage and achievements among non-MOH Hospitals; in this study we covered 2 university hospitals, 1 military hospital and 30 private hospitals in the Klang Valley (which covers the states of Selangor, Negeri Sembilan and Kuala Lumpur).

Significant survey findings were as follows:

(a) 32 (97%) of the hospitals stated that HIV screening among antenatal mothers is part of the antenatal package of their services.

(b) Average HIV test coverage for antenatal were 76% in 2014, 72% in 2015 and 71% 2016.

(c) Average syphilis test coverage for antenatal mothers were 69% in 2014, 64% in 2015 and 63% in 2016.

(d) RTK Combo test is the commonest (73%) method of screening test used by these hospitals (n=24), followed by EIA (n=5)

(e) The commonest form of confirmation test is the Western Blot (WB) i.e. n=15

(f) University Malaya Medical Centre (UMMC), being the biggest tertiary non-MOH facility recorded the highest number of stillbirths among all the hospitals which responded, citing 43 stillbirths in 2014, 44 in 2015 and 34 in 2016, which accounts for about 48% of all stillbirths recorded in hospitals (the hospitals surveyed in this study). All the cases of HIV and syphilis were treated in this hospital.

(g) None of the hospitals which responded recorded vertical transmission of HIV out of a total of 5 HIV+ mothers who delivered from 2014 until 2016.

(h) All hospitals surveyed had routine syphilis screening among antenatal mothers.

(i) VDRL is the commonest form of screening test (n=22) followed by RPR method (n=11), while TPHA (n=33) is the commonest test for confirmation.

(j) There were 7 babies born to TPHA+ mothers from 2014 to 2015; all were treated. However, one (1) case of congenital syphilis was recorded in 2015.

(k) 6 Hospitals reported giving Benzyl penicillin to TPHA+ mothers.

(l) 26 Hospitals (78.8%) of the hospitals surveyed mentioned that investigations will be conducted if there are cases of stillbirths (e.g. TORCHES).

Appendix 4

Main agencies directly responsible in implementing PMTCT of HIV and syphilis in Malaysia

(A) GOVERNMENT AGENCIES

1. Agencies under Ministry of Health Malaysia

The Ministry of Health Malaysia is the principal agency in Malaysia for the implementation of PMTCT programme in Malaysia. The Ministry of Health Malaysia formulates the national policies, rules, regulations, guidelines, training for all the delivery levels, state and national levels. The national level manages all data related to PMTCT programmes and activities which includes screening data for accuracy, completeness, summarises reports, produce relevant information either for top level management or public at large.

1.1 National level

1.1.1 The Public Health Programme at the National Level

The Public Health Programme is headed by the Deputy Director General of Public Health. Situated in Federal Administrative capital of Putrajaya (principally located in Parcel E), the lead Department for PMTCT programmes and activities is the Public Health Department of the Ministry of Health, and currently rests on the HIV/AIDS/STI/Hep C Sector, Disease Control Division of the Ministry of Health. For the PMTCT programme / activity, the HIV AIDS STI Sector is assisted by the Family Health Development Division of the Public Health Programme. Several other departments are assisting the HIV AIDS STI Sector in the implementation of the PMTCT project i.e. the Nutrition Department, Health Promotion, Medical Division).

1.1.2 The Medical Division of the Ministry of Health

The Medical Division of the Ministry of Health is headed by the Deputy Director General of Health (Medical services). This division is also situated in the Federal Administrative capital of Putrajaya, and its principal function is to formulate policy, guidelines, development of programmes and activities for the Hospitals throughout the country.

1.1.3 The National Institutes of Health / major referral centres

There are 6 Institutes for Health - Institute for Medical Research (IMR), the Health Management Institute (IHM), Institute Health Behavioural Research (IHBR), Institute for Public Health (IKU), Institute for Health Systems Research (IHSR) and Clinical Research Centre (CRC).

(a) Institute for Medical Research (IMR)

All PCR results of babies born by HIV+ mothers will be directly done and analysed by the Virology Department of IMR. Results usually take 6 weeks from the day the samples are received.

(b) Paediatric Institute of Hospital Kuala Lumpur

The Paediatric Institute of HKL serves as the tertiary referral centre for infectious disease management (e.g. HIV/AIDS and Congenital Syphilis) in Malaysia.

(c) Sungai Buloh Hospital, Selangor

This is the main referral hospital for infectious disease (e.g. HIV/AIDS, Dengue, etc) in the country, and is in Sungai Buloh in the state of Selangor.

1.2 State level

There are 3 Federal Territories (Kuala Lumpur, Putrajaya and Labuan) and 12 states in Malaysia. Each state health department is headed by a State Health Director (except for Putrajaya which administratively headed by the Kuala Lumpur State Health Department).

The State Health Department coordinates all the Hospitals in the state, convene meetings for clinical and health staff on PMTCT. Training, supervision and monitoring of staff on PMTCT is a joint effort between the State Health Department, District Health Office and the Hospitals in the particular state.

1.2.1 HIV/AIDS/STI and Hep C units of the State Health Department

The programmes / activities of the PMTCT programmes in all states is coordinated by the State AIDS Officers who are trained in Public Health, and he / she is answerable to both the Deputy Director of State Health (Public Health) and Director of the State Health Department.

The State AIDS Officer is assisted by Maternal and Child Health Officer to convene meetings and training with the clinical / health staff in the particular state on PMTCT programmes / activities, care and treatment of HIV+ mothers / babies. They are also entrusted to conduct monitoring and supervision and coordination with various network agencies in the state.

Every month, the HIV/AIDS/STI and Hep C unit of each state will collate data from the Hospitals (in the respective states), District Health Offices, summarises data on PMTCT and forward the data to the National Level.

1.2.2 Hospitals

Depending on the size of the state, each state Director is mandated to give directives, formulate policy into action. These facilities provide quality, standard antenatal care for pregnant women according to the latest guidelines from Ministry of Health Malaysia.

1.3 District level

Currently there are 141 District Health Offices in Malaysia which oversees all of the programmes / activities concerning PMTCT.

1.3.1 District Health Offices (DHO)

Each District Health Office is headed by a Medical Officer of Health (MOH) majority of whom have postgraduate training in Public Health. These agencies will translate all the policies into action, take part in capacity building of staff, provide material support to service outlets, supervise and monitor the activities / programmes being carried out, manage relevant data sets on PMTCT, produce reports, coordinates with the State / Headquarters agencies.

The facilities below provide pre-marital HIV screening for Muslim and Non-Muslim couples, pre / post-test counselling for HIV and syphilis, voluntary anonymous testing, laboratory diagnosis for HIV and syphilis (RTK / RPR rapid test kits), care and treatment for pregnant women with HIV/ syphilis, condoms / other forms of contraception

(a) Health Clinics *(Klinik Kesihatan)*
(b) Maternal and Child Health Clinics *(Klinik Kesihatan Ibu & Anak)*

These services are integrated with the outpatient / antenatal care services at the facilities with referrals to Hospitals or at the HIV / STI clinics. Such facilities also are the main centres where relevant data on PMTCT are collated and distributed to the state and HQ levels. Certain Community clinic and Klinik 1Malaysia perform HIV and Syphilis screening

2. Agencies other than the Ministry of Health

The following Hospitals are government run Hospitals but governed by different Ministry. Below is the list of non-MOH Hospitals which comes under the purview of the Ministry of Higher Learning (Tertiary Education).

a) University Malaya Medical Centre (PPUM)
b) Universiti Kebangsaan Medical Centre (PPUKM)
c) Universiti Sains Malaysia Medical Centre (PPUSM)
d) Universiti Teknologi Mara Hospital, Sungai Buloh
e) Universiti Islam Antarabangsa Hospital, Kuantan

The Hospital below comes under the purview of the Ministry of Defence.

a) Army Hospital Lumut Perak
b) Sungai Udang Army Hospital Melaka
c) Sultan Mizan Zainal Abidin Hospital Kuala Lumpur
d) Military Hospital Syed Sirajuddin Camp, Gemas, Negeri Sembilan

(B) NON-GOVERNMENT SECTORS / PRIVATE AGENCIES / NGOS

The examples below list some of the active NGOs / civil society partners of the government which are actively involved in the PMTCT programme on HIV & syphilis in Malaysia – in reference to Prongs 1, 2, 3 and 4

1. Malaysian AIDS Council

The Malaysian AIDS Council (MAC) was established in 1992 to serve as an umbrella organisation to support and coordinate the efforts of non-governmental and other organisations working on HIV/AIDS issues in Malaysia. MAC works in partnership with government agencies, the private sector and international organisations to ensure a committed and effective response to HIV/AIDS issues in Malaysia. Currently, MAC is comprised of the Secretariat located in Kuala Lumpur. Having 48 Partner Organisations (POs), MAC among others aims to provide nationwide coverage of community-based HIV services and serves as the common voice for the communities served.

2. PTF Foundation

PT Foundation, a CBO has been in existence for a long time in Malaysia. Among its many objectives, this CBO strives to be the leading CBO in Malaysia working with KPs affected and infected with HIV/AIDs, who are also often with gender identity and sexual health issues. PT also provides information on advocacy, HIV prevention, care and support services. Besides women affected by HIV/AIDS, among PT main clients include sex workers, transgender community, MSM, PWIDs and PLHIV.

3. **KLASS**

KLASS was initially set up to cater to the needs of the Chinese and Tamil speaking communities, where initially there was a huge gap in information, counseling and support for groups among the PLHIV in these groups. Language barrier was an issue to access of HIV information for these communities in government facilities. Currently, KLASS has grown to address the needs of people of all races and religions. At regular meetings initially held once a month, information such as treatment, nutrition, safer sex, as well as other relevant topics are provided. For the past 10 years, KLASS' activities have received continuous support from MOH, private companies and the respective communities.

4. SEED

SEED or *Pertubuhan Kebajikan dan Persekitaran Positif Malaysia* is the first Trans-Led community-based organization in Malaysia. Officially re.g.istered in 2014, SEED was created to principally serve the transgender communities especially in Kuala Lumpur. SEED which is located in the heart of Kuala Lumpur, aims to empower people who are socially excluded in Malaysia by providing access to a safe space, supporting sustainable livelihoods, facilitating access to healthcare services and linking people to resources that will improve quality of life of the TG community.

5. Komited MALAYSIA

Komited MALAYSIA was established in 1998 as the only peer-based NGO working on drug related issues. With the strength of committed staff and volunteers the services of Komited MALAYSIA are designed to complement a continuum of care and the expected needs of clients

6. PFDHA

The Penang Family Planning Association (FPA) was registered on 16 January 1962. This CBO aims to be one of the leading NGOs in the field of sexual and reproductive health for healthy family development.

7. Shelter Homes run by CBOs (principally for women and children)

7.1 Rumah Solehah

Rumah Solehah (RS) has been in existence for more than 10 years and it is one of the earliest shelter homes exclusively meant for women and children living with HIV/AIDS. This shelter home has received the Tun Dr. Hasmah Special Mention Award 2004 for excellence in care and support at the grassroots level. It is common to note that some of the women and children are abandoned by their families/parents, and Rumah Solehah has in the past and present able to provide comfort and support to children in the final stages of a terminal illness. This home is located in Ampang, in the state of Selangor (bordering the FT of Kuala Lumpur)

7.2 CAKNA Terengganu Shelter Home for women and children

CAKNA is the first CBO in state of the east coast i.e. Terengganu serving the interest of People Living with HIV. Founded in 2010, CAKNA's primary aim is to mitigate the ne.g.ative impact of HIV for the people of Terengganu. As the responsibilities of CAKNA grew, it (CAKNA) has expanded its scope to include having a shelter home for women and children affected and infected by HIV/AIDS.

7.3 Komited Malaysia – Casa Harapan

Casa Harapan is a home for women and children living with and affected by HIV/AIDS which opened its doors since 2008. The home and family ambience has offered women and children the opportunity to live a meaningful and quality life. The staff of Casa Harapan among other things also increases the awareness and reduce the stigma re.g.arding HIV/AIDS and will also try to instill confidence among the residents of shelter home through counseling activities and increase quality of living through education and life skill training. This shelter home is located in Kuantan, Pahang.

(C) INTERNATIONAL / MULTI-LATERAL AGENCIES

1. World Health Organization (WHO)

WHO has continuously provided technical assistance and support for PMTCT programme in Malaysia by providing information on the national norms of other countries. A lot of information concerning the standards for the prevention and of HIV including PMTCT, and treatment care and support for HIV was initiated by WHO country office in Malaysia.

2. UNICEF Malaysia

UNICEF Malaysia works with MOH and other government agencies on advocacy for universal access for HIV prevention treatment and care in the country.

Agencies responsible for the implementation of PMTCT programmes and activities in Malaysia (including their main roles and responsibilities)

1. GOVERNMENT DELIVERY SYSTEMS

Ministry of Health

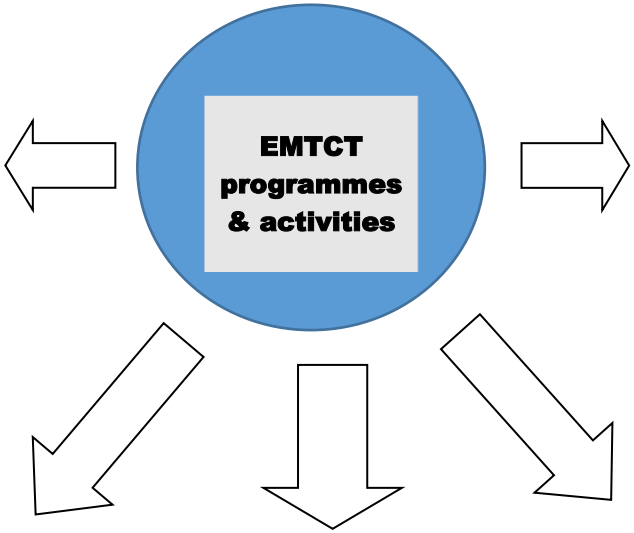
1.1 National, State & District Levels
1.2 Hospitals, Health Clinics,
1.3 Non-MOH Hospitals (University Hospitals, Defence)
1.4 National Reference Facilities (Tertiary Hospitals, Institute for Medical Research, Public Health Laboratory, Paediatric Institute

Other relevant Ministries

1.5 Other Government relevant government ministries e.g. Ministry of Women, Family & Community Development, Ministry of Home Affairs, Ministry of Housing and Local Government

Functions, roles and responsibilities

(a) Development of Strategic Plan on HIV/AIDS/STI
(b) Planning, policy making decisions e.g. development of circulars, CPGs, SOPs
(c) Monitoring and evaluation of programmes & activities
(d) Review of targets, indicators,
(e) Briefing to top management regarding progress, initiatives etc
(f) **BUDGET** – 95% of the HIV AIDS STI budget comes from the government
(g) **TRAINING** - in collaboration with all other main stakeholders



2. CIVIL SOCIETY / NON-GOVERNMENT ORGANISATIONS (NGOs)

2.1 Malaysian AIDS Organisations (MAC) & 45 other partner organisations (POs)
2.2 Other NGOs not under MAC but delivering services to PLHIVs e.g. PEWAHIM

Functions, roles and responsibilities

(a) Complements the efforts of the government on HIV/AIDS & STI prevention and control activities and programmes
(b) Advocacy on issues regarding human rights, gender community participation on PMTCT
(c) Partners in health on HIV AIDS STI programmes and activities to the government machinery
(d) The civil society / NGOs usually will collaborate with Government agencies to train other NGOs
(e) Government agencies / other non-Government agencies will disburse funds to NGOs for projects / training / conduct research / and other relevant projects

5. PRIVATE HOSPITALS, LABORATORIES

Functions, roles and responsibilities

(a) Complements the efforts made by the Government and NGOs on issues pertaining to PMTCT e.g. Antenatal and treatment, post-delivery, and follow-up of babies and mothers

4. CORPORATE BODIES / AGENCIES IN MALAYSIA (PMTCT)

E.g. Sime Darby Cooperation, PETRONAS, Hilton

Functions, roles and responsibilities

(a) Complements the efforts made by the Government and NGOs on issues pertaining to PMTCT e.g. assistance to Shelter Homes
(b) Part of the CCM Malaysia Committee Member

3. RELEVANT MULIT-LATERAL AGENCIES / INTERNATIONAL BODIES IN MALAYSIA (PMTCT)

3.1 World Health Organisation (WHO), UNICEF Malaysia, UNDP

Functions, roles and responsibilities

(a) Advises, give technical input on issues pertaining PMTCT, women's & child rights,

e-notice form for notifying Infectious Diseases (Act 342)

"SCHEDULE
(Regulation 2)
Form
(Regulation 2)
PREVENTION AND CONTROL OF INFECTIOUS DISEASES ACT 1988
PREVENTION AND CONTROL OF INFECTIOUS DISEASES (NOTICE FORM) (AMENDMENT) REGULATIONS 2011

Notification Form: Rev/2010
Serial No:

NOTIFICATION OF COMMUNICABLE DISEASES TO BE REPORTED

(Section 10, Prevention And Control Of Communicable Diseases Act, 1988)

A. PATIENT INFORMATION

1. Full Name (CAPITAL LETTER):

Accompany by(Mother/Father/Guardian):
(If under age/without Identity Card)

2. Identity Card Number / Travelling Document:
(For Non Citizen)
☐ Self ☐ Accompany by

Hospital/Clinic Reg Number: Ward:_____ Date of Admission: / /

3. Citizenship:
Citizen
☐ Yes Race/Ethnic:
Sub Ethnic:
(For Aborigines, Native of Sabah/Sarawak)
☐ No Country of origin:
Status of Entry: ☐ Legal ☐ Illegal ☐ Permanent Resident

4. Gender: ☐ Male ☐ Female

5. Date of birth: / /

6. Age: ☐ Year ☐ Month ☐ Day

7. Occupation:_____
(If unemployed, please state self reference)

8. Telephone No.: ☐ Resident ☐ H.phone ☐ Office -
(Contact purposes)

9. Current Address:

10. Address of Employer/School/College/University:

B. DISEASE DIAGNOSIS

1. Poliomyelitis
2. Viral Hepatitis A
3. Viral Hepatitis B
4. Viral Hepatitis C
5. Viral Hepatitis *(Others)*
6. AIDS
7. Chancroid
8. Cholera
9. Dengue Fever
10. Dengue Haemorrhagic Fever
11. Diphtheria
12. Dysentery
13. Ebola
14. Food Poisoning
15. Gonorrhoea
16. Hand, Food and Mouth Disease
17. Human Immunodeficiency Virus Infection
18. Influenza
19. Leprosy *(Multibacillary)*
20. Leprosy *(Paucibacillary)*
21. Leptospirosis
22. Malaria - *Vivax*
23. Malaria - *Falciparum*
24. Malaria - *Malariae*
25. Malaria - *Others*
26. Measles
27. Plague
28. Rabies
29. Relapsing Fever
30. Syphilis - *Congenital*
31. Syphilis - Acquired
32. Tetanus Neonatorum
33. Tetanus *(Others)*
34. Typhus - *Scrub*
35. Tuberculosis - *PTB Smear Positive*
36. Tuberculosis - *PTB Smear Negative*
37. Tuberculosis - *Extra Pulmonary*
38. Typhoid - *Salmonella typhi*
39. Typhoid - *Paratyphoid*
40. Viral Encephalitis - *Japanese*
41. Viral Encephalitis - *Nipah*
42. Viral Encephalitis - *(Others)*
43. Whooping Cough / Pertussis
44. Yellow Fever
45. Others: *please specify:* _____

Besides by written notification, the following diseases must be notified by telephone within 24 hours, such as:- Acute Poliomyelitis, Cholera, Dengue, Diptheria, Ebola, Food Poisoning, Plague, Rabies and Yellow Fever.

11. Case detection classification:
☐ Case ☐ Contact ☐ FOMEMA
☐ Screening Test _____

12. Status of patient:
☐ Live/alive
☐ Died - -

13. Date of Onset: - -

14. Laboratory investigation:
Investigation: (i)_____
(ii)_____ (iii)_____
Date of specimen taken: - -

15. Laboratory investigation result:
☐ Positive (_____)
☐ Negative
☐ Pending

16. Diagnosis Status:
☐ Provisional/Suspected
☐ Confirmed
Date of Diagnosis - -

17. Relevant Clinical Information:

18. Comment:

C. NOTIFIER

19. Name of Medical Practitioner:

20. Name and address of Hospital/Clinic:

21. Date of Notification: - -

Signature of Medical Practitioner

Appendix 6

TREATMENT AND PREVENTION OF MOTHER-TO-CHILD TRANSMISSION
(Adapted from Consensus Guidelines on Antiretroviral Therapy 2014)

Antenatal combination therapy is now the recommended method for prevention of maternal-to-child transmission (PMTCT). HAART must be started in all pregnant mothers who are HIV+ regardless of CD4 count. Ideally HAART should be started at 14 weeks of pregnancy. However, it is still efficacious when started as late as 28 weeks of pregnancy. The treatment of women who start HAART after week 28 must be discussed with an ID Physician. Strict adherence to HAART must be stressed throughout the pregnancy. A viral load must be done between 32-36 weeks to determine ongoing risk of transmission to the fetus. The mode of delivery will also be determined by the result. The decision to continue (Option B+) or stop cART post-delivery (Option B) must be discussed with the patient.

Women who are stable on cART before pregnancy
In general, the existing cART is to be continued throughout pregnancy and after delivery. Special effort must be made to determine the current CD4 and viral load during the early stages of pregnancy. Should the patient experience virological failure on her current regime, consultation with an ID Physician is strongly recommended.

Intrapartum Management of women receiving cART during pregnancy
In the past IV ZDV was recommended routinely for all women during the intrapartum period regardless of viral load. However, current evidence suggests that intrapartum IV ZDV has no additional benefit in prevention of vertical transmission in pregnant women on cART with suppressed viral load.

Women who present in labour with no prior ARV exposure
For woman who is diagnosed with HIV infection in labour who has not received prior ARVs, start IV ZDV infusion (2mg/kg for the first 1 hour followed by 1 mg/kg/h subsequently) immediately. Single dose NVP for the mother is not necessary. Giving intrapartum Nevirapine to the mother may select for resistance to NNRTIs and limit future ARV options.

The Pediatrician caring for the newborn must be notified to ensure appropriate post exposure ARV prophylaxis for the infant. The infants of mothers who are adequately receiving ART during pregnancy and infants on replacement feed will receive 6 weeks of infant prophylaxis with daily nevirapine or AZT twice daily. However, infants at high risk of acquiring HIV (born to mothers with HIV and receiving inadequate or not receiving ART) will be given dual prophylaxis with AZT (twice daily) and NVP (once daily) for the first 6 weeks of life.

Choice of agents used for PMTCT
cART used during pregnancy must consist of 2 NRTIs plus either a NNRTI or a boosted PI. The choice of agents is listed in Table 1.

Mode of delivery
Pre-labour Elective Caesarean Section (PLCS) has been proven to further reduce the risk of transmission. The decision between performing PLCS or allowing spontaneous vaginal delivery (SVD) is based largely on the VL at 32-36 weeks of gestation and whether the mother has received any ARVs in the antenatal period.

Women who have received cART before pregnancy or antenatally and have achieved maximal VL suppression, have a choice between PLCS or SVD (Table 2). There is no additional advantage of PLCS over SVD in terms of reduction of transmission in this group.

Table 1. Art regimen for pregnant women

Preferred	**Alternative**
TDF + 3TC (or FTC) + EFV*	AZT + 3TC + EFV AZT + 3TC + NVP# TDF + 3TC (or FTC) + NVP# TDF + 3TC (or FTC) + LPV / RTV

**In the past, Efavirenz was considered a Category D drug and contraindicated in the first trimester of pregnancy. However, there is now good level safety evidence to recommend it as the preferred NNRTI even in the first trimester.*
 # Nevirapine must be used with caution in women with CD4 > 350

Table 2. Options for mode of delivery for antenatal mother living with HIV

Viral load at 32 - 36 weeks	**Mode of delivery**
< 50 copies / ml 50 – 399 copies / ml ➢400 copies / ml or unknown viral load	SVD PLCS recommended * PLCS

**Take into account the trajectory of the viral load leading up to time of delivery, length of time on ARVs, adherence issues, obstetric factors and the woman's views*

Women who are diagnosed with HIV infection during labour or following rupture of membrane (ROM) should be managed on a case by case basis. There is insufficient data to routinely recommend caesarean section in this scenario. The decision for the mode of delivery has to take into account the duration of ROM and the expected time of delivery. After the ROM there is an increased risk of transmission of 2% per hour.

For women with viral load < 50, who present after ROM, Caesarean section is not recommended. However, for those with VL >50 or who have unknown VL, CS is recommended within 4 hours of ROM.

Breast feeding
Breast feeding is not recommended as it is associated with the risk of transmission up to 14%. For women on CART compliance must be stressed.

Notes

Option B+ Lifelong cART for all pregnant women (regardless of CD4)	Start cART and maintain post-delivery
Option B cART only during pregnancy for women with CD4 > 350	Start cART and stop post-delivery

Appendix 7

Benefits package - list of treatment, care and support provision for HIV+ women, exposed infants, spouse / partners and their families (as provided by the Government of Malaysia, Ministry of Health, other government agencies, corporate bodies, NGOs/ civil society and international bodies in Malaysia)

(1) HIV+ mothers

1.1 Anti-retroviral treatment (Option B+). Treatment is lifelong
1.2 Counselling services (all aspects of counselling – medical, social, religious)
1.3 Delivery in government hospitals
1.4 Post delivery services e.g. home visits, post-partum services at OPD in HC
1.5 Preventive counselling and services (e.g. condoms and PrEP after delivery)
1.6 Laboratory testing (e.g. PCR, RTK, confirmation tests, X-rays, Ultrasound and other relevant tests)
   (a) CD4 count
   (b) Viral load testing
   (c) Screening for Hepatitis C, HBs Ag
   (d) Haemoglobin levels
   (e) Screening tests for other opportunistic infections e.g. TB, CXR
   (f) Liver Function tests before initiation of ARV
   (g) Kidney Function tests

(2) Exposed infants

2.1 Infant formula for up to 2 years
2.2 Bactrim prophylaxis
2.3 PCR tests (at birth, 6 weeks and 6 months after birth)
2.4 Admission if warranted after delivery and other related charges (laboratory tests, drugs etc)
2.5 Opportunistic infections treatment

(3) Spouse / partners

3.1 Anti-retroviral treatment
3.2 Counselling services
3.3 Laboratory testing (e.g. PCR, RTK, confirmation tests, X-rays, Ultrasound tests, and other relevant tests)
3.4 Refer to HIV+ mothers

(4) The affected families

4.1 BR1M – a family earning RM 3,000 below are entitled to monetary benefits for RM 1,200 annually which has been allocated by the government since 2015

4.2 HIV Shelter Homes

   (a) There are 10 shelter homes meant for HIV+ women, men and children which has been allocated for nearly RM 1,000,000 annual grant by the Ministry of Health to the Malaysian AIDS Council

(b) There are at least 2 other shelter homes which have been provided by the Selangor Religious Department meant for HIV+ men, women and children in the state of Selangor

4.3 "Tithes" payment / alimony *(Zakat)*

The states of Selangor, Kuala Lumpur and Pahang reserves monthly "tithes payments" (*zakat)* which is a special form of aid given to HIV+ persons. (the affected families need to apply to the respective religious departments)

(5) EPF withdrawals

(6) UNHCR card holders

Non-Malaysians are administratively given 50% discount whenever they seek treatment at government Hospitals / Primary Care Clinics

Appendix 8

Treatment for syphilis

(Adapted from Malaysian Guidelines in the treatment of Sexually Transmitted Infections, Fourth Edition, 2015, page 13)

Treatment of early syphilis (Primary, Secondary and Early Latent Syphlis) and Late Syphlis (Late Latent, Gumma, Cardiovascular and Neurosyphlis)

EARLY SYPHLIS	**LATE SYPHLIS (excluding Neurosyphilis)**
Recommended regimen	
• Benzathine pencilline 2.4 me.g.a units IM in a single dose (Grade A, 1b) **OR** • Procaine Pencilline G, 600,000 units IM Daily for 10 days (Grade B, III)	• Benzathine penicillin, 2.4 me.g.a units IM weekly X 3 weeks (3 doses) (Grade B, III) **OR** • Procaine penicillin G, 600,000 units IM daily for 17 days (Grade B, III)
Alternative Regimen (These may be required for those with pencillin therapy)	
• Ceftrixone 500 mg IM daily for 10 days (Grade B, 1) – if no anaphylaxis to pencillin **OR** • Doxycycline 100 mg bd P.O for 14 days (Grade b, III) **OR** • Erythromycin stearate 500 mg qid P.O X 14 days (Grade B, III) OR • Ethromycin ethyl succinate 800 mg qid P.O X 14 days (Grade B, III) OR • Azythromycin 2g single dose PO (Grade B II) (concerns re.g.arding intrinsic macrolide resistance)	• Doxycycline 100 mg bd PO for 28 days (Grade C, IV) **OR** • Erythromycin stearate 500 mg qid PO for 28 days (Grade C, IV) **OR** • Erythromycin ethyl succinate 800 mg qid PO X 28 days (Grade C, IV)

*Treatment for mother who detected positive for syphilis; pencillin regimen appropriate for the women's stage of syphilis

Appendix 9

Laboratory Diagnosis of Syphilis

(Adapted from Malaysian STI Guidelines in the treatment of Sexually Transmitted Infections Forth Edition, 2015, pages 22-23)

Demonstration of Treponema pallidum from lesions or infected lymph nodes

1. Dark-ground / Dark field microscopy

- Should be performed by an experienced laboratory technician or doctor
- Success depends on a number of factors, including too little or too much fluid on the slide, improper thickness of the slide or cover slip etc. Treatment with antibiotics may result in a false negative finding
- Because of its limited sensitivity, failure to detect T pallidum by this test does not rule out syphilis

2. Polymerase Chain Reaction (PCR)

- Due to limited availability and the time taken to obtain a result, this is not a replacement for dark-field microscopy in the clinic setting
- In certain circumstances, PCR may be helpful in diagnosis by demonstrating T pallidum in tissue samples, vitreous fluid and CSF

SEROGOLOGICAL TESTS

Recommended screening

- RPR has replaced VDRL in both public and private laboratories
- Both non-treponemal RPR and treponemal tests should be routinely performed for all GU medicine clinic attendees
- Antenatal screening with non-treponemal RPR should be routinely performed
    - On first visit and at 28 weeks of gestation
    - Confirm positive results with treponemal tests (TPPA / TPHA)
- EIA (both IgG and IgM) is ideal screening test for blood bank / transfusion services since it is automated and specific
    - A quantitative RPR should be performed for positive tests to classify / stage the disease, determine the need for and monitoring of treatment
    - A RPR titre of >1:16 and / or positive IgM test indicate active disease and the need for treatment, although serology must be interpreted in the light of the treatment history and clinical findings

Sensitivity and Specificity of laboratory tests for Syphilis

Sensitivity (%) during stage of infection

TESTS	PRIMARY	SECONDARY	LATENT	LATE	SPECIFICITY (%)
NON-TREPONEMAL TESTS					
RPR	86	100	98	73	98
TREPONEMAL TESTS					
TPPA	88	100	100	NA	96
TPHA	86	100	100	99	96
FTA-ABS	84	100	100	96	97
EIA					
IgG	100	100	100	NA	100
IgM	93	85	64	NA	NA
RAPID TEST					
Immunochromatography Latex Agglutination		84.5 – 97.7			92.8 – 98
Dark field microscopy	74 – 86	-	-	-	85 - 100
PCR for T pallidum	94.7	80	-	-	98.6
CSF VDRL	NA	NA	-	-	100

Treatment for Syphilis in Pregnancy

(Adapted from Malaysian Guidelines in the treatment of Sexually Transmitted Infections, Fourth Edition 2015, page 18)

Antenatal screening for syphilis with non-treponemal tests (RPR) should be routinely performed on first visit and to repeat at 28 weeks of gestation. Positive results must be confirmed with treponemal tests (TPHA / TPPA / EIA)

Treatment

(1) Penicillin regimen appropriate for the woman's stage of syphilis is recommended

(2) Doxycycline and tetracycline are contraindicated in pregnancy. Erythromycin should not be used because of the high risk of failure to cure the foetus. If erythromycin is used, paediatricians must be alerted, and babies have to be treated prophylactically with penicillin and monitored

(3) Pregnant women with a history of penicillin allergy should be meticulously interviewed regarding the validity of the history. Skin testing and desensitisation can be done if necessary. Women who are treated in the second half of pregnancy are at risk of premature labour and / if fetal distress if their treatment precipitates a Jarisch-Herxheimer reaction

(4) They should be advised to seek medical attention if they notice any change in foetal movements or have any contractions following treatment.

Follow up

Monthly clinical and serological examination till delivery and thereafter follow-up is an in non-pregnant patients

Congenital syphilis

(Adapted from Malaysian Guidelines in the treatment of Sexually Transmitted Infections, Fourth Edition, 2015, pages 19-21)

Infants should be evaluated if they were born to sero-positive women who:

(1) Have untreated syphilis
(2) Were treated for syphilis less than 1 month before delivery
(3) Were treated for syphilis during pregnancy with a non-penicillin regimen
(4) Did not have the expected decrease in RPR titre after treatment
(5) Were treated but had insufficient serologic follow-up during pregnancy to assess disease activity

Evaluation of infant

(1) A thorough physical examination
(2) RPR (compare with mother's titre) / EIA
(3) FTA-Abs
(4) CSF analysis for cells, protein and CSF-VDRL test
(5) Long bones X-ray
(6) Chest X-ray

Therapy decisions

(1) Any evidence of active disease
(2) A reactive CSF-VDRL / FTA-Abs
(3) An abnormal CSF finding (WBC. 5/mm3 or protein > 50 mg / dl) regardless of CSF serology
(4) Serum RPR titre that are at least 4 times higher than their mother's
(5) Positive EIA-IgM antibody

Treatment for congenital syphilis

(a) Aqueous crystalline penicillin G, 50,000 units/kg/dose 12 hourly for first 7 days then 8 hourly for the following 3-7 days (Grade B, III)

OR

(b) Procaine Penicillin 50,000 units / kg daily IM for 10-14 days (Grade B, III)

OR

(c) IV / IM Ceftriaxone 75 mg / kg (< 30 days old) or 100 mg / kg (> 30 days old)

*If more than a day of treatment is missed, the whole course should be restarted

Infants who should be evaluated but whose follow-up cannot be assured should be treated with a single dose of Benzathine Penicillin, 50,000 units/kg IM

Appendix 12

List of Primary Care Laboratories participating in HIV EQA conducted by the National AIDS Reference Lab (NARL) in 2017

NO	NAME OF HEALTH CLINIC	ADDRESS
1	Klinik Kesihatan Bandar Kuah	Bandar Kuah, 07000 Langkawi, Kedah
2	Klinik Kesihatan Taman Ehsan	16, Jalan E 4/10, Kepong, 52100 Kuala Lumpur
3	Klinik Kesihatan Batu 9, Cheras	Jalan Hulu Langat, 43200 Batu 9, Cheras, Selangor
4	Klinik Kesihatan Tanglin	Jalan Cenderasari, Tasik Perdana, 50480 Kuala Lumpur
5	Klinik Kesihatan Mahmoodiah	JKR 6274, Jalan Mahmoodiah, 80100 Johor Bharu,Johor
6	Klinik Kesihatan Padang Tengku	Padang Tengku, 27100 Lipis, Pahang
7	Klinik Kesihatan Gua Musang	Pt 483 & 343, Jalan Galas,18300 Gua Musang, Kelantan
8	Klinik Kesihatan Penampang	Jalan Pantai Cahaya Bulan, 15350 Kota Bahru, Kelantan
9	Klinik Kesihatan Hiliran	Jalan Muhammad, Off Jalan Kemajuan, 20300 Kuala Terengganu,Terengganu
10	Klinik Kesihatan Kapit	Jalan Hospital, 96800 Kapit, Sarawak

Appendix 13

Consent Form for HIV & Syphilis testing in Health Clinics

BORANG KEBENARAN UNTUK PENGAMBILAN DARAH
BAGI UJIAN SARINGAN ANTENATAL
(adaptasi Rekod Kesihatan Ibu KIK/1(b)/96(Pin.2012)

Tujuan saringan darah bagi ibu-ibu mengandung adalah :

(1) Untuk memastikan ibu berada di tahap kesihatan yang optima
(2) Untuk pengesahan penyakit bagi membuka peluang kepada rawatan awal
(3) Untuk mence.g.ah jangkitan penyakit kepada bayi
(4) Untuk pengesanan awan dan membuka peluang kepada pasangan

Saya _____ No KP _____

telah memahami penjelasan yang diberikan secara lisan dan dengan ini memberi keizinan untuk darah saya diambil bagi ujian yang berikut :-

Sila tandakan ( ) dalam kotak yang bersesuaian

1. Kumpulan Darah & Rh factor
2. VDRL +/- TPHA
3. Hemoglobin (Hb)
4. HIV Rapid Test
5. Lain-lain (nyatakan) ……..

Sampel darah selanjutnya akan diambil untuk mana-mana ujian pengesahan sekiranya perlu.

Tandatangan klien	Tandatangan saksi
_____	_____
Tarikh	Nama : No KP : Tarikh :

Peringatan :

Klien perlu memaklumkan kepada petugas kesihatan sekiranya mempunyai factor risiko berikut :-

(a) Mengambil dadah
(b) Mempunyai hubungan seks dengan pasangan lain
(c) Pasangan merupakan penagih dadah
(d) Pasangan mempunyai hubungan seks dengan pasangan lain
(e) Pasangan disahkan pengidap HIV

Sekiranya klien mempunyai salah satu atau lebih factor risiko di atas dan ujian saringan HIV adalah tidak reaktif, ujian saringan ulangan perlu dilakukan untuk mengesan jangkitan dalm tempoh window (window period)

(Translation of Consent HIV & Syphilis Testing Form in Primary Health Clinic)

CONSENT FORM FOR BLOOD INVESTIGATION DURING ANTENATAL PERIOD

Blood taking during the antenatal period serves the following purposes:

(1) To be sure that the mother's health is at the optimum stage
(2) To detect treatable diseases during pregnancy so that interventions / treatment can be done early
(3) To prevent transmission of diseases to their unborn babies
(4) To detect transmissible / infectious diseases early. This will enable the spouse / partners be treated / counselled early.

I,_____ with Identity Card (IC) Number _____

hereby acknowledge that I have been explained verbally by the staff regarding the purpose of the blood investigations. I hereby give my consent to the staff to for the following blood investigations:

Tick ( ) where appropriate

1. Blood Grouping and Rh factor
2. VDRL +/- TPHA
3. Hemoglobin (Hb)
4. HIV Rapid Test
5. Others (kindly specify) _____

Another blood sample, if needed, will be taken for confirmation when necessary

Signature of client	Signature of witness
_____	----------
	Name of witness
	IC Number
Date	Date

Please take note:
Client needs to inform the health staff if she is having the following risk factors

1. The client is a drug user
2. The client is having sexual intimacy with other partners
3. The client's sexual partner is a drug user
4. The client's sexual partner has multiple sexual partners
5. The client's sexual partner is HIV+

Should the client is detected to have one or more risk factors, and the HIV screening test turns out be non-reactive, another screening test is strongly advisable to exclude infection during the window period

Appendix 14

Summary from PMTCT HIV line listing 2015 and 2016

Key points	2015	2016
Total number of pregnant HIV positive mother - Non-Malaysian	319 18.5%	311 18.5%
Outcome of pregnancy: - Live birth - TOP - Spontaneous abortion - Stillbirth	 308 (96.6%) 0 (0%) 2 (0.6%) 9 (2.8%)	 301 (96.8%) 2 (0.6%) 5 (1.6%) 3 (1%)
Number of father screened for HIV:	209 (65.5%)	224 (72%)
Type of delivery: - LSCS - SVD - Assisted SVD	 85.4% 14.3% 0.3%	 77.7% 20.3% 2.0%
Infant exposed to HIV positive mother on AZT prophylaxis	100%	99.7% (1 baby died after 13 hrs of life – Edward syndrome)
Infant exposed to HIV positive mother on Cotrimoxazole prophylaxis	75.6% - 4 babies went back to country of origin (non-Malaysian) - 23.1% diagnosed negative before 6 weeks of life	87.4% - 4 babies went back to country of origin (non-Malaysian) - 11% diagnosed negative before 6 weeks of life
Types of feeding for babies exposed to HIV positive mother - Formula milk - Breastfeeding	 100% 0%	 99% 0.33% *1 baby died after 13 hrs of life – Edward syndrome *1 no information because went back to country of origin

Summary from Congenital Syphilis line listing 2015 and 2016

*The line listing was extracted from the e-notification database for cases notify as congenital syphilis by health facilities (public or private). The variables in the notification system does not include information of the mother. However, this information is available in the case report investigation at the DHO.

Key points	2015	2016
Total number of congenital syphilis reported - Non-Malaysian	22 13.6%	15 20%
Age at time of diagnosis	Minimum 1 day old Maximum 7 years old	Minimum 12 days old Maximum 4 years old

NOTES

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