

PRE-VALIDATION ASSESSMENT REPORT (DRAFT):
TRIPLE ELIMINATION OF MOTHER-TO-CHILD
TRANSMISSION OF HIV, SYPHILIS, AND HEPATITIS B

NATIONAL HIV, AIDS & STIS CONTROL PROGRAM
DEPARTMENT OF PUBLIC HEALTH
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The outcome of the assessment is the result of the collaborative effort and hard work of the NVT, and the unwavering support of all stakeholders involved. We remain thankful to the lead national consultant for guiding us throughout the process. We are optimistic that the findings and information from this assessment will help the Ministry of Health to develop a clear roadmap for the triple elimination of these three infectious diseases on time.

Abbreviations

AFHS	Adolescent friendly health services
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Azidothymidine
CST	Care, Support and Treatment
DHIS	District health information software
DoMSHI	Department of Medical Supplies and Health Infrastructure
DoPH	Department of Public Health
EID	Early infant diagnosis
ELISA	Enzyme-linked immuno sorbent assay
eMTCT	Elimination of mother-to-child transmission
EQA	External quality assurance
HBV	Hepatitis B virus
HCT	HIV counselling and testing services
HBIG	Hepatitis B immune globulin
HepB-BD	Hepatitis B birth dose vaccine
HepB3	Three doses of hepatitis B vaccine
HISC	Health information and service centers
HIV	Human immunodeficiency virus
JDWNRH	Jigme Dorji Wangchuck National Referral Hospital
MCH	Maternal and child health
M&E	Monitoring and evaluation
MoH	Ministry of Health
MSPD	Medical Supplies Procurement Division
MTCT	Mother-to-child transmission
NACP	National HIV/Hepatitis & STIs Control Program
NDEC	National Disease Elimination Committee
NSP	National Strategic Plan
NVC	National validation committee
PHC	Primary health center
PMTCT	Prevention of mother-to-child transmission
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
RCDC	Royal Centre for Disease Control
RDT	Rapid diagnostic test
RMNCH	Reproductive maternal neonatal and child health
RRH	Regional Referral Hospital

SRH	Sexual and reproductive health
STIs	Sexually transmitted infections
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

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Foreword

As we gear towards ending the AIDS epidemic by 2030, the Ministry of Health is in the process of re-energizing its approaches to enhance case diagnosis through the implementation of differentiated HIV testing services across the country and strengthening other care cascades to achieve the 95-95-95 global targets by 2030. One of the important milestones that the Ministry of Health is looking forward to achieving is the triple elimination of Mother to Child Elimination (eMTCT) of HIV, congenital syphilis, and hepatitis B to ensure an AIDS-free generation.

The Ministry of Health through the funding support of WHO and UNICEF conducted the pre-validation assessment to see Bhutan's readiness for the regional validation and certification of triple eMTCT of these infectious diseases by 2025. This assessment will help the national program to understand the current situation of eMTCT of HIV, congenital syphilis, and hepatitis B, and the challenges that will enable the development of appropriate action plans for Bhutan's application for regional validation. The assessment employed the WHO global guidance on criteria, processes, and tools for validation and was carried out by the national validation team that comprised national experts in four core areas of the assessment. The four key areas assessed were data, laboratory, program services, and human rights and community engagement as per the WHO guidance to understand the current situation of the eMTCT of HIV, congenital syphilis, and hepatitis B in Bhutan.

The strategic information generated through this assessment will help the national program prepare for the regional validation process. The findings from this assessment will provide an opportunity to institute measures to overcome these challenges and gaps so that Bhutan will be able to apply for regional validation processes on time. This pre-validation assessment is the result of collaboration between the National AIDS, Hepatitis, and STIs Control Program (NACP) under the Ministry of Health and WHO, UNICEF, and the National Validation Team (NVT) for the eMTCT of HIV, Syphilis, and Hepatitis B.

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Executive summary

The Ministry of Health of Bhutan formally started the Prevention of Mother-to-Child Transmission (PMTCT) program in 2006. Services were nonetheless provided prior to the formal PMTCT program introduction, and the first PMTCT guideline was developed in 2006. PMTCT services are integrated into the general health system and are delivered as an integral component of mother and child health services. PMTCT is a core component under both the national strategic plans for the prevention and control of HIV/STIs (2018-2023) and viral hepatitis (2022-2026). These plans aimed to eliminate new infections among children by 2020 and end AIDs as a public health threat by 2030. The ministry also developed the first-ever national management guidelines for hepatitis B and C in 2019 and updated the policy guidelines for the prevention and control of HIV/STIs which also includes PMTCT interventions in 2020.

The well-functioning health system and high-level commitment to the national response, and the adoption and implementation of the globally recommended policies and strategies set the foundation for Bhutan to eliminate MTCT (eMTCT) of HIV, Syphilis, and HBV. This pre-validation assessment reviewed Bhutan's progress towards PMTCT of HIV, Syphilis, and HBV, and assess Bhutan's readiness for the validation of eMTCT. The WHO's guidance documents and tools designed to review the data quality, program, laboratory quality, and human rights, gender, and community engagement were used to conduct the assessment. The review was conducted in August and September 2022 by the members of the national validation team through - 1) a workshop setting to complete the pre-validation assessment checklist, and 2) administering the adapted validation assessment tools in a few health facilities. The key data and information were assessed mainly for the years 2019, 2020, and 2020. The findings and recommendations were reviewed and then presented to the National Disease Elimination Committee of the Ministry for endorsement.

The National Validation Report template provided by the WHO was adapted for this report with an additional sub-section on the recommendations for achieving the readiness for Bhutan's eMTCT validation application.

Key findings

Since the notification of the first MTCT of HIV in 2002, Bhutan has made commendable achievements in preventing MTCT of HIV, Syphilis, and HBV. The coverage of at least one ANC visit was around 95% in the last five years. Similarly, the average testing coverage of pregnant women for HIV, Syphilis, and HBV are above 95% for the last three assessment years putting Bhutan on track to achieving these coverage targets. One MTCT case of HIV was reported in 2020, and the most recent data suggest the HBsAg prevalence among the ≤ 5 -year-old birth cohort to be less than 0.1%. Around 11 congenital cases were reported annually on average in the past three years giving a case rate of >50 per 100,000 live births. Regarding HBV vaccination, the coverage for three doses of HBV infant vaccination was $>95\%$ for the last three years. However, the birth dose coverage in 2019 was $\sim 92\%$, and it was $<90\%$ in the two most recent years of assessment. All pregnant women living with HIV and Syphilis were receiving treatment.

There is no data on the treatment of eligible HBsAg+ pregnant women with anti-virals and the provision of immunoglobulin to exposed babies although services are being provided.

While there is a recording and reporting system for many eMTCT indicators that are integrated into the national information system, the national program is yet to roll out the system to all health facilities. Additionally, the current system does not capture data on care and treatment comprehensively and on some indicators of HBV and Syphilis. Reports both at the facility- and the national level are not reviewed routinely, and the data collected at the national level is usually not analyzed and turned into useful information. Likewise, supervision visits to the reporting centres are not frequent and planned. Occasionally, reporting is compromised due to inadequate staff, and many staff are not trained in recording and reporting. Data on HBV birth dose vaccination and infant testing are not always available at the MCH units, and there is no formal data-sharing mechanism between different units and departments. Similarly, there is no formal mechanism in place to facilitate inter-programmatic planning between the NACP and the RMNCH Program and the existing communication seems limited.

Overall, the quality of testing and vaccination data is good with a high proportion of testing and vaccination records reviewed indicating service provision. Nonetheless, data maintained in different data recording and collection tools are not always consistent and not updated regularly.

The PMTCT program is primarily funded by the government. All PMTCT services including testing are provided free of cost at all levels of the health system. However, service users often have to bear expenses, especially for transportation and accommodation to avail services from higher-level health facilities. Generally, there is adequate health staff to provide eMTCT services. Relevant training are conducted by the national program for different categories of health workers in the country. This is but not undertaken in a planned manner and the recent trainings were not able to cover all relevant health workers.

PMTCT services including testing and treatment services delivered are based on the recent WHO recommendations. Acute stockouts of test kits and reagents and delays in supply were reported in a few facilities indicating inadequate stock monitoring and supply management. The existing STI/Syphilis guideline developed in 2006 is barely available in health facilities.

The National External Quality Assessment Scheme (NEQAS) is organized by the Royal Centre for Disease Control (RCDC). The Ministry uses tests that are WHO-prequalified, and performance evaluation of test kits is done by RCDC and Drug Regulatory Authority (DRA). Rapid diagnostic testing is made available right up till the Primary Health Centre (PHC) level and ELISA testing is available at the referral hospitals. Laboratory services for early infant diagnosis just commenced in July 2022. Testing algorithms are in line with the WHO recommendations. However, the laboratory SOPs on HIV and related tests need to be updated, and algorithms especially for Syphilis testing are not consistently followed. On-site supervision is not carried out routinely and the follow-up on the recommendations is inadequate.

There is a Laboratory Information System (LIS) that connects all clinical laboratories. However, the system is not able to generate reports by pregnant women. There are no designated

standardized laboratory registers for STI, HBsAg, and Syphilis making it difficult to retrieve records. Although laboratories are well equipped, equipment such as micropipettes, water baths, centrifuges, and freezers are however not calibrated timely. Also, updated inventories on kits and equipment and their usage are lacking.

Bhutan has made a strong commitment to the protection and promotion of human rights. Ensuring confidentiality and privacy and ensuring informed consent are important components of the national HIV policy. The national program recognizes key populations as priority groups and targeted interventions are being implemented, and are also involved in different levels of HIV programming and service delivery. While there are no recent documented reports of a breach of confidentiality and privacy, PLHIV and other key populations appear to face stigma and discrimination including in health settings. Additionally, the criminalization of sex work and drug use presents some barriers to accessing HIV services. The levels of domestic violence also remain high. Only some of the health workers are trained in human rights, gender-based violence, and the needs and priorities of key populations. The current Adolescent Friendly Health Service (AFHS) package is not fully integrated into the health system and its coverage and utilization remain low.

Recommendations

The key recommendations are presented below.

1. Standardized recording and reporting systems integrated into the HIV module of the DHIS-2 that can capture comprehensive PMTCT/MTCT data, that enables data sharing and reporting between different units, and provide disaggregated data need to be instituted. Separate registers for HIV+ mother-infant pairs should be maintained.
2. All relevant healthcare workers (MCH, VCT, and Medical Records, etc.) should be periodically trained on PMTCT and HIV counselling and testing including recording and reporting of PMTCT.
3. In facilities with a high workload, the Ministry may consider assigning a dedicated person for recording and reporting of PMTCT data including the MCH system. To ease the human resource constraint, health facilities also should review their human resource within their facility and explore the possibility of redistributing staff based on the workload.
4. A protocol for assessing data quality needs to be developed. The national program and the Health Research and HMIS Section should analyze data reported quarterly and provide feedback for improvement. The national program should also have an annual monitoring plan and monitor the service delivery, data quality, and provide onsite support.
5. The national program needs to revise the national guidelines on STIs/Syphilis which should also include testing algorithms and recording and reporting requirements.

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6. The NACP in coordination with the DoMSHI needs to ensure an uninterrupted adequate supply of reagents, test kits, and related medical supplies by strictly monitoring stock and proper supply management.
 7. The NACP in coordination with relevant programs and departments should strengthen and/or explore the provision of some PMTCT services such as confirmatory diagnostic services, EID services, eMTCT services, and AFHS from PHCs and district hospitals as relevant.
 8. The NACP should ensure testing of male partners of seropositive pregnant women, and guidelines on testing after delivery for those missed during or have not booked pregnancy.
 9. The national program and the RCDC should ensure that all laboratories receive updated SOPs and conduct periodic training on diagnosis and quality management.
 10. All relevant health workers should be trained in human rights, gender-based violence, and the needs of key populations. The Ministry should consider including these components in the pre-service curricula of health training programs.
 11. The implementation of the National Guidelines for the Management of victims of Intimate Partner Violence and Sexual Violence in Healthcare Settings in Bhutan needs to be rolled out nationwide.
 12. The NACP in collaboration with relevant stakeholders should work towards creating and ensuring a safe and enabling environment for sex workers to access HIV services.
 13. The Ministry should continue to meaningfully engage relevant key population groups in program design, delivery and implementation, and monitoring.
 14. The next national strategic plan should also comprise a chapter on the eMTCT and considers actions addressing the recommendations of this assessment.

Conclusions

Bhutan has made commendable achievements in the implementation of the PMTCT program. There is a high level of commitment from the government and Bhutan follows the WHO-recommended interventions. PMTCT services are well integrated into the health system of the country which is built on the principles of primary health care. Many targets and foundational criteria for the validation of eMTCT have been fulfilled demonstrating Bhutan's potential to eliminate MTCT of HIV, Syphilis, and HBV.

Some targets nonetheless remain unachieved, especially for recent years which could be partly attributable to the disruptions induced by the COVID-19 pandemic. Similarly, certain components of eMTCT foundational requirements were not fulfilled. These shortcomings may preclude Bhutan's application for the validation of eMTCT.

These gaps nonetheless highlight the opportunities to strengthen the PMTCT program in the country. Some key priorities that need to be undertaken include revision of STI/Syphilis guidelines, revision and standardization of laboratory procedures, decentralization of provision of certain services such as EID and HIV confirmation tests, and improving the monitoring of stock and supplies. Additionally, the information system should be strengthened to ensure that data needed to monitor eMTCT indicators are wholly captured routinely and their quality is monitored. The eMTCT data needs should be fully integrated into the DHIS system. Plans to train all relevant health workers on the national guidelines and monitor service delivery and provide supportive supervision should be in place and implemented.

The Ministry with the support of the development and technical partners needs to work to address the recommendations emanating from this assessment and further strengthen the PMTCT program. A detailed plan with timeline that addresses the recommendations needs to be formulated to aid implementation. This will enable Bhutan to apply for the country validation assessment by the Regional Validation Team soon.

1. Country Context

1.1. Geography

Bhutan is a small Himalayan country in Southeast Asia sharing borders with China in the north and India to the south. The total area of 38,394 sq. km. is administratively divided into twenty districts, that is also divided into three regions namely the eastern, central, and western region. The districts are further divided into 205 local government-level or sub-district blocks. Its elevations range from a low of 100m above the sea level in the south to more than 7500m towards the north.

Bhutan is known for its pristine environment and biodiversity. High-rugged mountains, deep narrow valleys and ravines, glaciers, moraines, watercourses, river basins, and waterfalls depict Bhutan's geophysical structure. Forests account for nearly 70% of the total land cover and only around 3% of the total land area is arable.

1.2. Demography

The total projected population for 2022 is 763,249, and the male-to-female ratio is 1.08¹. The population growth rate is 1.3%, and the population density is 19.9 persons per sq. km. More than 60% of the population lives in rural areas. The median age is 29.4 years. People aged 15-64 constitute around 70% of the population and about 23% of the population is under the age of 14 years.

Bhutan is a low-middle-income country, and its economy is mainly driven by hydropower followed by agriculture and tourism. Agriculture is a dominant sector, particularly in rural Bhutan. The per capita GDP in 2022 was USD 3358.59. The adult literacy rate stands at 66.6% as of 2017, and the unemployment rate is 4.8% with a significantly higher rate among youths at 20.9%. A little over 8% of the population lives below the national poverty line, and the rate is much higher in rural compared to urban areas (11.9% vs 0.8%).

1.3. Key health indicators

Bhutan has been able to achieve high coverage of more than 90% of primary health care. The under-five mortality has reduced significantly from 134 in 1990 to 34.1 per 1000 live births in 2017. The infant mortality and neonatal mortality in 2017 were 15 and 21 per 1000 live births, respectively. Although stunting in children has reduced from 33% in 2010 to 21.2% in 2015, severe malnourishment is still a concern mainly in

¹ Statistical Yearbook 2022, National Statistics Bureau, Bhutan

rural areas and in the eastern region. More than 95% of the population has access to safe drinking water and safe sanitation facilities. The life expectancy is 70.2 years. Inadequate nutrition, perinatal and maternal conditions, poor sanitation, and parasitic infections still top the causes of major illnesses.

The maternal mortality ratio was estimated at 89 per 100,000 live births in 2017, a huge reduction from the rate of 380 per 100,000 live births in 1994. Delivery in health facilities is reported to be over 93% in 2017. Like many other countries in the region, non-communicable diseases are on the rise and accounts for nearly 70% of mortality in the country posing a significant public health challenge.

1.4. Brief description of NVT and review goals

The Ministry of Health (MoH) has formed a National Disease Elimination Committee (NDEC) to oversee and guide the elimination process for all infectious diseases in the country in 2019. Subsequently, the National HIV/Hepatitis & STIs Control Program (NACP) under the Department of Public Health (DoPH) of the Ministry started planning the review process for the triple Elimination of Mother-Child Transmission (eMTCT) of HIV, Syphilis, and Hepatitis B in the same year. However, due to the COVID-19 pandemic the initiative was delayed until recently.

The ToR for the NDEC and disease-specific National Validation Team (NVT) (Annexure 1) was developed and finalized in August 2019 through a consultation meeting involving all key stakeholders. The process was led by the DoPH. Following approval of the ToR by the Ministry, the first NDEC meeting was held from November 14-15 in 2019 aimed to sensitize the NDEC members on the roadmap and strategies for the diseases that are targeted for elimination such as HIV and Malaria. The NDEC recommended the NVT to accelerate the review process for eMTCT of HIV, Syphilis, and Hepatitis B (HBV).

The NVT for eMTCT of HIV, Syphilis, and HBV was then formed on November 6, 2020, in line with the order issued by the DoPH (Reference: MoH/DoPH/NACP/02/2020-2021). The composition of the national technical working team is provided in Annexure 2. United Nations agencies like World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), and United Nations Children's Fund (UNICEF) were also engaged in the planning and the review process to provide technical guidance and financial support.

The NACP in coordination with WHO CO organized the first regional virtual orientation on eMTCT guidelines by the WHO SEARO on November 12, 2020, for all the NVT members. However, from 2021 to early 2022 owing to COVID-19 restrictions, pre-validation assessment for eMTCT for HIV, Syphilis, and HBV could not be conducted.

The national strategic plans for the prevention and control of HIV/STIs and viral hepatitis sets out to eliminate MTCT of HIV, Syphilis and HBV by 2020. The main aim of this PMTCT program review was to assess Bhutan’s readiness for the validation of eMTCT of HIV, Syphilis, and HBV by 2025. The assessment is expected to help gain a comprehensive understanding of the eMTCT program situation and its status in the country. The specific objectives of the assessment were to -

- a. review the programmatic components relevant to the elimination,
- b. assess the reliability of the data generated to evaluate the achievement of the targets and ascertain the targets,
- c. verify the existence of an adequate laboratory network to provide the services needed to achieve and maintain an eMTCT program, and
- d. assess the basic human rights and gender equality considerations, and engagement of key populations.

The National Validation Report template provided by the WHO was adapted for this report with an additional sub-section on recommendations for achieving the readiness for the application of eMTCT validation.

1.5. Situation of HIV, Syphilis, and HBV

1.5.1. Situation of HIV

Bhutan has a low-level HIV epidemic with an estimated prevalence of 0.2% among adults aged 15-49 years old². The estimated incidence among the adult population is 0.02% and for all age categories is 0.1 per 1000 uninfected individuals¹. The cumulative number of cases reported from 1993 until June 2022 was 835 (433 males and 402 females). In the last four years (2018-2021), an average of 88,584 HIV tests were conducted annually with a yearly average case diagnosis ranging between 49 and 58 cases².

A majority (70.3%) of diagnosed cases are between the ages of 25-49 years, 13.3% between 15-24 years, 11.3% above 50 years, and the remaining 5.1% are below 15 years of age. Around 28% (n=233) were detected through contact tracing, 25.4% (n=212) via medical screening, 24.6% (n=205) through voluntary testing, 9.5% (n=79) from screening of pregnant mothers attending antenatal care (ANC), 8.3% (n=69) through onsite health screening, and the remaining 4.4% (n=37) via blood donor screening³. Most (93.5%)

² UNAIDS. Bhutan Spectrum File 2021. Bangkok, Thailand: UNAIDS; 2021.

³ National HIV, Hepatitis and STIs Control Program. Bi-annual HIV epidemic Report 2022. Thimphu, Bhutan: Ministry of Health; June 2022.

acquired infection through unprotected sex, 5% through mother to child, and 0.5% through injecting drugs ².

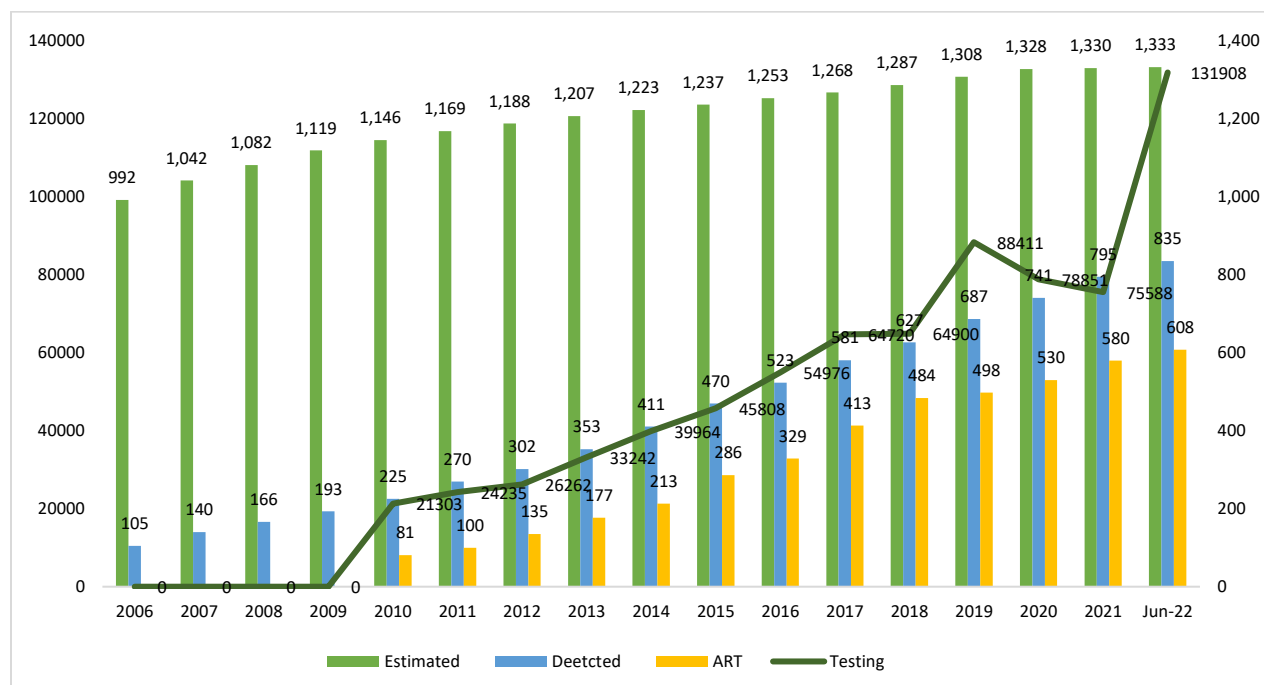


Figure 1: Estimated vs the cumulative diagnosed HIV cases and ART coverage from 1993-June 2022

Of the 1300 estimated HIV cases¹, 835 cases have been diagnosed to date leaving a case detection gap of 35.8% (Figure 1). The aggressive testing among key and general population including in the ANC has helped narrowed this gap over the period. The case detection has declined from 39% to 35.8% just in the last six months. At present, there are 628 diagnosed People Living with HIV (PLHIV) in the country, of which 608 are on ART giving a high treatment coverage of 96.8%. The routine program data show that 365 of the 608 PLHIV on ART have undergone viral load testing in 2022. Out of those tested, 91.5% (n=334) had suppressed viral load. The low viral load testing rate in 2021 could be attributed to COVID-19 triggered disruption in and reduced access to services.

1.5.2. Situation of syphilis

The number of reported cases of syphilis in the general population dropped from 157 in 2016 to 93 in 2017. However, cases started to increase sharply from 2018 onwards in both males and females (Figure 2)⁴. Around 55% of the total cases (in the last six years)

⁴ Annual Health Bulletin 2021, Total national morbidity at the national level from 2016-2020.

were among females, and the case notification rate was also greater among females than males (Table 1).

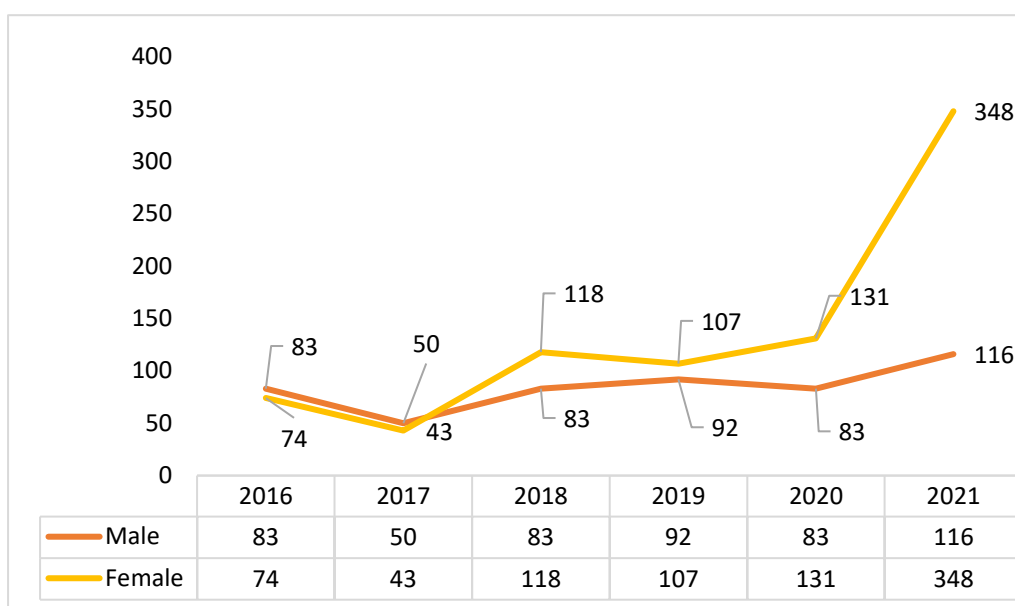


Figure 2: Trends in syphilis infection among general population by sex in Bhutan from 2016-2021

Table 1: Case notification rate of syphilis among males and females per 100000 live births from 2016-2021, Bhutan

<i>Year</i>	<i>Estimated pregnant mothers/ Birth</i>	<i>Male syphilis cases per year *</i>	<i>Case rate (Male)**</i>	<i>Female Syphilis cases per year **</i>	<i>Case rate (Female)**</i>	<i>Total cases per year</i>
2016	13090	83	634	74	565	157
2017	13101	50	382	43	328	93
2018	13057	83	636	118	904	201
2019	12960	92	710	107	826	199
2020	12831	83	647	131	1021	207
2021	12679	116	915	348	2745	864
Total	77718	507	3923	1821	6389	1721

Data source: ** Annual Health Bulletin (AHB) from 2016-2021; ** per 100000 population

In terms distribution by age, syphilis infection is primarily concentrated among those aged 15-49 years old followed by those between the ages of 50-59 years (Figure 3). There appears to be no considerable difference in the distribution of infection by gender.

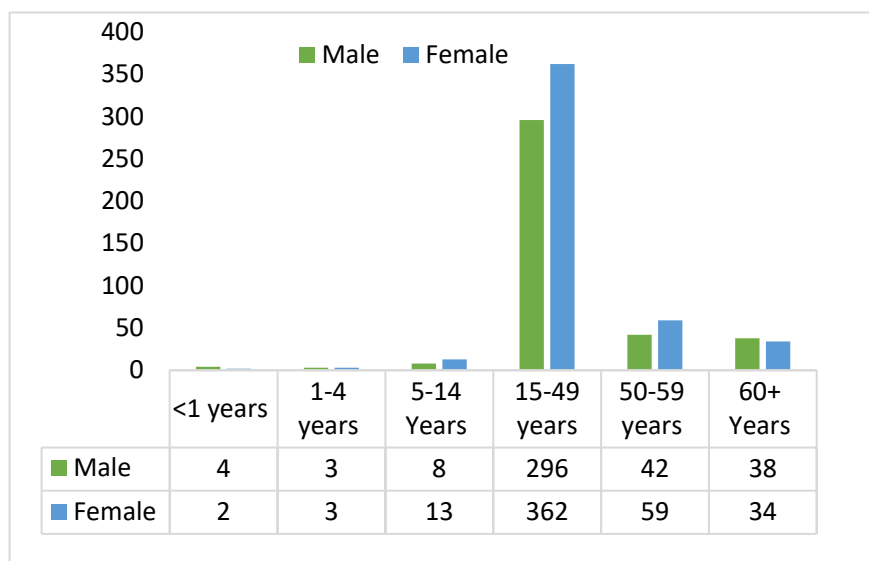


Figure 3: Distribution of syphilis infection among the general population by gender in Bhutan from 2016-2021

In the last four years, the number of reported syphilis cases (measured with treponemal assays) in pregnant women is about 264 (Table 2). The trend of syphilis diagnosis among pregnant women has remained stagnant with an annual average of 66 cases in the last four years. In the period 2018 to 2021, a total of 37,578 pregnant women were screened for syphilis (measured with treponemal assays)³ leading to the diagnosis of 264 TPHA+⁸ at the first ANC visit (Table 2).

Table 2: Trends of syphilis diagnosis in pregnant women screened for at least one TPHA during the first ANC visit from 2016-to 2021 in Bhutan

<i>Year</i>	<i>1st ANC visit</i>	<i>Received at least one TPHA test</i>	<i>Tested TPHA+ at first ANC visit</i>
2018	8481	8336	70
2019	9513	9373	63
2020	10246	10104	68
2021	9338	9292	63
Total	37578	37105	264

Data source: Care, Support and Treatment (CST) PMTCT report 2018-2021 & AHB 2016-2020.

A total of 48 syphilis cases (25 males and 23 females) were reported in the period 2016 to 2020 among children below five years giving an annual average case notification of about 9 cases (Figure 4)⁵.

⁵ Annual Health Bulletin 2021. Thimphu, Bhutan; Ministry of Health: 2021.

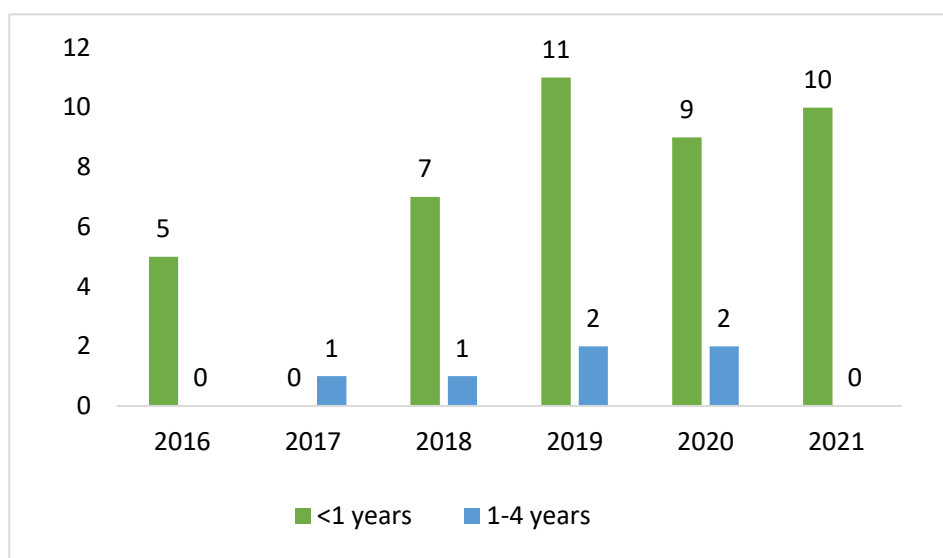


Figure 4: Number of congenital syphilis reported in children aged 1-4 years from 2016-2021

1.5.3. Situation of hepatitis B

The number of cases and the case rate of acute HBV cases are slightly higher in males than females in the last five years (Table 3). In both males and females case notification sharply rose in 2017 and 2018 and then declined in 2019. The trend of HBV seems to have slightly increased since then.

Table 3: Case notification rate of HBV among males and females per 100000 live births from 2016-2021

<i>Year</i>	<i>Male HBV cases/ year*</i>	<i>Rate (Male)**</i>	<i>Female HBV cases per year *</i>	<i>Rate (Female)**</i>	<i>Total HBV cases/ year</i>
2016	95	726	67	512	162
2017	174	1328	173	1321	347
2018	155	1187	146	1118	301
2019	72	556	54	417	126
2020	63	491	66	514	129
2021	65	513	70	552	135
Total	624	4800	576	4434	1200

*Data source: ** AHB report from 2016-2021; ** per 100,000 population*

The infection is concentrated among individuals aged 15-49 years old followed by those >49 years of age (Figure 5). There is no profound difference in HBV infection by age and gender (Figure 5). About 16 children were diagnosed with acute HBV in the period 2016-2020.

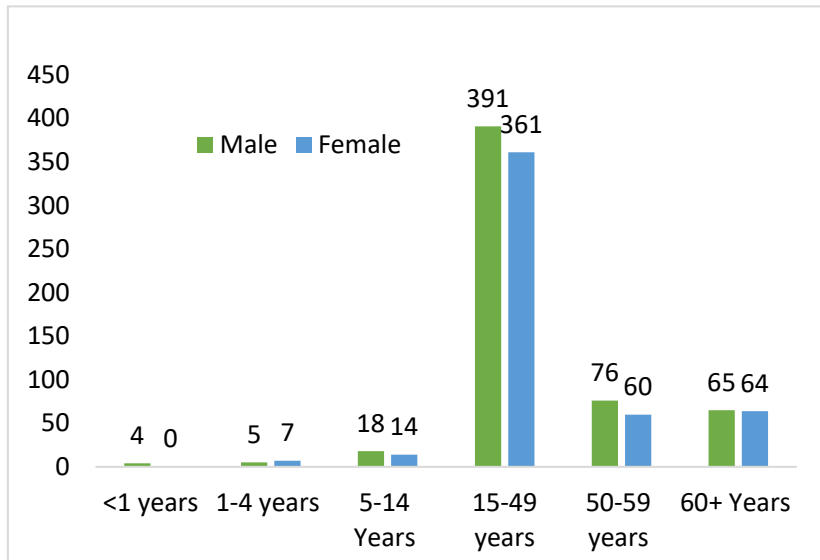


Figure 5: Distribution of hepatitis B infection among general population by age and gender

Although there was no national hepatitis control program until 2017, the prevention program for HBV in Bhutan was started since the introduction of HBV vaccination among children in 1997. As of 2017, the coverage of three doses of HBV (HepB3) stands at 90% and that of HBV birth dose vaccine at 81%. Recent data shows that the prevalence of HBV and HCV has reduced from 5.9% to 2% and from 1.3% to 0.3%, respectively⁹ (Figure 6).

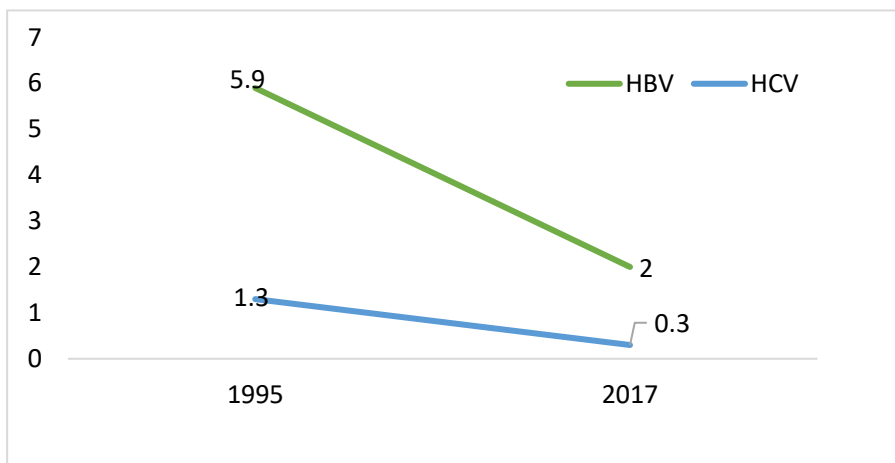


Figure 6: Trends of population level prevalence of HBV and HCV in 1995 and 2017

The diagnosis of HBV among pregnant women has remained stagnant in the recent years with an annual average of 54 acute hepatitis cases diagnosed in the last four years (Table 4). Of the 37,578 pregnant women who attended the first ANC visit, almost all (99%, n=37281) were tested for HBV, out of which 218 tested positive giving a positivity rate of 1%.

Table 4: Trends of HBV diagnosis in pregnant women during the first ANC visit from 2016-to 2021

<i>Year</i>	<i>1st ANC visit*</i>	<i>Received at least one HBV test**</i>	<i>Tested HBV+ at first ANC visit***</i>
2018	8481	8480	54
2019	9513	9465	59
2020	10246	10044	46
2021	9338	9292	59
Total	37578	37281	218

1.6. Modes and drivers of HIV transmission

Based on the case-based surveillance data, five main modes of transmission were identified (Table 5) ⁶. About 87% of the diagnosed PLHIV have acquired HIV infection through high-risk heterosexual transmission followed by 9% mother to child transmission (MTCT), 6.1% through low-risk heterosexual transmission, 1.6% through a parenteral transmission (consisting of injecting drug use, nosocomial and intentional skin penetration like tattooing, etc.,) and 1.4% via homosexuality.

Table 5: Mapping of risk attributions against the Mode of Transmission

<i>Risk attributions</i>	<i>n</i>	<i>%</i>	<i>MoT</i>
Injecting Drug Use (IDU)	3	0.68	Parenteral
Nosocomial (NOS)	2	0.45	
Skin penetration (SP)	2	0.45	
Subtotal	7	1.58	
Heterosexual contact reported by female (HETF)	19	4.29	

⁶ Khandu L, Choida N, Drukpa J, Tshering D, Wangdi S. Redefining the mode of HIV transmission through analysis of risk attribution among the reported HIV cases from 1993 to 2021 in Bhutan. AIDS Research and Treatment. 2022; 2022:1-8.

Heterosexual contact reported by males (HETM)	8	1.81	Low-risk Heterosexual
Subtotal	27	6.09	
Heterosexual contact with an HIV-infected person (HETHIV)**	124	27.99	High-Risk Heterosexual (HRH)
Sex Workers (SW)**	56	12.64	
Heterosexual contact with HIV with a person injecting drug use (HETIDU)**	1	0.23	
Heterosexual contact with a bisexual person (HETHOM)**	0	0	
Heterosexual contact with sex workers/clients of sex workers (HETSW)**	182	41.08	
Subtotal	363	81.94	
Homosexual contacts (HOM)	6	1.35	Homosexual
subtotal	6	1.35	
Mother Child Transmission (MTCT)	39	8.80	MTCT
Total	39	8.80	
Unknown risk	1	0.23	Unknown
subtotal	1	0.23	
Overall Total	443	100	

MoT: Mode of Transmission

1.7. Other information

1.7.1. Prevention of mother-to-child transmission (PMTCT)

The national biannual HIV Epidemic Report 2021 showed a cumulated 79 (9.3%) HIV-infected pregnant women diagnosed through ANC screening. The total number of reported HIV cases in the country was 795. The first cases of HIV-infected pregnant women were reported in 2004. Since then, sporadic cases of HIV-infected pregnant women were recorded with the highest number of 14 reported in 2011 followed by 13 in 2020 and then 7 in 2022 (Figure 7)⁷. On an average, about 8 pregnant mothers were diagnosed annually in the last five years (2017-2021). The HIV prevalence among pregnant mothers was 0.10% each in 2019 and 2020, while it dropped to 0.06% in 2021².

⁷ National HIV, AIDS and STIs Control Program. VCT Report (Excel Sheet) 2021. Thimphu, Bhutan; Care, Support and Treatment Unit, JDWNRH: 2021.

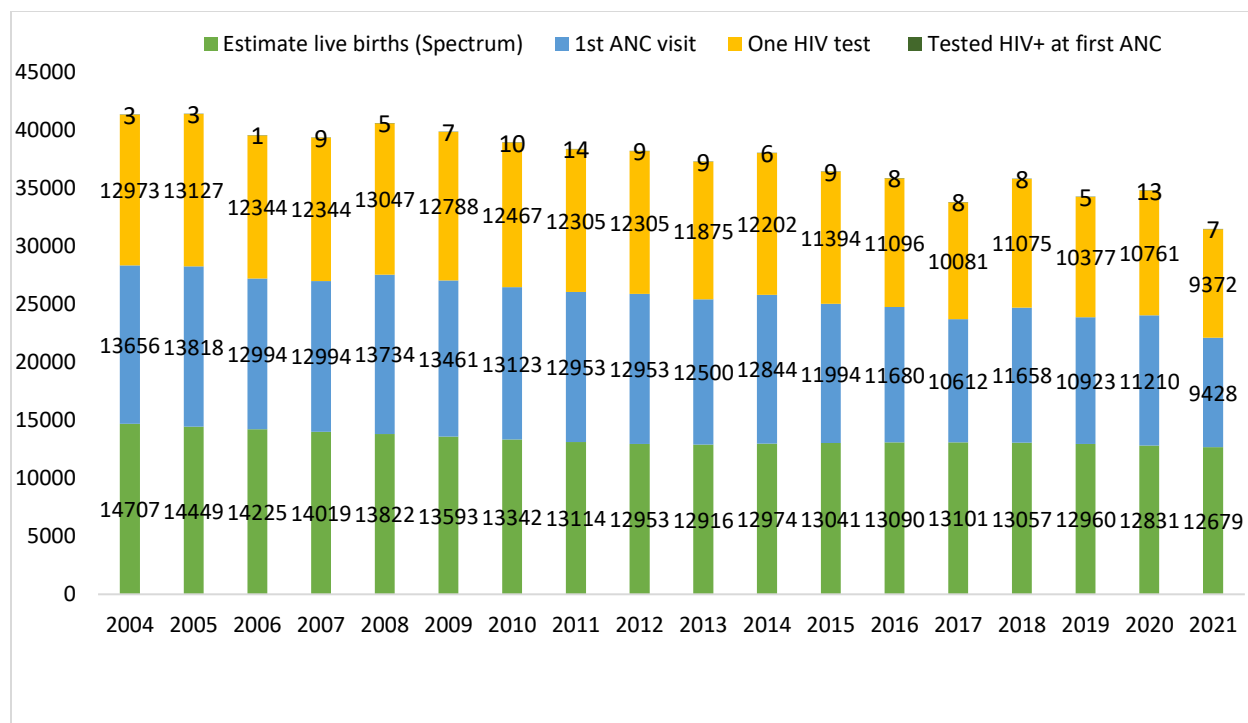


Figure 7: Number of first ANC visit versus the number tested and HIV positivity among pregnant women in Bhutan from 2004-2021

The annual average ANC coverage (one visit) and HIV testing coverage is $\geq 95\%$ in the last five years. In the period 2019 to 2021, the HIV testing coverage among 1st ANC attendees was about 95%, 96% and 99%, respectively. However, when the estimated number of births provided by the UNAIDS was used as the denominator, the one-time HIV testing coverage among pregnant mothers is about 80%, 84% and 74% for the same years.

1.7.2. Mother-to-child transmission (MTCT) cases

The routine program data from the Care, Support and Treatment (CST) of NACP based at the Jigme Dorji Wangchuk National Referral Hospital (JDWNRH) shows an average of <1 (0.2) MTCT cases and around 9 PMTCT cases (ANC HIV positive pregnant women) in the last five years (2018-2022) (Figure 8).

Based on program data, a total of 187 pregnant women were diagnosed having HIV since the diagnosis of first MTCT case in 2002. Regarding MTCT cases, 42 infants were detected HIV positive (39 MTCT cases infected without PMTCT intervention and 3 with PMTCT intervention), 127 were found to be negative and 4 were reported to have died. The remaining 11 were still waiting for confirmation of HIV status.

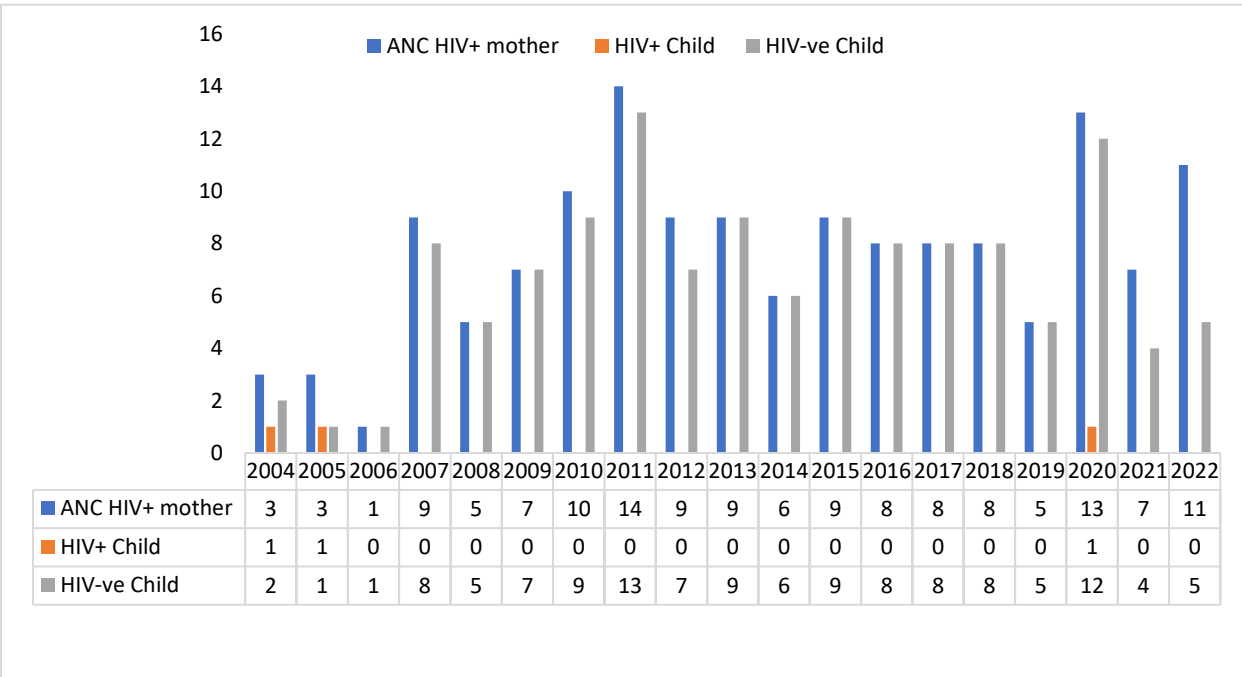


Figure 8: ANC cases vs MTCT cases from 2004-2022

1.8. Stillbirth trends and contributing factors

As per the retrospective review study that used institutional records, the stillbirth rate is estimated to be 10 per 1000 live births in 2015. The Lancet estimates Bhutan’s stillbirth to be 16 per 1000 live birth for the same year. The difference in the rates may suggest potential gaps in the recording and reporting of stillbirths in the country. Though data on stillbirths are reported to the Health Research and HMIS Section (HRS), the data generated in the information system is not used owing to potential underreporting.

Some of the key causes of stillbirth include congenital infection, pregnancy-induced hypertension, primiparity and parity (≥ 5 births), prolonged and obstructed labour, and placental abruptions.

2. Health Systems and Services in the Country

2.1. Health system

The health system in Bhutan is predominantly financed by the government and the private sector is limited to providing some basic diagnostic services. Health services are provided free of charge including referrals for specialized services out of the country. Healthcare services are delivered through a three-tiered health network that consists of a national referral hospital at the apex that also serves as the referral hospital for the western region, two regional referral hospitals, 53 district-level hospitals, 183 primary health centers, and 53 sub-posts at the block and/or community level that is spread across all the twenty districts. Except for at the national level, both traditional and allopathy medicine is provided in an integrated manner through the health system network in the districts. Many, especially those in rural areas, still frequent local healers, shamans, and priests, and are usually the preferred first point of contact when unwell.

All health facilities are equipped with the required human resources and facilities as per the standards. There is a total of around 5285 health workers comprising of medical specialists, general doctors, laboratory and pharmacy personnel, and other allied health workers. The health facilities provide preventive, promotive, and rehabilitative health services, and among them HIV/AIDS service is one key service provided.

2.2. The national program and service delivery

The National HIV/Hepatitis & STIs Control Program (NACP) under the Department of Public Health of the MoH is the nodal agency in planning and the management of the overall national response towards the prevention and control of HIV, HBV, and STIs in the country. The national response is well embedded within the overall health system.

At the district level, there is a Voluntary Counselling and Testing (VCT) unit manned by designated VCT and counsellors. There are around 31 VCT focal persons looking after HIV, HBV, and other STIs-related activities in the districts as an additional responsibility. VCT services are delivered through the MCH clinics in most of the health facilities. Other categories of health workers such as medical doctors, and laboratory and pharmacy personnel also play a critical role in the initiation of treatment, clinical management, enhancing case diagnosis, and supporting treatment adherence. All laboratory units are also well equipped with resources needed to perform testing of HIV, Syphilis, and HBV including other STIs as per the national guidelines and standards.

There are seven health information and service centres (HISCs) established in the major towns to mainly cater to key and vulnerable populations. These centres are adequately staffed with professional counsellors and outreach workers from key population communities like men having sex with men, transgender persons, and female sex workers to reach the unreached and key populations with comprehensive HIV prevention and related services. The main objective of establishing the standalone VCT centre/HISC is to carry out targeted interventions for key populations which in turn can help optimize outcomes of the national response toward the prevention and control of HIV and STIs. These centres are well-linked with health centres across the country and community-based organizations including NGOs for referral and linkages.

At the national level, the NACP has adequate staff and all the required resources and facilities to manage the program including management of externally funded grants. At present, four regular officers are working for the national program, and the program functions under the direct supervision of the national program manager. The program is positioned under the communicable disease division of the Department of Public Health, and the Chief of the division oversees the management of the national program.

2.3. PMTCT program in Bhutan

The PMTCT program was instituted in 2006 as an integral component of the mother and child health services in the country. Although some PMTCT services were provided, there was no formal PMTCT program prior to 2005.

The national PMTCT guidelines and policies for all three diseases are based on the WHO recommendations. As part of the PMTCT services, VCT of HIV, Syphilis, and HBV are routinely offered in the antenatal clinics to pregnant women through an opt-out approach. Other services like the distribution of condoms and behavior change counselling are also provided. The national program introduced the policy to provide two-time testing for these three diseases in 2018. The first testing is provided during the first ANC visit and the second testing is offered during the third trimester before delivery. HIV testing services were decentralized right up till the primary health centres (PHCs) in 2013 to ensure universal access to testing services for all pregnant women.

Vaginal delivery for HIV+ pregnant women was encouraged until 2010, and cesarean was considered only for indications of obstetric complications. The national policy recommends no breastfeeding, and a single dose of zidovudine is administered to the infants. From 2010 to 2013, option B triple regimen (ZDV/3TC/NVP) was provided to HIV-positive women from 14 weeks with elective cesarean section. From 2013 until

2018, the option B+ treatment regimen (TDF+3TC+EFV) was initiated as early as possible with the elective cesarean at 39 weeks of gestation.

With the introduction of the ‘treat all’ policy in 2016, all pregnant women diagnosed with HIV are now provided with ART treatment irrespective of CD4 count level. Children born to HIV-positive mothers are also provided prophylaxis consisting of daily doses of AZT within the first 6-12 hours of delivery for the first 6 weeks of life with replacement feeding. The government provides free replacement feeding for two years to all HIV-positive mothers. Infants born to HIV-positive mothers are tested for HIV using a rapid diagnostic test kit at 9 months and a repeat test is conducted at 18 months. Early Infant Diagnosis (EID) was introduced in July 2022 to ensure all infants born to HIV-positive mothers are tested and diagnosed early on.

Hepatitis B vaccination was introduced in Bhutan in 1997 and the HBV birth dose in 2012. Until 2017 there was no standalone national program managing the prevention and control of HBV in the country. In 2017 the hepatitis program was created formally and integrated into the NACP, and prevention and control activities were intensified thereafter.

The first national strategic plan and treatment guidelines were developed in 2020. As part of the PMTCT of HBV, all pregnant women are screened for HBV at the first ANC visit and then during the last trimester along with HIV and Syphilis. Upon completion of the 3 doses of the HBV vaccination series, the booster dose is being provided to those infants born to HBsAg-positive mothers at 9-12 months and 1-2 months of age. The national guideline recommends that all babies born to HBsAg-positive mothers are provided with the HBIg within 12 hours of life. Infants of HBsAg-positive mothers are provided post-vaccination testing for HBsAg and anti-HBs titer at 9-12 months of age. If HBsAg tests negative and the anti-HBs titre is less than 10mIU/ml, then 3 doses of HBV vaccine at 0, 1, and 6 months are provided.

The first STIs guidelines was developed in 2006. The prevention and control of STIs are well integrated into Bhutan’s national HIV program since 1988. Similar to HIV and HBV screening, pregnant women are also screened for Syphilis as part of the PMTCT program at the first ANC visit and then during the last trimesters. For the screening of syphilis, nontreponemal tests such as rapid plasma reagin (RPR) are provided and then confirmed using the treponema pallidum hemagglutination (TPHA) test. The treatment for early syphilis in HIV-infected patients is not different from those not infected with HIV. All infants born to seropositive mothers are treated with a single intramuscular dose of benzathine benzylpenicillin. All mothers of children born with congenital syphilis are

tested for HIV; if the mother's HIV test is positive, the infant is referred for follow-up and HIV testing.

2.4. MCH services

Mother and Child Health (MCH) Services are made available at all levels of the health system in the country. There is a dedicated MCH unit in all the health facilities mandated to provide all the essential services for pregnant women, mothers, and children as per the national MCH guideline and National Midwifery standard. At the national level, there is the Gyaltshen Jetsun Pema Mother and Child Hospital in the capital. All health facilities in the country are adequately equipped to provide the full range of essential health services, which also includes MCH services. The VCT and MCH units are usually integrated in all the health facilities.

Additionally, health education and awareness of the importance of utilizing MCH services are also provided through different platforms such as media and sensitization programs. These efforts seemingly have still not been effective especially at the community level in rural areas and among those from low socioeconomic backgrounds. Some key indicators depicting low uptake of services and missed opportunities such as low exclusive breast-feeding rate (51%), low coverage of recommended 8 ANC visits (26%) and 4 PNC visits (75%), stunting (21%), and high anaemia prevalence among pregnant mothers (27.3%), are of concern.

Bhutan's national breastfeeding policy recommends exclusive breastfeeding for 6 months. The rate of early initiation of breastfeeding as per the National Nutrition Survey in 2015 stands at 78%. The national HIV policy, however, does not recommend women living with HIV breastfeed their infants.

Family planning services and programs are available in all health facilities free of charge and are delivered to service users based on their informed choice. Family planning services provided include temporary methods like condoms, DMPA, oral contraceptive pills, IUD, and permanent methods like tubal ligation and vasectomy.

2.5. Health care needs and access for vulnerable populations

Similar to the general population, health services are also provided to non-citizens including a large number of migrant workers from the neighbouring country free of charge. However, some marginalized populations such as those from low socioeconomic backgrounds and key populations could be facing financial and logistical difficulties in accessing health services. As per the 2017 Bhutan Living Standards Survey, indirect costs mainly rituals and transportation accounted for the greatest household health

expenditure, and health expenditure was greater in rural areas than urban areas⁸. The healthcare financing assessment report showed that the household contribution accounted for 18% and 15.4% of the total health spending in the 2018-2019 and 2019-2020 fiscal years, respectively ⁹. The out-of-pocket payments represented for USD 264,321.00 (8%) of the total AIDS spending ¹⁰.

Stigma and discrimination and unfriendly laws could be also preventing key populations such as men having sex with men, sex workers, transgender persons, and drug users to access HIV and related services. The NACP with the support of the Global Fund-funded national and regional grants is working to remove gender and human rights-related barriers to accessing and ensuring sustainable HIV and related services for the key populations in Bhutan.

⁸ National Statistics Bureau, Bhutan Living Standards Survey, 2017

⁹ Ministry of Health, Healthcare Financing Policy Brief - 2018-2020

¹⁰ Ministry of Health, National AIDS Spending Accounts (NASA), 2020

3. Methods and Use of Tools

3.1. Description of the pre-validation assessment process

This pre-validation assessment was carried out in August and September 2022. The tools and checklists developed by the WHO to conduct a preliminary assessment and the more detailed tools to assess the four key areas were used to guide the conduct of the assessment (Available here - <https://www.who.int/initiatives/triple-elimination-initiative-of-mother-to-child-transmission-of-hiv-syphilis-and-hepatitis-b/validation/process-and-tools>)¹¹. The four thematic areas assessed were -

1. Data quality
2. Programme assessment
3. Laboratory quality assurance
4. Human rights, gender equality, and community engagement

Before the field visits, the National Validation Team, some of whose members were also part of the assessment team, were orientated on the Guidance on Criteria and Processes for Validation of Triple EMTCT of HIV, Syphilis, and HBV using the guidance documents provided by the WHO. The orientation was conducted from June 29-30, 2022. The main documents that were referred to are as below.

1. Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis, and HBV, 2021
2. Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis: an overview of validation structures and responsibilities at national, regional, and global levels, 2020
3. Interim guidance for country validation of viral hepatitis elimination, 2021

The key components assessed include primary prevention, ANC services, HIV/HBV/syphilis testing, treatment of HIV- and syphilis-positive pregnant and postpartum women, and treatment of infants and children exposed during pregnancy, delivery, and breastfeeding.

The preliminary validation assessment tool was filled by the team during the orientation workshop to help the team get a sense of the status in terms of meeting the foundational requirements and the eMTCT achievement targets. The validation team members also agreed to conduct a more detailed assessment using the WHO tools to get a nuanced understanding of the status and gaps and challenges in terms of the

¹¹ World Health Organization, Validation of eMTCT of HIV, syphilis and hepatitis B - Processes and tools

country's readiness to apply for the validation of eMTCT. Following this, the team members were orientated from August 4-5, 2022, on the four data collection checklists/tools during which a plan for field assessment was also prepared and agreed upon. Figure 9 illustrates the steps of the assessment undertaken.

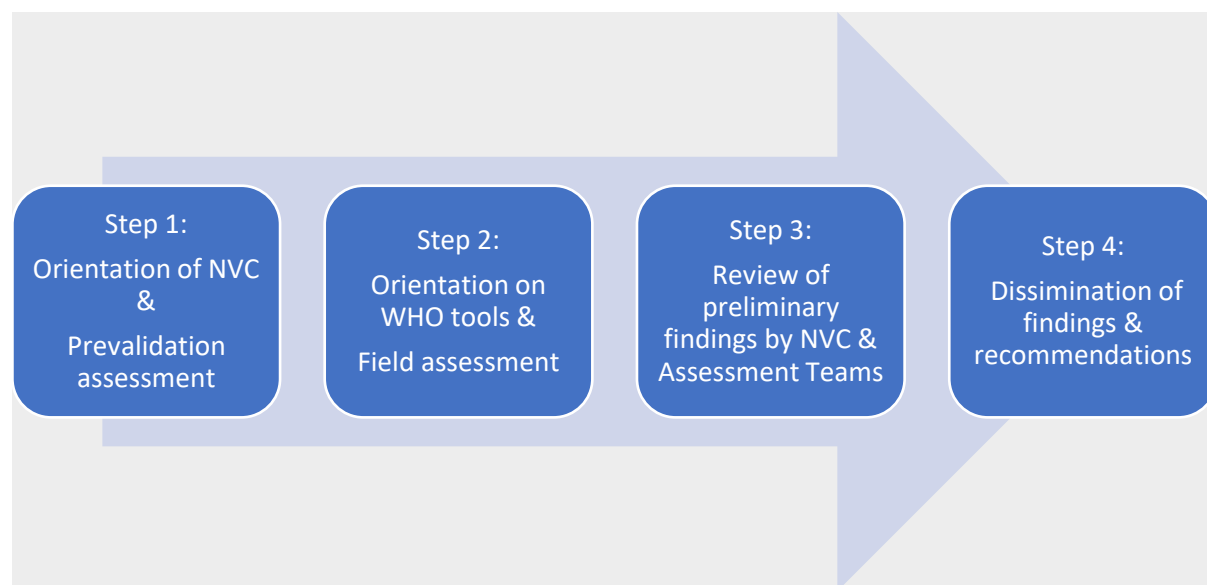


Figure 9: Pre-validation assessment process

Two teams comprising of relevant technical professionals (clinical, laboratory, program, and data and surveillance) and representatives of key population organizations in each of the team were formed to collect information and data using the assessment tools. Health facilities were selected considering the need to ensure adequate representation of different levels of health facilities. The facilities visited and assessed were -

1. Jigme Dorji Wangchuck National Referral Hospital, Thimphu
2. Central Regional Referral Hospital, Gelephu
3. Samdrup Jonkhar Hospital, Samdrup Jonkhar
4. Phuentsholing Hospital, Phuentsholing
5. Paro District Hospital, Paro
6. Dawakha Primary Health Centre, Paro

Interviews were conducted with the NACP and the members of the organization working for people living with HIV. Forms and registers used to record and report data and information at the facility were reviewed, and where possible the available data between registers, forms and patient files were cross-checked. The data submission

process was also reviewed. The list of health workers and officials met are provided in Annexure 3.

Additionally, key program policies, guidelines, and related documents were reviewed. The information and data collected were analysed and synthesized. Information and data gathered in each tool and through multiple sources were also triangulated. Moreover, several one-on-one meetings with the NACP, CST unit, and the HRS were held to review and verify the national-level data and indicators. The information and the findings and recommendations were then developed into a draft report.

A consultative workshop was convened from November 14-15, 2022, with health workers from the districts or facilities visited, relevant national programs, and the validation team members to review the preliminary observations and the data and information collected during the field assessment. The district health officials that participated in the consultation included medical doctors, district health officers, MCH staff, VCT in charges, and laboratory staff. The comments and inputs were addressed and incorporated into the draft report and was again shared with all stakeholders including the technical partners for inputs and feedback.

4. Findings and Recommendations

4.1. Status on the achievement of eMTCT targets

4.1.1. ANC coverage

As per the routine data from the DHIS-2, the ANC coverage of at least one visit was 96% in 2019, then fell to 92% in 2020 and rose again to 94% in 2021 (Figure 10). The decline in coverage for the years 2020 and 2021 could be attributable to the disruption in access to service due to the COVID-19 pandemic. The average five-year coverage is just above 95% if the two years preceding the pandemic is considered.

The indicator uses the BCG vaccine administered as the denominator given the issues around the inability to capture live births wholly in the country by the existing information system. Although seemingly low considering the high institutional delivery rate (93.4% institutional delivery and 97.2% births attended by skilled professionals)¹², live births at home, zero ANC bookings, and births outside of the country are usually not captured by the current information system. Moreover, deliveries taking place in higher-level facilities, especially the referral hospitals for which the ANC attendances are recorded in the lower-level facility (when the pregnant women contact the health system) could be possibly counted twice. Hence, live births data though available is usually not used to compute health indicators. These issues are expected to be resolved upon completion of the roll out of the MCH tracking system.

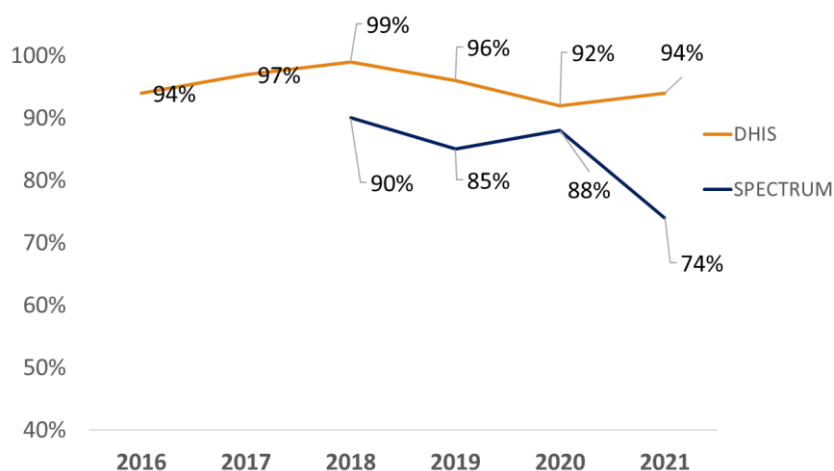


Figure 10: ANC Coverage by year, 2015-2021 (target: $\geq 95\%$)

¹² National Statistics Bureau of Bhutan, Population and Housing Census of Bhutan 2017

The coverage was less than 90% in the last three years when the UNAIDS estimate of live birth is used and around 94% when routine data is used. Going by the eMTCT criteria, the available data suggest that Bhutan has not achieved the eMTCT target of $\geq 95\%$ ANC coverage.

4.1.2. HIV targets

In 2019 and 2020, 99% of pregnant women were screened for HIV, whereas the coverage was 86% in 2021 (Table 6). The prevalence of HIV among pregnant women was 0.05 (n=5), 0.12% (n=13), and 0.07% (n=7) in 2019, 2020, and 2021, respectively. Except for the lone case in 2020, there were no cases of MTCT of HIV in 2019 and 2021.

All (100%) pregnant women living with HIV are on treatment for all past three assessment years as per the records maintained with the CST Unit at JDWNRH. While the data indicates the attainment of the impact and the ART coverage indicators, the target for testing coverage was not realized especially for the most recent year, i.e., 2021.

Table 6: Key indicators for EMTCT of HIV

<i>Indicators</i>	<i>Target</i>	<i>2019</i>	<i>2020</i>	<i>2021</i>	<i>Comments</i>
MTCT rate of HIV in non-breastfeeding populations	<2%	0 (0/5)	7.7% (1/13)	0 (0/7)	No born to HIV+ mother, (numerator/denominator)
Case rate of new paediatric HIV infections due to MTCT (per 100,000 live births)	≤ 50	0	7.79 (1/12831)	0	Using live birth estimate from spectrum as denominator
Coverage of HIV testing of pregnant women	$\geq 95\%$	99%	99%	86%	Using DHIS data as denominator
	$\geq 95\%$	(65.4%)	(74.07%)	(80.81%)	Using spectrum data as denominator
ART coverage of pregnant women living with HIV	$\geq 95\%$	100% (5)	100% (13)	100% (7)	CST data, (no of HIV+ pregnant women)

4.1.3. Syphilis targets

Bhutan introduced the policy to screen pregnant women for Syphilis formally in 2006 though services were provided prior formal implementation of the PMTCT program. The Syphilis testing coverage among pregnant women has been consistently maintained at $\geq 98\%$ since 2019 (Table 7). Likewise, the treatment coverage is 100% for all the past three assessment years, suggesting the achievement of these two process targets.

However, 11 congenital cases were reported annually on average through the DHIS-2 in the past three years giving a case rate of >50 per 100,000 live births for all three years assessed (Table 7), indicating non-achievement of this target.

Table 7: Key indicators for eMTCT of Syphilis

<i>Indicators</i>	<i>Target</i>	<i>2019 (n)</i>	<i>2020 (n)</i>	<i>2021 (n)</i>	<i>Comments</i>
Case rate of CS (per 100,000 live births)	≤50	123 (13) *	106 (11) *	86 (10) *	DHIS-2, AHB 2022 data
Coverage of syphilis testing of pregnant women in ANC	≥95%	98%	98.6%	98.3%	CST data
Adequate treatment of syphilis-seropositive pregnant women	≥95%	100% (63)	100% (68)	100% (63)	CST data

Source: DHIS-2. *The denominator used is total BCG vaccine administered

4.1.4. HBV targets

The most recent HBV prevalence survey in Bhutan was conducted in 2017 which revealed that none of the children less than 5 years of age were HBsAg positive, though the prevalence among adults was shown to be 2% (Table 8). The low prevalence and the reduction in prevalence among the 0-12 years age group by a significant 86% when compared with the rate of 5.2% in 1997 can be explained by the positive effect of HBV vaccination introduced in 1997. While the data suggest that the HBV eMTCT impact target might have been achieved by Bhutan, the criteria require that data demonstrating accomplishment should overlap the period in which the HIV and syphilis data are being assessed.

Table 8: Key indicators for EMTCT of HBV

<i>Indicators</i>	<i>Target</i>	<i>2019</i>	<i>2020</i>	<i>2021</i>	<i>Comments</i>
HBsAg prevalence among the ≤5-year-old birth cohort (and older children)	≤0.1%	0*	NA	NA	*The most recent data is for the year 2017.
Coverage of HBsAg antenatal testing among pregnant women	≥90%	100%	100%	97.7%	
Coverage with antivirals for eligible HBsAg+ pregnant women with high viral loads	≥90%	NA	NA	NA	Not reported at the national level.
Coverage of HBV-exposed babies with hepatitis B immune globulin (HBIG), where available	≥90%	NA	NA	NA	Not reported at the national level.

Coverage with three doses of HBV infant vaccinations (HepB3)	≥90%	99.3%	96%	99.6%	VPDP Annual data
HepB timely BD coverage (with universal program) or infants at-risk (with targeted timely HepB-BD)	≥90%	91.7%	87.7%	83.7%	VPDP Annual data

As per the record maintained at the CST Unit, the HBsAg antenatal testing coverage among pregnant women was well above the target, with 100% coverage in 2019 and 2020 (Table 8). The coverage of antivirals for eligible positive pregnant women with high viral loads and HBIg for HBV-exposed babies could not be assessed due to the absence of record for these indicators at the national level. The services are, however, being provided since 2020 as per the national guidelines.

Based on the data of the Vaccine Preventable Diseases Control Program, Bhutan has been able to consistently maintain the coverage of HepB3 infant vaccinations at >95% in the last three years (Table 8). However, the coverage of timely HepB BD was below 90% in the two recent years though the coverage was around 92% in 2019. The provision and recording of BD for infants delivered at home are often missed and HBV BD is also usually not provided to infants with body weight below 2 kgs. These could have led to low BD coverage. The recent National Strategic Plan for Prevention and Control of Viral Hepatitis (2022-2026) also highlights the need to strengthen recording and reporting of birth dose.

4.2. Data assessment

4.2.1. National and HIV information systems

The HRS under the Policy and Planning Division of the ministry is responsible for managing the national health information system. Data related to all health systems functions and facilities are collected regularly (every month) from the health facilities throughout the country and are compiled and analysed at the national level. The information generated is disseminated primarily through Annual Health Bulletins.

The HRS is currently managed by an Information Officer, two Research Officers, and a Research Assistant at the national level. There are trained Medical Record Officers or Technicians at the JDWNRH and the two other regional referral hospitals responsible to collect and report health data via the District Health Information Software 2 (DHIS-2) system. At the district-level hospitals and PHCs, a trained administrative person collects and reports health data and information. The DHIS-2 has been rolled out to all hospitals and PHCs at the block level that has an internet connection.

The NACP has a separate Tracker Capture system integrated into the DHIS-2 that was rolled out to all district-level hospitals. The NACP has plans to take it further to the PHCs. The system captures information on HCT, care for PLHIV, management of Hepatitis B & C, and condoms and lubricants program. It is the responsibility of the M&E Officer to monitor the system and the data entered by the VCT Focal Persons, HISCs, and key population organizations.

The NACP has a case-based surveillance system where all cases detected through VCT from the health facilities and HISCs across the country are recorded and reported to the HIV CST Unit at the JDWNRH through the District Health Office. The aggregated information is then reported to the NACP. The NACP produces a six-monthly national epidemic report and is disseminated widely. The national M&E guideline was revised in 2022 which also includes PMTCT indicators and other key population data.

The data collected at the CST unit quarterly is maintained in a Microsoft Excel sheet by the unit in charge which is entered into the DHIS-2. Individual case files and treatment records are maintained at respective VCT centres. The key recording and reporting forms currently used are - i) routine general HIV/hepatitis and syphilis testing and counselling register, ii) case-based surveillance form for diagnosed PLHIV, iii) HIV patient master form, and iv) quarterly HIV/STIs reporting form. Data is collected using both paper and electronic based formats.

4.2.2. Data collection mechanisms and quality

The national program has recently updated the existing DHIS-2 system to capture information on HIV, HBV, and syphilis testing and counselling including the care and treatment. Testing and treatment information are now all recorded and reported into the DHIS-2 system directly. However, the current system does not capture information on care and treatment and some data to report indicators of HBV and syphilis.

The revised national M&E guideline seems to be not disseminated adequately and many health workers are not aware of the recording and reporting roles and tools prescribed in the guidelines. Some PMTCT indicators included as part of the overall national M&E framework, are listed in Table 9.

While there appears to be proper recording and reporting systems in place for HIV and MCH, this is lacking for MTCT of syphilis and HBV. Additionally, the current recording and reporting system of HIV is not able to adequately capture data on some EMTCT indicators such as provision of ART for pregnant women and the number of infants born to HIV+ mothers. For instance, record on HIV MTCT and ARV was absent in Phuentsholing hospital. HISCs do not systematically collect and record data on ART provision, linkage,

and follow up. Provision of treatment for syphilis, HIV and HBV positive pregnant women could not be assessed due to a lack of recording and reporting system in the MCH. Moreover, although women who tested positive are referred to appropriate units, they are rarely followed up since there is no formal system in place.

Table 9: Indicators included in the national M&E Guideline 2022

<i>Sl</i>	<i>Indicator/s</i>
1	Number of pregnant women attending ANC at least once during the reporting period and who know their HIV status
2	Percentage of pregnant women attending antenatal clinics with a confirmed HIV+
3	Estimated percentage of children newly infected with HIV from mother-to-child transmission among women living with HIV delivering in the past 12 months
4	Percentage of infants born to HIV infected mothers who are infected or Percentage of new HIV infections due to MTCT
5	Percentage of HIV-exposed infants whose outcome status is known
6	The percentage of infants born to HIV+ women in PMTCT programs who are alive at 12 months of age and HIV negative
7	Percentage of HIV+ pregnant women who received a complete course of antiretroviral to reduce the risk of mother-to-child transmission of HIV
8	Percentage of HIV-exposed infants who receive a virological test for HIV within 2 months (and 12 months) of birth
9	Percentage of women accessing antenatal care (ANC) services who were tested for syphilis at first/any ANC visit
10	Percentage of reported congenital syphilis cases (live births and stillbirths)
11	Percentage of women accessing antenatal care (ANC) services who were tested for HBV at first ANC visit

Periodic studies and surveys are taken based on the need. Some studies undertaken include HIV sentinel surveillance, HBV prevalence survey, key population size estimation, and IBBS in 2016. For HIV burden, the national program uses the estimates provided by the UNAIDS. The data collected through routine reporting systems and periodic surveys and assessments are used at the program level for planning and monitoring, for example for the development of the National Strategic Plan, Global Fund Proposals, and formulation of strategies for key populations, etc.

Congenital and maternal syphilis case definitions appear to be consistently applied following the WHO or the Centres for Disease Control and Prevention (CDC) guidelines by the physicians. The existing guideline that is barely available in health need to be updated as a priority.

The review of the quality of reports both at the facility level and the national level is not conducted routinely. Data collected through the DHIS-2 are also not regularly analyzed and turned into information useful for routine and long-term planning, and improvement of health services, especially at the district level. Besides, data collected is not always well disaggregated into age, sex or gender, or other factors.

There are no formal feedback mechanisms established between the NACP and the HRS unit at the central level and the districts that can help improve recording and reporting. Currently, any issues observed at the facility level while compiling the report for submission are resolved by seeking clarifications over the call. Similarly, supervision visits to the reporting centres are not frequent and planned although a supervision checklist is provided in the recent national M&E guideline.

In all the facilities, while generally there appears to be adequate staff to deliver PMTCT services including performing recording and reporting responsibilities, recording, and reporting are occasionally compromised due to inadequate staff at the MCH clinic in a few facilities. At times, when burdened with the delivery of routine services, staff are compelled to keep on hold the recording and reporting system for weeks. This could potentially lead to loss of data and/or recording error. Moreover, many staff directly involved in recording and reporting are not trained with most trained only in MCH reporting.

Data on infants born to HBV and syphilis positive mothers are usually recorded only in the admission register presenting data retrieval challenges. Subsequently, the provision of HBIG to infants is not recorded in the MCH register. There is no separate register maintained for HIV+ mother-infant pairs or HIV-exposed infants. For HIV exposed infants, there is no register recording the receipt of formula feed and the conduct of follow up testing. Moreover, HBV BD and infant testing records are not always available at the MCH. While pregnancies are registered and followed up at the MCH, the deliveries happen at the ward/labour room. And, in the absence of a formal data and information sharing and standardized system, MCH units do not have these data. Similarly, at JDWNRH, many births are not recorded at the MCH unit especially of those cases referred and individuals coming from other districts.

Although there is no standardized recording tool for syphilis treatment as such, a few facilities maintain a syphilis treatment register. However, the register is not able to provide information on whether the case is a pregnant woman or not, doses provided, and do not have provision to capture cases <18 years of age. The total number of tests conducted and data for some PMTCT indicators are not reported through the DHIS-2 currently.

Overall, the data quality for testing of pregnant women and provision of HBV vaccination appears to be good with a high proportion of testing and vaccination records reviewed indicating service provision. However, in some cases test uptakes were low. Syphilis testing was low in Paro hospital which was attributable to stockout of reagents for that particular period.

Some of the records were prepared manually at the facility level and not standardized. This could lead to a potential error in counting cases and records. Data and records maintained in different data recording and collection tools are not always consistent. The number of eligible infants and the number of HBV+ mother does not match with the pharmacy indenting records. In a few facilities, data for a few tests conducted are not recorded.

While testing (for HIV and syphilis) is conducted at the first initial contact, the second testing is not always conducted in a few of the facilities. The national policy guidelines seem to have been not adequately disseminated especially at the PHC level. Likewise, in CRRH, all infants born to HBV+ mother in 2020 and 2021 were not tested although the national guidelines mandates performing infant testing at 9-12 months.

4.2.3. Recommendations

1. Standardized recording and reporting systems that can capture essential data for PMTCT/MTCT of both syphilis and HBV which also should include associated tools and protocols on recording and reporting need to be developed and instituted. The systems for all three diseases should be able to capture data on follow-up of pregnant women who are found positive and provide necessary disaggregated data. This ideally should be a single system accessible by all relevant health workers at different levels of health facilities.
2. The data and information need of PMTCT/MTCT of all three diseases should be integrated into the HIV module of the DHIS-2 and this needs to be rolled out to all health facilities.
3. All relevant healthcare workers (MCH, VCT, and Medical Records) should be periodically trained on the HIV, HBV, and syphilis recording and reporting system/s.
4. In facilities and districts with high case and workload, the Ministry may consider assigning a separate focal person for recording and reporting of these three diseases including the MCH system. Additionally, to overcome acute staff shortage, the health facilities and districts may consider reviewing their human resource in terms of staff strength and explore the possibility to redistribute staff based on the workload.
5. Well-defined procedures as part of the recording and reporting system should be put in place to ensure data in the maternity ward and birthing centers are reported and/or shared with the MCH/VCT unit. Such mechanisms between units including the laboratory can help improve communication and coordination among units.

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6. A protocol needs to be developed that can help assess data quality at different levels for all indicators, which is supported by training relevant staff on the use of the protocol.
 7. The national program and the HRS should review and analyze the reports and data submitted by all the reporting centers quarterly and provide feedback to the reporting centers for improvement.
 8. The recording and reporting of HIV and MTCT also need to be reviewed and revised so that it captures information on the provision of ARV to HIV+ mothers/pregnant women, infant diagnosis, and cases of MTCT of HIV. Separate registers should be maintained for HIV+ mother-infant pairs, HIV-exposed infants, and contact tracing.
 9. Similarly, some HIV and associated MCH recording tools need to be reviewed and made standard across all facilities.
 10. National guidelines and policies including the M&E guidelines need to be adequately disseminated right until the PHC level to ensure consistent provision of services and application of recording and reporting system requirements.
 11. The national program needs to revise the national guidelines on syphilis which should also include written guidelines on recording and reporting to capture data on key indicators.
 12. The national program should have an annual M&E visit plan and monitor the service delivery and data quality as per the plan, and provide support to improve the recording and reporting of related data during the visits.
 13. The NACP in coordination with the DoMSHI needs to ensure an uninterrupted supply of reagents, test kits, and related medical supplies by strictly monitoring stock and proper procurement planning.

4.3. Assessment of program and services

4.3.1. Leadership and governance

There is a national strategic plan (2017-2023) for the national response toward the prevention and control of HIV and AIDS, and the elimination of MTCT of HIV, syphilis, and HBV is an important component of the strategy. The national policy for the PMTCT of HIV, syphilis, and hepatitis was started sometime in 2006 and the action plan was formulated into the annual work plan of the national program. There is an integrated national guideline on the treatment and management of HIV and AIDS revised in 2020

which also includes a chapter on PMTCT. The first national treatment and management guidelines for hepatitis B and C and the national strategic plan (2019-2023) were developed in 2019. There is a high-level commitment for the implementation of the EMTCT programme.

Although there is no formal mechanism to facilitate the inter-programmatic planning between the NACP and the Reproductive, Maternal, Neonatal and Child Health (RMNCH) Program, the two programs collaborate for the PMTCT program as and when needed. There appears to be limited communication and coordination between the different units and departments within the health facility indicated by some staff being not aware of services provided, reporting, and referral mechanisms.

There are no policies prohibiting PMTCT services including testing and SRH services for both the national and non-nationals. The national policy requires two times opt-out testing for HIV, syphilis, and HBV (first ANC visit and last trimester). The national program works with private diagnostic clinics in the country to promote HIV testing as an alternative option. However, the testing through these centres is mainly targeted at the general population and migrant workers and not at pregnant mothers.

4.3.2. Financing

The PMTCT program that is integrated into the routine MCH services is primarily funded by the government and there is no or very limited support from external donors. The UNICEF and WHO provide some support in the procurement of test kits and capacity building for health workers. Procurement of test kits and some other supplies are also partially supported by the Global Fund.

All PMTCT services including testing are provided free of cost at all levels of the health system throughout the country. However, when there are no test kits at the PHCs at the community level, the pregnant mother has to travel to the nearest hospital to avail PMTCT services which incur out-of-pocket expenses such as travel, accommodation, and food.

4.3.3. Human resources

Generally, there is adequate health staff to provide eMTCT services. There are about 3-5 health workers engaged in providing eMTCT and other ANC services. Among them, one is identified as the VCT in charge, who is the district focal person for HIV and AIDS including the PMTCT program. There are dedicated staff to provide services for adolescents at the national and regional referral hospitals, and testing for HIV, syphilis

and HBV is usually provided without parents' consent and in some cases, proxy consent is sought.

Though not undertaken in a planned manner, in-service training for the VCT in charge, laboratory staff, and HSIC Counselors including medical doctors are provided by the national program. These training are however not able to cover all relevant staff including the new recruits. The last training on the national HIV/AIDS guidelines was conducted in 2020, other STIs in 2018, and viral hepatitis in 2019. MCH staff are not well acquainted with the provision of treatment for HBV+ pregnant women and HBIg including syphilis treatment.

4.3.4. Service delivery

The MCH unit is mandated to provide all essential services for pregnant women, mothers, and children. The NACP started the PMTCT services by integrating the VCT services into the MCH in 2006. The national PMTCT plan is based on the four-pronged approach recommended by the WHO that includes antenatal services and HIV testing during pregnancy, access to ART, safe childbirth practices, and appropriate infant feeding. While there is no plan specific for eMTCT, it is a part of the overall annual national plan that is informed by the national strategic plan. There is a proper referral mechanism among the different relevant service points including the HISCs, and among different levels of health systems in place to facilitate service delivery.

All pregnant mothers visiting ANC are usually offered two times testing (the first visit and towards the last trimester) considering the window period for HIV. For those who have missed testing before delivery, testing is initiated after delivery based on clinical judgment of the mother's health condition during the PNC visits though there is no specific policy guidance on this. The eMTCT service also includes provider-initiated HIV, HBV, and syphilis testing for the sexual partners especially the husband based on their willingness. However, the testing status of the partners is not recorded. HIV confirmation done at the RCDC, the national reference laboratory in Thimphu usually takes around 2-3 weeks. Whereas the HBV and syphilis rapid test results are provided within a day or two. Syphilis test guidelines are not available in the facility and there isn't an algorithm for a repeat test.

All HIV-positive women receive lifelong ART in line with the 'treat-all' national policy to provide ART to all the diagnosed PLHIV irrespective of CD4 count. Similarly, treatment is provided to HBV and syphilis positive pregnant women including children. In most cases treatment is initiated on the same day. All pregnant women and mothers are treated the same for testing for HIV, syphilis, HBV, and other MCH services as per

the national guidelines. However, HIV-positive pregnant women are given priority for treatment, and their privacy is protected while providing ART and other services like post-test counselling. Similarly, in the case of teenage pregnancy and HIV-positive mothers with HBV-positive, the management is done on a case-by-case basis.

All HIV cases including chronic HBV cases are being followed up as a part of the standard care and support by the concerned VCT focal person. However, in some settings, HBV cases are not being followed up and HBV data are not fully reported through the DHIS-2 system. The new hepatitis guidelines recommend the follow-up of infants exposed to HBV at 9 months which was not practised earlier. The follow-up of HBV-exposed infants is not adequate at the moment. Testing for HIV-exposed infants was carried out only after 18 months using rapid diagnostic kits until the introduction of the Early Infant Diagnosis (EID) facility at JDWNRH in July 2022.

Although the national guidelines mention the provision of pre-exposure prophylaxis (PrEP), it is not currently being implemented and services are not available. All HIV+ cases are sent for HBV testing including other STIs at the time of ART monitoring. All HBV sero-discordant couples are screened, and vaccination is provided if negative. Family planning is offered to women and girls living with HIV and HBV.

Replacement feeding is provided free of cost by the government for two years. Mothers are counselled during pregnancy on replacement feeding, and feeds are issued after delivery from the respective health facilities. Immunoglobulin requisition is done during pregnancy usually at first diagnosis and stock is maintained in the pharmacy.

The 2018 National Policy for Midwifery Trained Personnel for Safe Motherhood Practice recommends ANC initiation as early as 8 weeks if USG is available.

The national program recognizes key populations like people living with HIV, MSM, TG persons and female sex workers as a priority population and targeted interventions are being implemented mainly through six priority districts with high key population concentration. Specific training for vulnerable groups for health workers is not provided but is done as a part of core HIV training.

4.3.5. Medical products and technology

The forecasting of test kits and other laboratory consumables is conducted based on past consumption pattern by the respective health centres and submitted to MSPD under DoMSHI. Test kits, laboratory consumables, and medicines are procured through

the annual tendering and procurement cycle by the MSPD. Emergency procurement is also initiated as and when needed.

The RCDC also conducts the rapid diagnostic test kit performance evaluation as part of quality assurance. The national guidelines mention dual HIV and syphilis testing for pregnant mothers, but this is not formally introduced. The blood samples for EID, started in July 2022, from the district hospitals are transported to the National Referral Hospital in Thimphu. Since the number of samples is negligible (about five samples in a year), logistics is not seen to be a concern.

There is generally no record of major stock-outs of rapid test kits, ARVs, condoms, and contraceptives in the past 12 months. However, acute stock out of test kits was reported from some PHCs and a few district hospitals which were resolved through internal mobilization from nearby facilities. This possibly suggest that the current supply and stock monitoring mechanism is not adequate. Stock-outs of syrup AZT or 3TC for children were also experienced due to unavailability in the market. However, dispersible tablets of AZT/3TC are being used as alternatives.

Condoms and contraceptives are being procured and supplied in all the health facilities across the country by the government. The lubricants are also made available for key populations like MSM, TG, and FSWs through the support of the Global Fund.

4.3.6. Recommendations

1. The current NSP-III (2017-2023) needs to be revised which should also comprise a chapter on the eMTCT and considers actions addressing the recommendations of this assessment. The plan should also highlight approaches to maintain eMTCT for HIV, syphilis, and HBV.
2. The NACP should develop new STIs/syphilis guidelines to strengthen case detection, treatment, and routine surveillance as a priority. The NACP should explore support and ensure procurement of dual HIV and syphilis test kits.
3. The NACP in coordination with the RMNCH Program should explore expanding the existing mechanism of providing ANC and eMTCT services from PHCs and district hospitals to minimize out-of-pocket expenses. Similarly, plans for inter-programmatic planning and data sharing at all levels should be developed and implemented.

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4. The NACP in collaboration with other divisions and relevant institutions should ensure that plans are in place for timely capacity-building programs on PMTCT, other HIV-related services, and on recent national guidelines for all relevant health workers including new recruits.
 5. The NACP should reinforce the guidelines on the need to follow up on HBV and HIV in pregnant women and mothers and reporting of MTCT data.
 6. AFHS unit staff of the national and regional referral hospitals need to be trained on HIV counselling and testing (HCT) guidelines. The national program may also coordinate with the Adolescent Health Program to strengthen and or expand the AFHS to all district-level facilities as needed and ensure HIV services are integrated into the AFHS unit.
 7. The national program in collaboration with the RCDC needs to explore the possibility to decentralize HIV confirmation service to the regional referral hospitals and some of the district hospitals to reduce the turnaround time of HIV confirmation. Similarly, to facilitate the delivery of the rapid test result for HIV, syphilis, and HBV on the same day, the NACP may consider a policy to test all pregnant women at the VCT and/or MCH units instead of sending them to the laboratory. Additionally, the national program in collaboration with the RCDC and NRH laboratory should study the feasibility to take down EID testing to the district hospitals that have GeneXpert machines.
 8. The HCT guidelines should include guidance on testing after delivery (post-partum) for those who have not booked pregnancy and missed the recommended testing schedules before delivery.
 9. The NACP should reinforce the policy to test male partners of pregnant women and discuss with RMNCH Program to create options to record the test results in the MCH card or register.
 10. The national program in coordination with the district health sector should ensure timely quantification and adequate supply of test kits and related supplies to avoid any shortages, in all facilities including PHCs. The procurement of rapid test kits including self-testing kits needs to be integrated into the routine national procurement plan to ensure uninterrupted supply in the future.
 11. Similarly, the national program may explore and establish procurement mechanisms to mobilize liquid formulation of AZT or 3TC for children.

4.4. Laboratory assessment

Medical laboratory services in Bhutan are provided as per the health service standards where the availability of diagnostic facilities is determined by the level of medical service provided at that health centre. There is no separate policy for laboratories in the country. However, some tests of public health importance like HIV, HBsAg, HCV and syphilis are guided by the National Blood Bank Policy and National HIV/STI testing and treatment guidelines.

4.4.1. Laboratory quality management

Laboratory Quality Management System (LQMS) is currently being developed to generally address the quality needs of health laboratories. All the laboratories participating in the National External Quality Assessment Scheme (NEQAS) for STI/TTI RDT serology are organized by the RCDC (Table 10). The panels for NEQAS are sent out to the participating laboratories once a year. Additionally, RCDC participates in the EQA scheme sent by the NRL, Australia; and laboratories of regional referral hospitals such as the CRRH and ERRH participate in PPTC (FULL FORM) from New Zealand.

No laboratory in the country is SLIPTA validated or has obtained any formal accreditation. Private laboratories are not included in the quality assessment scheme as well as training initiated by the government. These laboratories are however mainly involved in the screening of migrants and usually do not screen pregnant women.

Records of previous participation in NEQAS or other schemes are not maintained well. While some facilities did maintain a file for corrective and preventive actions (CAPA), proper documentation was found lacking in both hard bound as well as electronic files.

Table 10: Participation in EQA Schemes by laboratories

<i>EQA Scheme</i>	<i>Frequency</i>	<i>Responsibility</i>
External Quality Assessment Scheme for HIV Serology	Annually	RCDC is the organizing agent. All hospital laboratories are participants.
External Quality Assessment Scheme for CD4 Count	None	
External Quality Assessment Scheme for HIV viral load testing	None	
External Quality Assessment Scheme for Syphilis serology	Annually	RCDC is the organizing agent. All hospital laboratories are participants.
External Quality Assessment Scheme for HBV serology	Annually	RCDC is the organizing agent. All hospital laboratories are participants.

There were a few instances of stock-out of HIV and syphilis testing supplies and reagents in some of the facilities including at the national referral hospital. Similarly, delays in the supply of test kits were reported in some facilities. Some of the stock out was partly attributable to other ad hoc programs such as the Flagship Program implemented by the Ministry and De-Suung program, requiring the facility to use existing supplies to screen individuals. And data for stockouts are usually not maintained. Although plans exist for emergency procurement and re-tendering in the event of stockouts, the processes are not straightforward and take considerable time (as long as 3 months) for the supplies to reach the laboratory. Health facilities try managing the situation by mobilization supplies from nearby facilities during such times.

Table 11: Participation in HIV, syphilis, and HBV EQA by laboratories performing eMTCT testing

	2019		
	HIV	Syphilis	HBV
No. of laboratories	48	48	48
Average performance	91.7 % concordance	93.8 % concordance	89.6% concordance

**Due to pandemic restrictions, the NEQAS panel for 2020 and 2021 was not dispatched. NEQAS panel for 2022 is prepared and ready for dispatch.*

4.4.2. Quality of HIV, HBV, and Syphilis tests

The Ministry uses tests that are WHO-prequalified or approved by a stringent authority. All medical supplies including test kits also need to be evaluated by and registered with the Drug Regulatory Authority (DRA) of Bhutan. The national testing strategy and testing algorithms followed are in line with the WHO recommendations.

Laboratories of all the health facilities follow the government’s annual tendering cycle which is done once a year. Each laboratory submits its required quantity against the standard list of reagents maintained by the DoMSHI. The department is also responsible for procurement and distribution. Quantity forecasting is done by the respective laboratory by considering the previous year’s consumption and a buffer of around 10%.

The selection of kits is done at the central level, usually by the national referral hospital. Performance evaluation of test kits such as sensitivity and specificity are done by RCDC and DRA for all test kits registered with DRA. This activity, however, could not be carried out in the past few years due to disruptions caused by the COVID-19 pandemic. Quality inspection upon receiving supplies is done by JDWNRH, which is usually a quick physical check of compliance with standards and specifications.

There is no system of lot testing currently. Similarly, there is no policy for the disposal of expired test kits. Laboratories informally try finding out other laboratories that require test kits and mobilize accordingly prior expiry where possible.

4.4.3. Quality of testing

Laboratory services for HIV, HBV, and syphilis diagnosis in pregnant women are widely available across the country including at the standalone HSCs. Rapid diagnostic testing is made available right up till the PHC level and ELISA testing is available at regional and national referral hospitals. ELISA services established at the regional referral hospitals however are currently not used to test samples and laboratory services for HIV diagnosis in exposed infants using Gene Xpert just commenced in July 2022. Contact tracing is usually initiated as per the national guideline once a positive case is detected.

As per the national HIV testing strategy, all HIV+ diagnoses are retested for confirmation at the RCDC. Confirmation at the RCDC is done as per national guidelines which are in alignment with WHO recommendations of testing with test kits of 3 different principles. Confirmation for HBV and syphilis, on the other hand, happens at the health facility level where the initial test is conducted. However, in the event the results are doubtful, the laboratory refers the specimen for testing to either RCDC or a higher-level health facility.

For syphilis, although guidelines recommend a parallel testing scheme of treponemal and non-treponemal tests, not all health facilities follow this. In some facilities, only a treponemal or non-treponemal test, depending on what the prescriber has advised, is carried out.

The laboratory SOPs on HIV and other tests need to be updated in almost all the facilities. Similarly, algorithms especially for syphilis testing are not consistently followed. Supply storage record was also lacking in almost all the facilities.

Although corrective actions following the NEQAS are recommended by RCDC to the laboratories, on-site supervision is not carried out routinely and the follow-up on the recommendations is also inadequate. Moreover, in-service training on quality management is not conducted in a planned manner but conducted depending on the availability of the budget from the national program.

4.4.4. Laboratory data management

There is a Laboratory Information System (LIS) which connects all clinical laboratories. The system allows retrieval of test results and effective documentation. All the records

of test requests for HIV, HBV, and syphilis are captured by the LIS. To maintain the confidentiality of the test results, the results of HIV positives are not entered into the system. The RCDC is not connected to the LIS as the centre mostly handles only surveillance and confirmatory testing. These diseases (HIV, HBV, and syphilis) are not a part of the disease surveillance system of the RCDC since they are taken care of by the national program. The system is also not able to generate reports segregated by pregnant women. There are no designated physical laboratory registers for STI and HBsAg and syphilis that precluded the review for these aspects.

Care is taken to ensure the confidentiality of patient's test results, especially of HIV. Upon confirmation of a positive result on a sample, RCDC forwards the result to the responsible focal person at the facility (VCT) who then contacts the patient for counselling and treatment. This is not followed for syphilis and HBV results where results are given out as usual to the patient. The turn-around time for specimens referred to RCDC from clinical sites is 3-4 days. Meanwhile, for the routine testing of HIV, syphilis, and HBV, the report is given within 24 hours.

4.4.5. Other laboratory observations

Laboratory procedures such as specimen collection, recording, testing, and reporting are all carried out as per the standard operating procedures (SOPs). Laboratories are well equipped with the necessary facilities for specimen storage and temperature logs are usually maintained. The major setback, however, is the power fluctuation with inadequate UPS backups. The room temperature in some facilities, e.g., CRRH, Gelephu was not found ambient for testing as the HVAC of the hospital had some issues. Equipment such as micropipettes, water baths, centrifuges, and freezers were not calibrated in a timely manner. Also, updated inventory on kits, equipment and their usage were lacking.

4.4.6. Recommendations

1. Regular planned supervision of the health facility laboratories needs to be instituted, and records of corrective and preventive actions need to be maintained, implemented, and followed-up for improvement.
2. The NACP and the RCDC should ensure that all laboratories receive updated SOPs and conduct periodic training on laboratory diagnosis and quality management.

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3. Health facilities should also ensure ambient conditions such as room temperature and humidity for kit storage and testing and maintain proper documentation on the usage of kits.
 4. The NACP should update the national STIs/syphilis guidelines which should also ensure proper testing algorithms for syphilis testing in all facilities, i.e., parallel testing of TP and non-TP.
 5. The national program, RCDC and the national referral lab may consider setting up early infant diagnosis in all the health centers where GeneXpert is available.
 6. Systems should be put in place in the health facilities to strictly maintain the confidentiality of the test results, including for HBV and syphilis.
 7. The NACP and the central procurement agency should monitor the supplies regularly and ensure no stockouts of supplies and test kits in the facilities. The districts and facilities should also consider likely major events and programs that could be undertaken in their catchment areas/districts based on previous years' experience while forecasting and quantifying the annual supply needs.
 8. All laboratory personnel should have adequate access to the LIS system to facilitate service delivery and data quality checks.
 9. Regular planned training and continuing medical education programs need to be conducted to update laboratory staff on the new policies/ guidelines/ tests/ SOPS.

4.5. Assessment of human rights, gender, and community engagement

As a member of the United Nations, Bhutan has made a strong commitment to the protection and promotion of human rights. Accordingly, Bhutan has acceded to or ratified many international conventions and fulfilled many of its obligations in respect of such instruments. Though not formally assessed, the measures taken by the government towards the protection and promotion of human rights and maintaining gender equality could have certainly contributed to HIV prevention including that of MTCT in the country.

Informed consent in medical settings is governed by the provisions of the 2005 Medical and Health Council Regulations issued under the Medical Council Act of 2002. Informed consent is required for HIV testing in Bhutan as per the national policy and testing is characterized as voluntary and confidential. The Ministry has introduced Provider

Initiated Testing and Counselling (PITC) only at certain service delivery points that include in ANC and tuberculosis treatment and care units. Ensuring confidentiality and privacy while managing and providing services to PLHIV and patients with STIs are also important components of the national policy.

There are no laws that force contraception or abortions on pregnant women with HIV, syphilis, and HBV. Abortion is illegal in Bhutan, except to save the life of the mother, when the mother is mentally unstable, and in cases of rape or incest. Same-sex sexual relations were decriminalized in Bhutan in 2021.

There are also no laws or judicial precedents that criminalize non-disclosure of HIV/syphilis/hepatitis status to sexual partners, but Section 410 of Bhutan's Penal Code makes knowing or intentional transmission of disease dangerous to life punishable. Drug use, sale, and possession are criminalized under the Penal Code and the Narcotic Drugs, Psychotropic Substances, and Substance Abuse Act of Bhutan 2015. Also, sex work is illegal, and sex workers, brothel owners, and clients (Chapter 16 of the Penal Code, sections 373 and 380) are criminalized. These laws, therefore, present some barriers to accessing HIV and related services by some key population groups such as sex workers and drug users. Additionally, the guideline requiring the consent of caregivers for individuals below the age of 18 years accessing HIV and STI testing may pose some obstacles to accessing services. However, this is not actually put into practice, especially for general services including those delivered through adolescent health service units.

The Royal Decree by His Majesty the Fourth King explicitly calls for non-discrimination of people living with HIV. Moreover, Bhutan's Constitution spells out the right to equality, which protects individuals against violations. The Labour & Employment Act of 2007 also stipulates provisions to prevent discrimination and provides for occupational health and safety for all. While there are no recent documented reports of breach of confidentiality and privacy, PLHIV and other key populations appear to face stigma and discrimination while accessing services. Discussions with PLHIV members revealed instances of intentional delay leading to long waiting hours, stigmatization, and differential treatment while accessing services. Additionally, despite free HIV services and treatment, some PLHIV also faced difficulty in terms of meeting expenses for transportation and other associated costs incurred while visiting the health facility, especially to higher-level centres, for services not available within their place of residence.

Gender-based violence has been given due importance in the country. There are mechanisms in place to report gender-based violence that is instituted in line with the 2013 Domestic Violence Prevention Act. Bhutan is a signatory to the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW). However, the levels

of domestic violence remain high. According to the National Study on Women’s Health and Life Experiences 2017, around 45% of women in Bhutan have ever experienced partner violence. The general societal status including the education and income levels of women in the country could affect women’s ability to make their own decisions about health and access services.

Usually, civil society organizations and key population organizations including those working for PLHIV and women living with HIV are involved at several levels of planning, implementation, and monitoring of HIV and related programs. These organizations are also adequately represented in the Country Coordinating Mechanism established to oversee the planning and implementation of Global-Fund-funded projects. PLHIV and other key population organizations are also members of the National HIV/AIDS Commission and technical working groups constituted for related activities including the National Validation Committee for eMTCT. The Ministry works closely with these organizations to build their capacity in the delivery of HIV services and reaching services to key populations mainly through the regional multi-country Global Fund-funded program.

Only some of the health workers are trained in human rights including gender-based violence, gender equality, sexual and reproductive rights, respectful care, and the needs and priorities of key populations. The Ministry has recently developed the National Guidelines for Management of victims of Intimate Partner Violence and Sexual Violence in Healthcare Settings in Bhutan and the implementation is yet to be fully rolled out. The current National Adolescent Health Strategy highlights that the Adolescent Friendly Health Service (AFHS) package is not fully integrated into the health system and the coverage and utilization remain low possibly attributable to inadequate awareness and capacity. The completed preliminary review assessment matrix is provided as Annexure 4.

4.5.1. Recommendations

1. Health workers especially those directly involved in the delivery of HIV and related services to key populations should be trained in human rights including gender-based violence, gender equality, sexual and reproductive rights, respectful care, and the needs and priorities of key populations. The Ministry should consider including these components in the curricula of different pre-service health training programs.
2. The Ministry should institute mechanisms and implement policies to prevent and reduce stigma and discrimination, especially against PLHIV and other key populations in the health facilities.

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3. The implementation of the National Guidelines for Management of victims of Intimate Partner Violence and Sexual Violence in Healthcare Settings in Bhutan needs to be rolled out nationwide.
 4. The Ministry should continue to meaningfully engage and involve relevant key population organizations in program design, delivery and implementation, and monitoring.
 5. The Ministry may consider designing a comprehensive service package that also includes CD4 count and viral load tests that are usually available at higher-level facilities and make it easily available and accessible.
 6. MoH to explore the feasibility of allowing HIV testing for individuals under 18 years of age by reviewing the age of consent for HIV testing based on the existing international guidelines.
 7. The NACP in collaboration with relevant stakeholders should work towards creating and ensuring a safe and enabling environment for sex workers and drug users to access HIV services including sexual and reproductive health services.

5. Limitations of the Assessment

There are a few limitations to this assessment which needs to be considered while using and interpreting the results. The assessment years of this pre-validation assessment overlapped with the years of the COVID-19 pandemic (2020 and 2021). COVID-19 as evident has impacted and led to disruption of delivery of essential services to some extent. The HIV testing uptake has decreased from 88,411 in 2019 to 78,851 in 2020 and 75,588 in 2021. Likewise, the viral load testing for PLHIV was also affected and the coverage was only 50% (of the eligible 608 PLHIV) in 2021. Thus, as evident the reach and coverage of interventions for HIV, syphilis, and HBV services were limited which could have impacted the achievement of targets. Similarly, owing to COVID-19, NEQAS for 2020 and 2021 were not conducted.

Many indicators were calculated using the data from the DHIS-2 and routine surveillance which had its limitations surrounding quality. The newly developed integrated DHIS-2 system for HIV, syphilis, and HBV with the patient tacker system has not been fully rolled out, thus the data for recent past years are not comprehensive to provide a clear picture at the national level. While it is reasonable to consider the BCG vaccine administered as the closest alternative, there are issues surrounding the quality of the data. The total ANC one visit slightly exceeds the BCG for some years (e.g., 2019). This could be due to underreporting of BCG delivered in the higher-level facilities. For instance, BCG provided for births at the referral hospitals from deliveries referred from lower-level facilities are usually not recorded. Equally, verification and validation for some indicators were not possible due to the absence of recording and reporting system.

Given that this was a pre-validation assessment, the validation did not specifically consider assessing performance in lowest performing areas and/or districts. Thus, data by such areas are not provided. However, a few districts such as Chukha, Sarpang, and Samdrup Jongkhar including the capital have the greatest HIV burden and high concentration of key populations which could also give a fair understanding of the situation of low performing districts.

6. Conclusions

Bhutan has made commendable achievements in the implementation of PMTCT of HIV, syphilis, and HBV. There is a high level of commitment from the government for the PMTCT program as well as the overall national response. Some of the targets and foundational criteria for the validation of eMTCT of HIV, syphilis, and HBV were accomplished. There are PMTCT policies that aligns with global recommendations and strong systems in place fulfilling many of the eMTCT validation criteria and requirements. All these achievements and the commitment demonstrate Bhutan's potential to eliminate MTCT of HIV, syphilis, and HBV.

However, some targets for indicators such as MTCT rate, HIV testing coverage, ANC coverage (mainly for the years 2020 and 2021), congenital syphilis case rate, and HepB BD vaccine coverage were not attained. Similarly, some components of eMTCT foundational requirements were not fulfilled and data for a few indicators could not be assessed due to the absence of recording and reporting system. These shortcomings may preclude Bhutan's application for the validation of eMTCT of HIV, syphilis, and HBV.

There are still opportunities to strengthen PMTCT program and service delivery and address gender and human rights barriers to accessing PMTCT and related services. The national STI guideline needs to be updated and laboratory SOPs and testing algorithms should be standardized and made available in all facilities. Provision of EID and HIV confirmation tests may be taken up till the facilities with resources to provide these services and not limited to national or referral hospitals only. Similarly, the provision of certain PMTCT services may be decentralized in collaboration with the RMNCH program.

The Ministry should ensure adequate and proper monitoring of stock and supplies needed to deliver PMTCT services so that facilities do not face acute stockouts. Additionally, the information system should be strengthened to ensure that data needed to generate and monitor eMTCT indicators including for some HIV indicators are captured routinely, and monitoring of data quality. The eMTCT data needs should be integrated into the DHIS system, and the information system should link data of mothers and their infants, and record retention and follow-up of cases. All national guidelines and policies need to be disseminated right up till the lowest-level facilities and the ministry should ensure that there are plans to train all relevant health workers on the national guidelines and policies periodically.

The Ministry with the support of the development and technical partners such as the WHO, UNAIDS, and UNICEF needs to work to address the recommendations in this report and strengthen the PMTCT program so that Bhutan can aim to propose for the country

validation assessment by the Regional Validation Team soon. A detailed plan outlining the implementation of the recommendation and the next actions with the timeline may be helpful to accelerate the implementation of the recommendations and apply for the validation assessment.

Annexure 1: TOR and Composition of eMTCT National Verification Team (NVT)

Background

Bhutan is one of the countries in South Asia with a low HIV prevalence of 0.1% among the general population. The total cumulative HIV cases reported from 1993 until November 2018 stands at 627 (323 male and 304 female). In terms of route of HIV transmission, about 92% are transmitted through unsafe heterosexual practices, while 6% through MTCT and remaining 1% each through blood transfusion and injecting drug use (IDUs). The majority (87%) of the diagnosed HIV cases fall between the ages of 15-49 years and the remaining 7% are above 50 years of age while 6% are below 15 years of age.

In Bhutan, the prevention of mother-to-child transmission (PMTCT) of HIV was started in 2006 with the aim of zero vertical transmission. The National HIV/AIDS and STIs Control Program initiated the PMTCT services by integrating them into the Mother and Child (MCH) Clinic in all the hospitals in the year 2006. The integration of these services with MCH was considered important to improve the efficiency and quality of MCH services and to offer women more comprehensive primary care services. As a part of universal access to HIV Testing and Counseling (HTC) services, in 2013 the HIV testing facilities were further expanded to all the Basic Health Units (BHUs) at the Block level with the primary target population as pregnant mothers, followed by STIs patients and then patient with other health condition including the walk-in clients.

Since the introduction of PMTCT services in all the health centres across the country, the number of HIV cases among newborn babies has reduced drastically as compared to those days with no such targeted interventions. For example, out of 107 HIV-positive pregnant mothers who underwent PMTCT services only three newborn babies were infected with HIV which is also among those positive mothers on single-dose nevirapine in 2004 and 2005.

In line with the global agenda to end the AIDS epidemic by 2030 Bhutan has also adopted the national goal of gearing towards the triple elimination of MTCT of HIV, Hepatitis B and Syphilis by 2020. However, data validation has not been carried out to understand the current situation of eMTCT in Bhutan and its preparedness towards elimination status. Therefore, to realize the goal of eMTCT by 2020, the NACP needs to prepare and validate the available information at various levels of health facilities to meet the eligibility criteria for the elimination status. As a result, it is of paramount importance to form a National Validation Team (NVT) and National Validation Committee (NVC) to prepare the comprehensive validation report. However, in Bhutan's context, there is an established National Disease Elimination Committee (NDEC) which can play the role of the National Validation Committee (NVC) while the Technical Advisory Group can play the role of the NVT.

Objective

1. To gather evidence and validate the national validation report submitted by TAG.
2. To provide directives and coordinate the internal validation process.
3. To ensure strong communication with MoH by the TAG and RVT.
4. To guide the national program on further prevention measures that are needed to sustain the zero mothers-to-child transmission for all times to come.

Roles and responsibilities

5. NVC (NCDE)/NVT (TAG) to closely liaise with RVC and MoH to carry out the validation exercises.
6. To ensure the quality of data for validation exercises by visiting the current recording and reporting system for PMTCT activities (Case diagnosis, case investigations, treatment and loss to follow-up).
7. To carry out an onsite visit to health centres and segregate and classify the data as per the existing WHO validation guidelines.
8. To review QA/QC on HIV diagnosis in Bhutan at the field level and RCDC including the clinical laboratory in the national/regional referral hospitals, Thimphu.
9. To produce a comprehensive report with a clear plan of action and recommendations to sustain the zero-vertical transmission for all times to come.
10. Organize a meeting as and when required in consultation with the NACP and report to the NVC (NCDE) on a timely basis.
11. To develop a draft of a national validation report for onward submission to the NVT/TAG.

Agency of officials to whom NVT reports

12. The NVT/TAG meeting minutes and findings of the assessment on the routine surveillance for prevention of mother-to-child transmission of HIV, Hepatitis B and Syphilis will be reported to the Ministry of Health and NCDE.

Secretariat Support

13. National HIV, AIDS and STIs Control Program (NACP), Department of Health, Ministry of Health shall be secretariat to TAG and provide management and support services.

Composition of TAG

A. Core member

14. The TAG shall consist of the ex-officio members from the following organization who shall be appointed by the Department of Public Health upon the recommendations of the NACP based on the WHO guidelines for eMTCT.

15. The following are the core members of TAG.

<i>Sl</i>	<i>Speciality</i>	<i>Designation</i>	<i>Organization</i>	<i>Responsibility</i>
1	Dr Sonam Jamtsho	Gynecologist	JDWNRH	Chair
2	Dr Mimi Lhamu	Pediatrician	JDWNRH	Vice Chair
3	Dr. Ambika Pradhan	Dermatologist	JDWNRH	Member
4	Medical Specialist	HoD	JDWNRH	Member
5	Mrs Tashi Choden	Microbiologist	Clinical Lab, JDWNRH	Focal Point for Laboratory quality assurance tool
6	Mrs Sonam Peldon	Immunologist	Serology Unit, RCDC	Focal Point for Laboratory quality assurance
7	Mr Kinley Dorji	Statistical Officer/Research Officer	HMIS, MoH	Member
8	Mr Wangda Dorji	Executive Director	Lhaksam/NGO	Focal Point for human rights, gender equality and community engagement
9	Mr Lekey Khandu	Program Manager	NACP, DoPH	Focal Point for program and services assessment tool.
10	Mr Jurmi Drukpa	Sr. Counselor	CST, JDWNRH	The focal point for Data quality assessment and verification
11	Mrs Tashi Choezom	Program Officer	RH Program	Member

16. The Chair and the Vice-chair shall be elected from amongst the core members and shall serve for a period of five years. They shall be eligible for re-nomination.

Co-opt members

- a. The Secretariat upon the prior approval of the TAG Chairperson may invite relevant experts based on the needs and relevancy of the agenda.
- b. The experts shall not have the decision-making authority and the experts shall leave the meeting upon fulfilling his/her role.

Terms of Membership

17. The core group members shall serve for 5 years with a maximum of 3 consecutive terms. The term shall be overlapping of the old and the new members.
18. The core member shall lose his / her membership if he/she fails to attend three consecutive meetings, fail to declare the conflict of interest and then unbecoming of the TAG members.

Meeting frequency

19. The TAG members shall meet at least twice a year. The chairman can convene emergency meetings as and when required and upon the request of the Secretariat, Ministry of Health.

Procedures of meeting

20. The meeting shall be arranged by the secretariat in consultation with the chairman of TAG.

Agenda setting and information sharing

21. The secretariat shall prepare the meeting agenda in consultation with the chairperson and then circulate the agenda and other materials related to the meeting one week before the commencement of the NHAC meeting.

Quorum

22. The Meeting shall be convened if 2/3 of the total core members are present.

Record keeping

23. The secretariat shall keep the minutes of every TAG meeting including emergency meetings.
24. The draft of the minutes shall be circulated to the members within one week after the meeting.
25. The members shall communicate their comments within one week of circulating the minutes.
26. The secretariat shall then finalize and submit the final draft of minutes to the chairman for endorsement.

Communication of recommendations

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27. The decisions of the meeting shall be submitted to the Ministry of Health and members within a week of endorsement of the minutes of the meeting.
 28. The Secretariat will implement the recommendations of the TAG.

Voting procedure

29. The decision of the NHAC shall be taken through a simple majority of the TAG members present at the meeting.
30. Notwithstanding anything in clause 10.1. in the event of the equality of votes, the Chairperson shall have the authority to decide.

Conflict of Interest management

31. Members shall declare their Conflict of Interests at the beginning of each meeting and before each agenda item requiring a decision.

Appointment of the working committee

32. The TAG may constitute committees consisting of members of the TAG and non-members to perform any of its functions.
33. A committee shall be chaired by a member of the TAG and the formation of such committees shall be determined by the Commission.

Operational costs and allowances

34. The operating cost of the meeting shall be met by the Royal Government of Bhutan through National HIV, AIDS and STIs Control Program (NACP).
35. The remuneration for attending the meeting will be as per the Royal Government of Bhutan's rules and regulations.

Annexure 2: The National eMTCT Validation Assessment Team

List of assessment team members

Sl	Name	Designation	Organization	
1	Mr. Rixin Jamtsho	Officiating Director	DoPH	Chairperson
2	Dr. Sonam Gyamtsho	Gynaecologist	JDWNRH	Vice chair
3	Dr. Mimi Lhamu	Pediatrician	JDWNRH	Member
4	Dr. Ambika R Pradhan	Dermatologist	JDWNRH	Member
5	Ms. Sangay Zangmo	Dy. Chief Lab Officer	RCDC	Member
6	Ms. Tashi Choden	Dy. Chief Lab Officer	JDWNRH	Member
7	Mr. Jurmi Dukpa	Counselor	CST/JDWNRH	Member
8	Mr. Lekey Khandu	Program Manager	NACP/DoPH	Member
9	Ms. Tashi Tshomo	Program Officer	RMNH/DoPH	Alternate Member
10	Mr. Kinley Dorjee	Asst. Research Officer	HMIS/MoH	Alternate Member
11	Ms. Cheten Zangmo	Asst. Program Officer	VPDB/DoPH	Alternate Member
12	Mr. Sonam Wangdi	National Program Officer	WHO	Alternate Member
13	Dr. Chandralal Mongar	UNICEF	UNICEF	Alternate Member
14	Mr. Wangda Dorji	Executive Director	Lhak-Sam	Alternate Member
15	Ms. Tshering Choden	Member	Lhak-Sam	Alternate Member
16	Mr. Dolley Tshering	Sr. Program Officer	NACP/DoPH	Secretariat
17	Ms. Choki Dolkar	Asst. Program Officer	NACP/DoPH	Secretariat
18	Ms. Dorji Zangmo	Key Population Coordinator	NACP/DoPH	Secretariat

Annexure 3: List of officials and health workers met

List of health official and workers met during filed visit

<i>Sl.</i>	<i>Name</i>	<i>Designation</i>	<i>Facility/Organization</i>
1	Ms. Denka	VCT Focal Person	Gelephu hospital
2	Mr. Tshering Tashi	HISC Counselor	Gelephu hospital
3	Mr. Dorji Wangdi	Pharmacist	Gelephu hospital
4	Mr Sangay Wangdi	Laboratory Technician	Gelephu hospital
5	Ms. Sonam Chimi	Laboratory Officer	Gelephu hospital
6	Dr. Purushotam Bhandari	Pediatrician	Gelephu hospital
7	Dr. Nidup Gyeltshen	Gynaecologist	Gelephu hospital
8	Dr. Kezang Wangdi	Chief Medical Officer	Samdrup Jongkhar hospital
9	Mr. Karma Wangdi	VCT Focal Person	Samdrup Jongkhar hospital
10	Mr. Ugyen Tashi	HISC Counselor	Samdrup Jongkhar hospital
11	Mr. Naseema Rehman Chhetri	Pharmacy Technician	Samdrup Jongkhar hospital
12	Ms. Chokey Dema	Sr. Nurse	Samdrup Jongkhar hospital
13	Ms. Rinchen Yangzom	Sr. Health Assistant	Samdrup Jongkhar hospital
14	Mr. Mon Bdr. Pradhan	Sr. Laboratory Officer	Samdrup Jongkhar hospital
15	Dr. Ugyen Wangdi	Chief Medical Officer	Paro hospital
16	Dr. Yowaan Thapa	Sr. Medical Officer	Paro hospital
17	Dr. Tsheltrim	Medical Officer	Paro hospital
18	Mr. Sonam Wangchuk	Dy. Chief Laboratory Officer	Paro hospital
19	Mr. Inda Tshering	Sr. Health Assistant	Dawakha BHU
20	Mr. karma Chedup	District Health Officer	Paro
21	Dr. Thinley Pelzang	Chief Medical Officer	Phuentsholing hospital
22	Ms. Dechen Tshomo	Sr. Health Assistant	Phuentsholing hospital
23	Ms. Karma Choden	HISC Counselor	Phuentsholing hospital
24	Mr. Kinzang Tobgay	Laboratory Officer	Phuentsholing hospital

Annexure 4: Review of human rights, gender equality and civil society engagement

Table on review of HRG and CSO engagement

<i>Issue</i>	<i>Yes</i>	<i>No</i>	<i>If yes, does this affect the decision to validate for elimination? Why? What are the suggested recommendations for the country?</i>
Is there criminalization of vertical transmission?		N	However, Bhutan's Penal Code (410) makes knowing/intentional transmission of disease dangerous to life punishable.
Is there mandatory or coerced testing and/or treatment for HIV and syphilis?		N	
Is there a lack of informed consent?		N	
Is there forced and coerced abortion, contraception and/or sterilization?		N	
Is there a lack of confidentiality and privacy?		N	
Is there a lack of equality and non-discrimination?		N	Some instances of stigma and discrimination experienced by key populations.
Is there a lack of availability, accessibility, acceptability, and quality of sexual and reproductive health (SRH) and ANC services?		N	
Is there a lack of accountability and an absence of participation and community engagement?		N	
Are there laws to protect women from gender-based violence?	Y		
Is there a lack of access to justice, remedies and redress?		N	