CASE STUDY

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

Ministry of Health Malaysia

World Health Organization
Representative Office
for Malaysia, Brunei Darussalam,
and Singapore

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ABBREVIATIONS

ANC	antenatal care
ART	antiretroviral therapy
AZT	azidothymidine
EMTCT	elimination of mother-to-child transmission
MCH	maternal and child health
MTCT	mother-to-child transmission
MU	million unit
NGO	nongovernmental organization
PCP	*Pneumocystis carinii* pneumonia
PCR	polymerase chain reaction
PMTCT	prevention of mother-to-child transmission
RDT	rapid diagnostic test
RVT	Regional Validation Team
SOP	standard operating procedure
STI	sexually transmitted infection
TPHA	*Treponema pallidum* haemagglutination
TPPA	*Treponema pallidum* particle agglutination
WHO	World Health Organization

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EXECUTIVE SUMMARY

The World Health Organization (WHO) *Global Health Sector Strategies on HIV and Sexually Transmitted Infections 2016–2021* outlined the targets for the elimination of mother-to-child transmission (EMTCT), namely, to achieve zero new HIV infections among infants by 2020 and less than or equal to 50 cases of congenital syphilis per 100 000 live births by 2030. In 2016, Malaysia commenced the validation process for EMTCT of HIV and syphilis, based on an assessment against impact and process indicators defined by WHO.

In October 2018, Malaysia was officially presented with the validation certificate for EMTCT of HIV and syphilis, becoming the first country in the WHO Western Pacific Region to be certified for elimination. This report highlights the strengths of Malaysia's response to HIV and syphilis, the process involved in attaining the EMTCT validation as well as the challenges and opportunities identified to sustain this achievement and to further strengthen the country's efforts.

The prevalence of HIV and syphilis among pregnant women in Malaysia remained low throughout the HIV epidemic. HIV prevalence was reported to be between 0.06% and 0.07% since 2011, and syphilis prevalence among pregnant women was estimated at 0.04% in 2016. Both the under-5 and infant mortality rates decreased nearly by half between 1990 and 2017, dropping from 16.8 to 8.4 per 1000 live births and from 13.1 to 6.9 per 1000 live births, respectively. These low rates of maternal and child mortality reflect Malaysia's progress in health care.

Malaysia's achievements have been attributed to the following key factors: (1) strong political commitment; (2) ubiquitous service coverage of the national public health-care system and primary health care; (3) integration of EMTCT in maternal and child health services; (4) prevention of mother-to-child transmission of HIV and syphilis programmes; (5) effective monitoring process for infants exposed to HIV and syphilis; (6) procurement and quality assurance of diagnostic services; (7) partner notification and contact-tracing for HIV and syphilis cases; (8) surveillance and monitoring and evaluation systems; and (9) community engagement in local government.

While these achievements are celebrated, it is important to also identify gaps and future challenges. Malaysia still encounters some stigma and discrimination in implementing EMTCT programmes, especially against key populations. Similarly, although migrants are not denied access to medical care, challenges remain in meeting the health-care needs of migrants and other subpopulations. Furthermore, limited sharing of information from private health facilities was one of the limitations of the programmatic monitoring system observed during the validation process. Financial sustainability continues to be a priority for the Malaysian Government to sustain the EMTCT programmes.

Recommendations made during the validation and endorsement of the EMTCT programmes provide the country with a new set of targets in moving forward. Malaysia is encouraged to consider the following: (1) strengthen the national EMTCT monitoring system; (2) strengthen the provision of EMTCT services; (3) facilitate access to services by vulnerable groups and address issues of stigma and discrimination; and (4) strengthen laboratory systems to deliver quality testing services. With continued strong political commitment and actionable policies to enhance health systems on prevention, diagnosis and treatment for HIV and syphilis, accompanied by collaboration from multisectoral stakeholders, adherence to international guidelines and optimal financial resources, Malaysia's EMTCT programmes can be further strengthened in the years to come.

1. INTRODUCTION

BETWEEN 1990 AND 2017, THE INFANT MORTALITY RATE WAS REDUCED NEARLY BY HALF.

Malaysia is an upper-middle income country with an estimated population of 32.6 million people in 2018. About 24% of the population is below the age of 15, with an average of 1.9 children born among women aged 15–49. In 2017, life expectancy at birth was 72.7 years for males and 77.6 years for females, while the number of live births and deaths were 15.9 and 5.3 per 1000 population, respectively (Table 1).

Malaysia continues to show progress in health care, with maternal and child health indicators showing low rates of maternal and child mortality. Malaysia's under-5 mortality rate decreased 50% between 1990 and 2017, from 16.8 to 8.4 per 1000 live births. In that same period, the infant mortality rate was reduced nearly by half, from 13.1 to 6.9 per 1000 live births.

Similar progress has been reported for the maternal mortality ratio, which declined from 44 to 25 per 100 000 population *(1,2)*.

TABLE 1. Basic statistics, Malaysia, 2018

INDICATOR	STATISTICS
Total population (millions)	32.6
Life expectancy at birth: male/female (years)	72.7 / 77.6
Population under 15 years (%)	24.0
Total fertility rate (births per woman)	1.9
Number of live births (per 1000 population)	15.9
Number of deaths (per 1000 population)	5.3
Under-5 mortality rate (per 1000 live births)	8.4
Infant mortality rate (per 1000 live births)	6.9
Maternal mortality ratio (per 100 000 population)	25.0
HIV mortality rate (per 100 000 population)	2.75
Syphilis mortality rate (per 100 000 population)	0.02

Source: Demographic statistics fourth quarter (Q4) 2018, Malaysia. In: Department of Statistics Malaysia [website]. Putrajaya: Department of Statistics Malaysia; 12 February 2019 (https://www.dosm.gov.my/v1/index.php?r=column/cthemeByCat&cat=430&bul_id=UzliaFYxbW1nSFovbDYrLzFFR29zZz09&menu_id=L0pheU43NWJwRWVSZklWdzQ4TlhUUT09).

1.1 Elimination of mother-to-child transmission of HIV and syphilis

On 8 October 2018, Malaysia was officially presented with the validation certificate for the elimination of mother-to-child transmission (EMTCT) of HIV and syphilis, becoming the first country in the World Health Organization (WHO) Western Pacific Region[1] certified for elimination *(3)*.

The vertical transmission of HIV and syphilis can be effectively controlled through early diagnosis and treatment; yet globally there are still an estimated 150 000 cases of new paediatric HIV infections and 350 000 cases of congenital syphilis each year. The dual EMTCT of HIV and syphilis has been identified as a global public health priority. WHO has outlined targets in the *Global Health Sector Strategies on HIV and Sexually Transmitted Infections 2016–2021* to achieve zero new HIV infections among infants by 2020 and less than or equal to 50 cases of congenital syphilis per 100 000 live births by 2030 (Fig. 1) *(4,5)*. In 2014, WHO issued the *Global Guidance on Criteria and Processes for Validation: Elimination of Mother-to-Child Transmission of HIV and Syphilis (5)*. Cuba was the first country to receive WHO certification for EMTCT of HIV and syphilis in 2015, followed in 2016 by the Republic of Moldova (syphilis only), Belarus and Thailand *(6)*. In 2017, Anguilla, Antigua and Barbuda, Bermuda, Cayman Islands, Montserrat, and Saint Kitts and Nevis were also certified by WHO *(7)*.

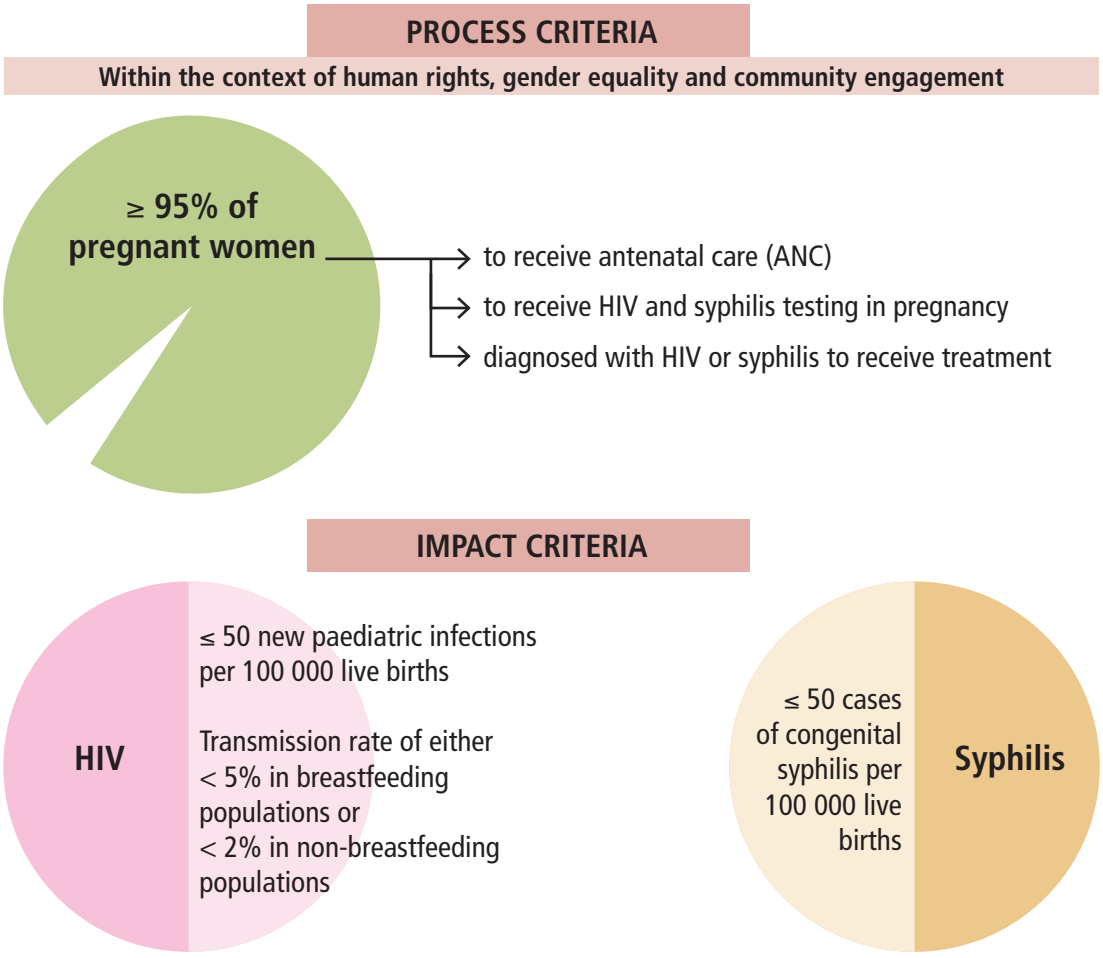
1. The Western Pacific Region is home to almost 1.9 billion people across 37 countries and areas.

Based on the experiences of these initial countries validated, five principles for successful EMTCT were identified *(6)*. These were:

» strong government commitment,
» integration of prevention of mother-to-child transmission (PMTCT) into maternal and child health (MCH) services,
» monitoring of infants exposed to HIV,
» quality-assured diagnostic services, and
» compliance to human rights and gender equality principles.

Through a rigorous process of assessment and validation of data for quality, reliability and representativeness, it was determined that Malaysia has met all EMTCT criteria for both HIV and congenital syphilis, in accordance with global targets (Table 2). This success was possible because of a combination of factors such as high-level political commitment, strong MCH systems capacity, early diagnosis, and the availability and accessibility of treatment for HIV and syphilis.

FIGURE 1. Requirements for the validation of EMTCT of HIV and syphilis



Source: Ministry of Health Malaysia *(8)*.

TABLE 2. Summary of EMTCT of HIV and syphilis impact and process indicators, Malaysia, 2015–2016

INDICATOR	TARGET	2015		2016	
Impact indicators		Programme	Modelled	Programme	Modelled
MTCT rate	< 2%	0.65%	2.46%	0.66%	1.99%
Annual rate of new paediatric HIV infections per 100 000 live births by birth cohort	≤ 50	0.38	1.54[a]	0.39	1.18[a]
Annual rate of congenital syphilis per 100 000 live births	≤ 50	4.22	5.37[b]	2.95	3.54[b]
Process indicators	**TARGET**	**2015**		**2016**	
Antenatal coverage – at least one visit	≥ 95%	95.6%		96.7%	
HIV testing coverage of pregnant women	≥ 95%	95.1%		95.8%	
Syphilis testing coverage of pregnant women	≥ 95%	95.1%		95.8%	
Antiretroviral therapy (ART) coverage of HIV-infected pregnant women	≥ 95%	97.2%		97.5%	
Treatment coverage of syphilis-infected pregnant women	≥ 95%	100.0%		100.0%	

a: spectrum – b: WHO syphilis estimation tool

Source: Ministry of Health Malaysia *(8)*.

2. EPIDEMIOLOGY OF HIV AND SYPHILIS

Malaysia has a mature and concentrated HIV epidemic, with seroprevalence rates above 5% among people who inject drugs, sex workers and men who have sex with men. The estimated general population prevalence of HIV among adults aged 15–49 years was 0.4% in 2016, with very low prevalence among pregnant women at 0.06–0.07%. Among the estimated 84 000 adults living with HIV in Malaysia in 2016, 15 000 were women aged 15–49 years; out of the total 3397 new HIV cases reported in 2016, approximately 12% (413 cases) were female.

The early epidemic was largely among people who inject drugs, but modes of transmission have been changing. In 2016, an estimated 85% of new infections occurred through sexual transmission, with the majority among men who have sex with men. The HIV notification rate fell from a high of 28.5 per 100 000 population in 2002 to 11 per 100 000 population in 2009 and was stayed around this level since then *(8,9)*. There is geographical variation in HIV prevalence and trends between states: HIV prevalence among pregnant women, for example, ranged from 0.04% in Sarawak to 0.13% in Kelantan in 2016.

THE NATIONAL PREVALENCE OF SYPHILIS AMONG PREGNANT WOMEN HAS REMAINED VERY LOW.

Syphilis cases in Malaysia are concentrated among men aged 20–39 years. The incidence rate of syphilis in the general population fell from an estimated 10 cases per 100 000 population in the 1990s to 3 cases per 100 000 population in 2005–2011. Since 2011, however, the syphilis case rate has increased gradually to 6.5 cases per 100 000 population in 2016. Similarly, between 2009 and 2016, a threefold increase in the incidence rate of gonorrhoea was observed, from 3.2 to 9.12 per 100 000 population *(10,11)*. Nonetheless, the national prevalence of syphilis among pregnant women has remained very low at 0.08% in 2012 and 0.04% in 2016, ranging from 0% in the state of Melaka to 0.15% in Sarawak in 2016.

Early detection during antenatal screening and high treatment coverage among syphilis-positive mothers reduced the number of congenital syphilis cases diagnosed *(8)*. The decline in the number of cases of congenital syphilis diagnosed in Malaysia over the last decade is also attributed to the better understanding of the definitions and differentiation between "acquired" and "congenital" syphilis, as outlined in *Case Definitions for Infectious Diseases in Malaysia, 2006 (8)*.

Overall, HIV prevalence among pregnant women has stabilized nationally, between 0.06% and 0.07% since 2011, and syphilis prevalence among pregnant women was estimated at 0.04% in 2016.

3. VALIDATION PROCESS FOR THE ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION

Malaysia initiated the process for the validation of its status in the EMTCT of HIV and syphilis in 2016. Four technical working groups were formed and the terms of reference were formulated as stipulated by the 2017 *WHO Global Guidance on Criteria and Processes for Validation: Elimination of Mother-to-Child Transmission of HIV and Syphilis (12)*. These working groups covered the following topics: data, service delivery, laboratory and human rights. They comprised various technical experts including policy-makers, epidemiologists, public health physicians, pathologists, civil society representatives, and clinicians from both state and national levels.

Meeting the needs of the validation process

The validation of the EMTCT of HIV and syphilis was made based on an assessment against impact and process indicators defined by WHO and described in the 2017 EMTCT guidelines *(12)*. The effort was supported by WHO, the United Nations Children's Fund and the Joint United Nations Programme on HIV/AIDS. Figure 2 outlines the main steps of the validation process, along with the committees responsible for each step.

THE EFFORT WAS SUPPORTED BY WHO, THE UNITED NATIONS CHILDREN'S FUND AND THE JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS.

The national technical working groups dedicated to this process used various methods to ascertain completeness and quality of information. These methods included surveys, consensus discussions through meetings and workshops, and a desk review of reports, programme data, guidelines, standard operating procedures (SOPs) and other verified sources. Additionally, focus group discussions were conducted among HIV-positive mothers who had gone through the EMTCT programme to gauge their feelings, experiences and expectations. The team also conducted quick assessments and surveys to determine the extent of EMTCT programme implementation outside Ministry of Health facilities such as hospitals under the purview of the Ministry of Education, Ministry of Defence and the private sector.

To generate the impact indicator estimates, the Malaysian Ministry of Health used the HIV modelling tool, *Spectrum,* as the primary data source for HIV, and the *WHO Syphilis Estimation Tool* for congenital syphilis. Both sets of estimates were supplemented by programmatic data *(8)*. The validation process by the Regional Validation Team was undertaken virtually – through videoconferences and other telecommunication methods, over two months. The Regional Validation Team reported their findings to the WHO Global Validation Advisory Committee, along with the recommendation on the status of validation in Malaysia. This validation represents an endorsement of the EMTCT programme and EMTCT services in Malaysia and comes with a set of recommendations to further strengthen components that have the potential to pose current or future challenges.

FIGURE 2. Main steps of the global validation process

THE VALIDATION PROCESS

A country can submit a validation request and a national report to WHO when the country believes that it has achieved the impact targets for at least one year and the service delivery targets for at least two years.

The validation process consists of a series of national, regional and global programme and data reviews.

NATIONAL	REGIONAL	GLOBAL
Country Ministry of Health • *Requests validation* • *Establishes and convenes a National Validation Team and Technical Working Groups* National Validation Team • *Collects country data and prepares a country report for submission to the Regional Validation Committee*	Regional Validation Committee • *Reviews the country report* Regional Validation Team (RVT) • *Reviews the country report* • *Conducts a country mission to validate data*	Global Validation Advisory Committee • *Reviews RVT report* • *Advises WHO on validation* WHO Global Secretariat • *Grants validation with a formal certification sent to the country Ministry of Health*

Source: WHO *(12)*.

3.1 Malaysia's strengths in achieving elimination of mother-to-child transmission of HIV and syphilis

3.1.1 Political commitment

The *National Strategic Plan: Ending AIDS 2016–2030* emphasizes the importance of EMTCT. If Malaysia is to achieve the objectives set out in this plan, relevant stakeholders must: a) provide quality and comprehensive national EMTCT services, aligned with WHO's recommended strategies; b) strengthen community awareness towards HIV through enrolment in EMTCT programmes and other related activities; and c) ensure the availability of EMTCT services for HIV and syphilis in all antenatal care (ANC) in the public and private sectors. In addition to improving client-friendly services – targeting populations at high risk – for sexually transmitted infections (STIs) and for sexual and reproductive health, the Ministry of Health also intends to review its premarital health module every five years, to include more information on HIV and STIs *(8)*.

The Ministry of Health's Disease Control Division, which includes the HIV/STI/Hepatitis C Sector, and the Family Health Development Division jointly plan, fund and implement

the prevention of mother-to-child transmission (PMTCT) programme at national and state levels. Almost 95% of the total budget for the HIV/AIDS and STI prevention and control programmes in Malaysia – including treatment, care of people living with HIV and the PMTCT programmes – is funded by the Government. In 2016, the total government expenditure on HIV and AIDS programmes exceeded 221 million Malaysian ringgit (US$ 48 million) *(8)*.

BOX 1. Malaysia's EMTCT goals

Increasing testing coverage among women of reproductive age
Reducing the loss to follow-up among HIV-positive women in the PMTCT programme at health clinics
Reducing new HIV infections among women
Reducing late booking among pregnant women
Strengthening voluntary testing of partners of antenatal mothers
Promoting adherence to treatment among HIV-positive pregnant women
Improving the repeat testing among HIV-negative women during ANC
Expanding HIV testing for women at private facilities
Provision of zidovudine syrup to exposed infants
Recommending Option B-plus[a] for all HIV-positive antenatal mothers

a: Option B-plus stands for lifelong antiretroviral treatment.

3.1.2 The national public health-care system and primary health-care service coverage

Currently, it is estimated that there is one doctor for every 656 people in Malaysia. The Malaysian health-care system is built on a large network of public primary health-care services, where the health-care costs for Malaysian citizens is entirely subsidized by the Government. There are over 300 family medicine specialists in over 1000 government health clinics. There is also a growing private health-care sector, mostly located in urban areas, available for clients who are able to pay out of pocket or have private insurance *(8)*.

The majority of pregnant women (15–49 years) are accessing ANC services in government facilities (83.1%), about 9.2% access private health-care facilities, and some (7.3%) access ANC in both private and public facilities *(8)*. Prevention of MTCT of infections is fully integrated in the Government's MCH services. First-line antiretrovirals, including those for PMTCT, have been provided for free to all Malaysians since 2002 in all government facilities. Since the adoption of the Fee Act amendment in 2014, non-Malaysian pregnant women generally have to pay for ANC services in the public sector *(8)*.

However, treatment for infectious diseases of public health significance, including HIV, syphilis and tuberculosis, is provided free of charge. Specifically, if a non-registered migrant pregnant woman is diagnosed with an HIV infection while she resides in Malaysia, she is entitled to free antiretroviral therapy (ART) for the duration of her pregnancy (Option B: offered treatment during pregnancy). While living in Malaysia, her exposed infant will receive free antiretroviral prophylaxis, free ART (if eligible) and free infant formula until the age of 24 months. Option B-plus – in which pregnant women are immediately offered treatment for life regardless of their "cluster of differentiation 4" count – for HIV-infected antenatal mothers was introduced in 2012, and the policy was reaffirmed in 2014 *(8)*.

3.1.3 Integration of elimination of mother-to-child transmission in maternal and child health services

SYPHILIS TESTING AMONG PREGNANT MOTHERS HAD STARTED MORE THAN THREE DECADES AGO.

Being the pillar of primary health care, MCH services have been an integral component of Malaysian health care for many decades *(8)*. The initiative to introduce PMTCT interventions was rolled out nationwide in all government facilities in 1998 and was later expanded to private sector facilities. Meanwhile, syphilis testing among pregnant mothers had started more than three decades ago *(8)*.

WHO recommends that pregnant women have eight antenatal contacts during pregnancy, with at least one contact being with a qualified medical practitioner. Box 2 outlines the success of ANC services in Malaysia. EMTCT is part of a comprehensive package for all pregnant women seeking ANC and similar packages are offered in the private sector (Box 3). HIV and syphilis treatment services are provided for free at public facilities and offered for a fee at private health facilities.

BOX 2. Success of ANC services in Malaysia

Antenatal care
Approximately 95.6% and 96.7% of pregnant women had a least one ANC visit in 2015 and 2016, respectively. A population-based survey in 2016 (National Health and Morbidity Survey) revealed at least 97.4% of women in Malaysia had a minimum of four antenatal visits *(17)*.
HIV and syphilis screening
More than 95% of pregnant women (95.1% in 2015 and 95.8% in 2016) were screened for HIV and syphilis.
HIV antiretroviral therapy
More than 95% of antenatal mothers living with HIV received ART (97.2% in 2015 and 97.5% in 2016).
Syphilis treatment
100% of antenatal mothers with syphilis received appropriate treatment.

Source: Ministry of Health Malaysia *(8)*.

Health clinics use the standard HIV rapid tests (purchased centrally) for testing of antenatal mothers and use the testing algorithms recommended by the Ministry of Health. For syphilis rapid plasma reagin tests, health clinics use several types of tests as outlined by the respective state health departments and follow the treatment guidelines as stipulated by the Ministry of Health. Samples for confirmatory testing for both HIV and syphilis are sent to the nearest hospital laboratory. Treatment and follow-up of HIV-positive mothers and exposed babies are based on the Ministry of Health's SOPs (Fig. 3).

For women who have not attended ANC, rapid HIV testing with informed consent is conducted during labour for women with no record of previous HIV testing (an estimated 8000 women or 1.7% of all pregnant women in 2016). Those women with reactive HIV tests in labour are given intravenous azidothymidine (AZT). Confirmatory testing is conducted after delivery *(13)*.

Once a pregnant woman has been found to be infected with HIV, she is started on lifelong treatment (Option B-plus). The preferred ART regimen is tenofovir plus emtricitabine plus efavirenz *(14)*. In 2016, about one third of HIV-infected pregnant women were already on ART before their current pregnancy *(8)*, and 70% of first ANC visits took place in the first trimester of pregnancy. Women diagnosed in the private sector are referred to the public sector in order to access free ART. There is access to ART at university and military hospitals, and women may choose to continue their care there. All health-care providers from these sectors will follow the same SOPs for notification and for treatment guidelines for both mothers and their exposed infants *(8)*.

BOX 3. HIV and syphilis services

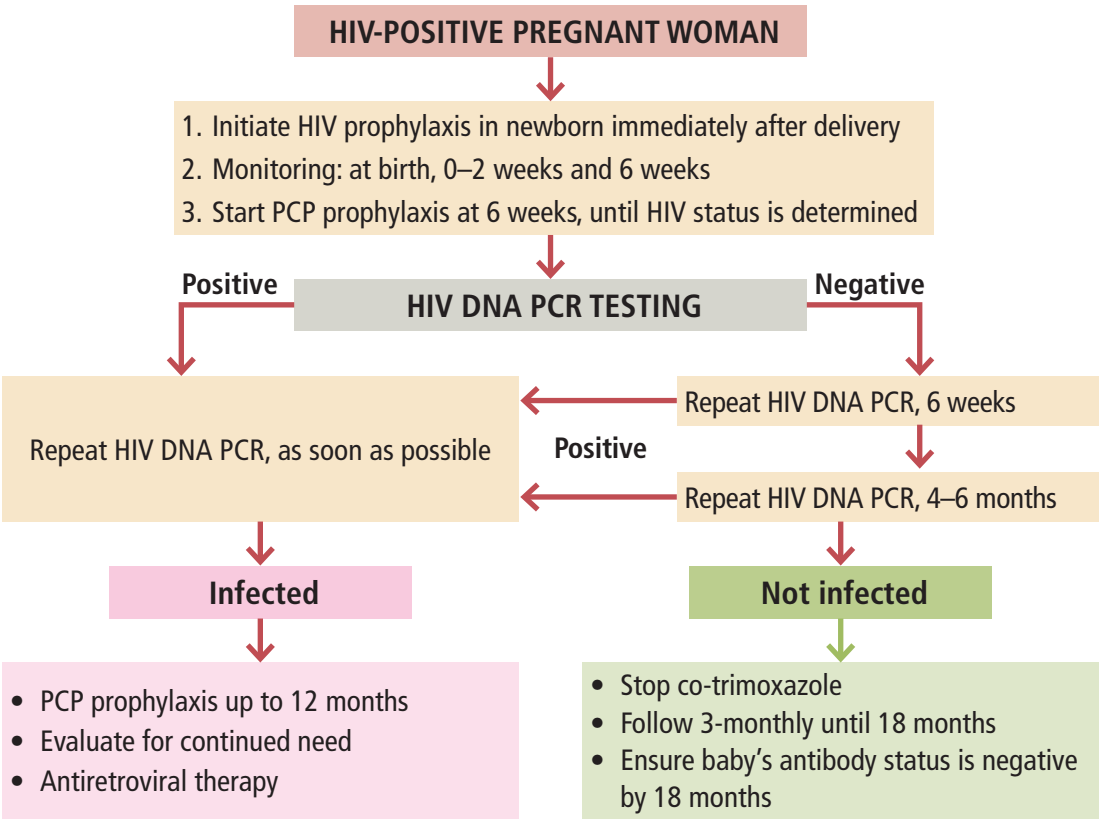
Group pre-test counselling
Voluntary opt-out testing for HIV and syphilis during pregnancy confirmatory tests
Repeat testing at 28 weeks gestation for pregnant women at high risk
HIV/syphilis treatment and care
Diagnostic testing, treatment and care to the exposed infants
Free infant formula up to 2 years for the HIV-exposed infants and, if chosen, advice on breast-feeding practices
Referral for treatment and care to the mother and infants, during delivery and postpartum
Couple counselling and voluntary optional HIV testing
Home visits by nurse post-delivery
Paediatric follow-up by paediatricians for the exposed infants
Referral to other relevant services (for example, social welfare, religious departments, nongovernmental organizations, shelter homes)

HIV-exposed infants are followed by paediatricians for two years post-delivery. They are given free oral AZT twice daily immediately after delivery and continuing for six weeks. *Pneumocystis carinii* pneumonia (PCP) prophylaxis with co-trimoxazole is started at 6 weeks of age and continued until HIV status is determined. HIV-positive infants will be treated according to national guidelines (Fig. 3).

For syphilis, the recommended treatment regime for early syphilis is intramuscular benzathine penicillin (2.4 million unit [MU] in a single dose) or intramuscular procaine penicillin G (600 000 units daily for 10 days); and for late syphilis, intramuscular benzathine penicillin (2.4 MU weekly for three weeks) or procaine penicillin G (600 000 units daily for 17 days) is recommended. For those with a penicillin allergy, an alternative regimen is recommended based on the *Malaysian Guidelines in the Treatment of Sexually Transmitted Infections (16)*.

Patients lost to follow-up (adults and children) can be minimized through follow-up activities carried out by the district health office. The attending physician will alert the nearest district health office, and the respective health inspector and/or paramedics will initiate communication with the client, followed by a home visit *(8)*.

FIGURE 3. Management of HIV-exposed infants



PCP: *Pneumocystis carinii* pneumonia; PCR: polymerase chain reaction

Source: Ministry of Health *(15)*.

3.1.4 Prevention of mother-to-child transmission of HIV and syphilis

The statistics demonstrate the impact of EMTCT of HIV and syphilis in Malaysia, as outlined in Table 2.

3.1.5 Monitoring of infants exposed to HIV and syphilis

For HIV-exposed infants or HIV-infected infants, clinical management of HIV is monitored closely by a family medicine specialist and/or trained medical officers, or a hospital paediatrician *(8)*.

SOPs are in place to ensure optimum antenatal and postnatal care, including safe delivery, HIV-positive and syphilis-positive mothers are referred to hospitals for "joint care" under a multidisciplinary team consisting of infectious disease physicians, obstetrics and gynaecology specialists, and paediatricians. The exposed infants will be followed up by paediatricians in hospitals for a minimum of two years post-delivery *(8)*.

According to Malaysia's 1993 national breastfeeding policy, which was revised in 2006, all mothers are encouraged to exclusively breastfeed their infants up to six months. In contrast, HIV-positive mothers are encouraged to avoid breastfeeding – this is repeatedly emphasized through counselling during antenatal and postpartum home visits. The Government provides free infant formula in government hospitals and health clinics for HIV-exposed infants up to 24 months of age, regardless of nationality. However, if women choose to breastfeed, they receive breastfeeding counselling.

3.1.6 Procurement and quality assurance of diagnostic services

A rapid diagnostic test (RDT) is used as the first HIV screening test for pregnant women in public health centres. The selection of the type of RDT used is accomplished through an open tender system, subject to technical evaluation and additional evaluation by the Institute for Medical Research. One of the prerequisite standards that has been adopted is to ensure that RDTs have 99.9% sensitivity and 99.8% specificity rates. It is also standard practice for each consignment of RDTs to be evaluated by the Institute for Medical Research *(8)*.

THE GOVERNMENT PROVIDES FREE INFANT FORMULA FOR HIV-EXPOSED INFANTS UP TO 24 MONTHS OF AGE.

Syphilis testing is conducted using rapid plasma reagin tests in health centres, which is then confirmed by *Treponema pallidum* haemagglutination/particle agglutination (TPHA/TPPA) tests *(16)*.

Confirmation of HIV/syphilis, HIV polymerase chain reaction (PCR) and viral load blood samples are done in designated public hospital laboratories. Currently, there are two reference laboratories, 14 state hospital laboratories, and 53 major and minor specialist hospital laboratories providing the confirmation tests for both HIV and syphilis *(8)*.

3.1.7 Partner notification and contact tracing

Under the provisions of the Prevention and Control of Infections Diseases Act 1988 *[Act 342],* 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. This can be done either through manual written reports or electronically (e-notification) *(8)*. All confirmed HIV/AIDS cases are subsequently registered in the electronic National AIDS Registry. Notification is conducted using unique identifiers (identification numbers for Malaysians and passport numbers for non-Malaysians) to avoid duplication *(8)*. Data entry is usually done by nurses, assistant medical officers or environmental health officers who are stationed at hospitals, health clinics or district health offices. District medical health officers 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 are only available to designated officers who are responsible for data management.

THE OFFER OF PARTNER VOLUNTARY TESTING IS CARRIED OUT IN 6 OUT OF 14 STATES.

Contact tracing for STIs is mandatory under the Prevention and Control of Infections Diseases Act 1988 *[Act 342],* and partner notification of HIV-positive antenatal mothers is encouraged, with assisted partner notification offered in clinics. Once the HIV or STI status of the partner is known, diagnosis and treatment will be offered. The offer of spousal or partner voluntary testing is carried out in six out of 14 states *(8)*. Voluntary male partner HIV and syphilis testing is not part of the standard package for HIV testing for mothers accessing ANC; thus pretest counselling for male partners may differ from one facility to another.

3.1.8 Evolution of the surveillance and monitoring and evaluation systems

About 10% of government health clinics are connected to an online e-notification surveillance system that requires mandatory notification of communicable diseases, including HIV/AIDS and syphilis. This online surveillance system allows data to be viewed centrally in the Ministry of Health and assists district health offices and 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 the Ministry of Health, and this includes data collection from the private sector (clinics and hospitals) as well. This already extensive network of surveillance systems is expected to be expanded *(8)*.

There are still areas for improvement in the surveillance system. For syphilis, there is a lack of clear case definitions and guidelines on reporting congenital syphilis for surveillance purposes. Thus, most cases reported to the surveillance system were based on clinical, including presumptive, diagnosis.

3.1.9 Community engagement

Validation for eliminating MTCT of HIV and syphilis requires that interventions intended to reach the targets have been implemented in a manner consistent with international human rights standards (Box 4), and have engaged the community of women living with HIV. The Malaysian Ministry of Health has a strong partnership with the Malaysian AIDS Council.

BOX 4. Rights-based principles for EMTCT of HIV

Non-criminalization of HIV/syphilis transmission in law and policy, and in practice
Voluntary HIV and syphilis testing and treatment in law and policy, and in practice
Informed consent in law and policy, and in practice
Elimination of forced, coerced and otherwise involuntary sterilization, contraception and/or abortion in law and policy, and in practice
Confidentiality and privacy of HIV and health information in law and policy, and in practice
Gender equality and non-discrimination in law and policy, and in practice
Accountability, community engagement and participation of people affected by HIV and other key populations
Availability, accessibility, acceptability and quality of services in law and policy, and in practice
Access to justice, remedies and redress in law and policy, and in practice

4. CHALLENGES

4.1 Stigma and discrimination

Current laws do not discriminate against any person who seeks health care, in either public or private facilities. However, stigma and discrimination against people (including women) living with HIV in health-care settings may be one of the reasons for late presentation and loss to follow-up. Despite comprehensive ANC service provision, there are still, albeit very few, pregnant women who present late at antenatal check-ups, showing up only during labour, or who have poor adherence to highly active ART. Therefore, the Ministry of Health, in collaboration with civil society partners, is developing national guidelines to counter stigma and discrimination, especially against key populations *(8)*.

4.2 Migrants and other subpopulations not previously reached

Meeting the health-care needs of the migrant population in the country remains a challenge. 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 *(8)*.

In general, migrants are not denied access to medical care, including ANC services, but have to pay a fee for services. Below are some of the steps taken by various international bodies, nongovernmental organizations (NGOs) and the Ministry of Health to provide services to the migrant population *(8):*

i. One of the leading NGOs in the country, which has a long history working with migrants, is Tenaganita. It champions the rights of migrant populations in estates, construction sites and service industries. Other NGOs, such as the Red Crescent Society and the outreach programmes of the Muslim Youth Movement of Malaysia, provide medical assistance to migrant populations.

ii. Partner organizations of the Malaysian AIDS Council, an organization that coordinates the efforts of organizations working on HIV/AIDS issues in Malaysia, have outreach programmes to reach out to female sex workers (including foreigners) who may need ANC services. The exact numbers of foreign pregnant women and mothers currently reached by ANC is unknown.

iii. Undocumented migrants with identification cards issued by the United Nations High Commissioner for Refugees (UNHCR) are entitled to a 50% discount on all public health-care fees in the country.

iv. Compulsory health insurance schemes for all registered migrant workers residing in Malaysia have been introduced to reimburse for services provided in the country.

Following the implementation of the new Fees Act in 2014, non-Malaysian pregnant women must now pay for basic ANC consultations in the public sector *(8)*. It is also noted that female migrant workers who are registered through a hiring agency are often sent back home if found to be pregnant during employment, subject to contractual agreements. However, a non-Malaysian antenatal mother diagnosed as HIV positive while a resident in the country is currently entitled to receive free ART throughout pregnancy. In addition, the exposed infant is entitled to receive free ART prophylaxis and treatment (as appropriate) as well as free formula for feeding until the age of 24 months. Overall, despite medical charges imposed on non-Malaysians within the public health sector, the majority of non-Malaysian pregnant women do prefer to access ANC services in the public sector – 77.7% versus 19.5% accessing ANC services in the private sector *(17)*. Notably, HIV-infected pregnant women who are unregistered migrants with UNHCR cards are entitled to a 50% discount for lifelong ART after delivery (Option B-plus).

4.3 Private health-care services and programmatic monitoring

One of the limitations of the evaluation methods during the in-country evaluation process was limited information from private health facilities. The survey among facilities that are not under the Ministry of Health, including private facilities, was limited to Klang Valley.

4.4 Sustainability

On average, only 5% of the country's annual budget for HIV/AIDS and STIs comes from international donors. However, Malaysia is confident that funding of HIV/AIDS/STI projects will continue to be on the Government's agenda *(8)*. 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.

5. NEXT STEPS

With the validation and endorsement of the EMTCT programme, recommendations were also made regarding the need to strengthen components of the programme to address potential risks in the future. These include:

» **Strengthening the national EMTCT monitoring system**

Data reporting to also include the private sector and facilities outside the Ministry of Health, such as university and military hospitals; disaggregation of data by subpopulation groups; monitoring of loss to follow-up between initial and confirmatory testing; and monitoring the impact of the Fees Act amendment on ANC visits by non-Malaysian women. The national case definition and laboratory diagnosis of congenital syphilis should be in line with global standards; implement active case reporting of congenital syphilis and revise the stillbirth monitoring to track syphilis stillbirths.

» **Strengthening the provision of EMTCT services**

To work with clinical providers to ensure that comprehensive and balanced information is provided both before and during pregnancy in order for women to make informed choices about delivery, breastfeeding and contraceptive options. Also to expand voluntary and confidential partner testing for HIV and contact tracing for syphilis.

» **Facilitating the access to services by vulnerable groups and addressing issues of stigma and discrimination**

To obtain and analyse data on stigma and discrimination experienced by women living with HIV in health-care settings; reassess policies that create legal barriers or limit access to HIV and sexual and reproductive health services; and invest in community empowerment particularly vulnerable women.

» **Strengthening laboratory systems to deliver quality testing services**

To regulate the quality management system and operational procedures of private laboratories, including adherence to national testing strategies, standards as well as participation in external quality assurance; and to ensure the consistency of service coverage with periodic reporting to a central governing unit.

6. CONCLUSIONS

The success of the PMTCT programme, specifically in the EMTCT of HIV and syphilis in Malaysia, signifies a milestone in the continuous quest to provide quality of care to prevent the transmission of infections from mother to child and to ensure that every child in Malaysia has a healthy start in life. Stronger health systems, as well as timely prevention, diagnosis and treatment for infectious diseases such as HIV and syphilis, are crucial. Political commitment and actionable policies, along with broad multi-stakeholder participation and adherence to international guidelines and secure financing, mean Malaysia is ready to achieve and sustain the goals of EMTCT in the years to come.

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