



MARKET ANALYSIS FOR A NEW POINT-OF-CARE DIAGNOSTIC TEST FOR GONORRHOEA IN IN VIET NAM

FIND
June 2021

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ACKNOWLEDGEMENTS

This report was developed by Ipsos and FIND, the global alliance for diagnostics, with funding from the Global AMR Innovation Fund (GAMRIF).

We would like to thank all those who contributed to the development and review of this market analysis:

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ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome	NG	<i>Neisseria gonorrhoea</i>
AMR	Antimicrobial resistance	NGO	Non-governmental organization
AMS	Administration of Medical Services	NHDV	National Hospital of Dermatology and Venereology
ART	Antiretroviral therapy	NIHE	National Institute of Hygiene and Epidemiology
ARV	Antiretroviral	non-IDU	Non-injecting drug user
CDC	U.S. Centers for Disease Control and Prevention	NSCPA	National Steering Committee on the Prevention of AMR
CE IVD	CE-approved in vitro diagnostic medical device	OOP	Out-of-pocket
CHE	Current health expenditure	OUCRU	Oxford University Clinical Research Unit
CHS	Community health station	PCR	Polymerase chain reaction
COP/ROP	Country/Regional Operational Plan	PEPFAR	The US President's Emergency Plan for AIDS Relief
CT	<i>Chlamydia trachomatis</i>	PHC	Primary healthcare
DMEHW	Department of Medical Equipment and Health Works	PLHIV	People living with HIV
DoH	Department of Health	POC	Point of care
FDA	U.S. Food and Drug Administration	PrEP	Pre-exposure prophylaxis
FSW	Female sex worker	PWID	People who inject drugs
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria	RDT	Rapid diagnostic test
GVN	Government of Viet Nam	SHI	Social health insurance
HCMC	Ho Chi Minh City	STIs/ STDs	Sexually transmitted infections/diseases
HIV	Human immunodeficiency virus	TCVN	National Standards of Viet Nam
IBBS	Integrated Biological and Behavioural Surveillance	TGW	Transgender women
IDU	Injecting drug user	TV	<i>Trichomonas vaginalis</i>
IVD	In vitro diagnostic	UNAIDS	Joint United Nations Programme on HIV/AIDS
ISO	International Organization for Standardization	UNFPA	United Nations Fund for Population Activities
KPs	Key populations	VAAC	Viet Nam Administration for HIV/AIDS Control
KSI	Key stakeholder interviewee	VND	Vietnamese dong
LF	Lateral flow	WHO	World Health Organization
LMIC	Low- and middle-income country		
MoH	Ministry of Health		
MSM	Men who have sex with men		
MSW	Male sex worker		
NASU	National AMR Surveillance Unit		

EXECUTIVE SUMMARY

The purpose of this report is to:

- ▶ describe the epidemiological characteristics of the Vietnamese population, principally with regards to sexually transmitted infections (STIs) other than HIV/AIDS;
- ▶ describe the administrative structure of the public and private healthcare systems, especially services relating to prevention and treatment of STIs and HIV/AIDS;
- ▶ examine the care-seeking behaviours relating to STIs, including HIV/AIDS, of key population groups; and
- ▶ evaluate the circumstances under which the two proposed tests (lateral flow rapid diagnostic test [NG RDT] and molecular [POC NG/CT]) could be successfully and impactfully brought to market.

Over the last decade, Viet Nam has made significant progress in reducing the incidence and prevalence of HIV/AIDS. From 2010 to 2018, Viet Nam nearly halved its incidence of HIV/AIDS infections. However, incidence and prevalence has increased for other STIs, such as *Neisseria gonorrhoea* (NG), *Chlamydia trachomatis* (CT), or urogenital warts caused by human papillomavirus. Other factors contributing to increased STI prevalence include the young average age of the population, increasingly liberal attitudes towards sex (leading to greater numbers of sexual partners), and migration into the cities.

The Ministry of Health (MoH) administers four levels of public health facilities. There is a very wide range of competence observed: Level 1 facilities perform complex and difficult tests and treatments with ease, while Level 4 facilities struggle to adequately complete simple diagnostic analysis. Treatment for serious illness and definitive testing tends to happen in Level 1 and 2 facilities. Level 3 (district health facilities) and Level 4 (commune health centres) provide primary healthcare services, including examination and treatment of common diseases, follow-ups for noncommunicable diseases as a part of the continuum of care, referral, health

promotion and preventive health services. The private healthcare sector, an integrated part of the general health system, consists of a wide range of hospitals, clinics, and pharmacies. The private facilities are usually smaller and more flexible in their operations than the public ones, although some facilities (e.g. Vinmec, Hoan My, etc.) are quite large. Pharmacies (the largest part of the private sector in terms of number of facilities) are the most used healthcare services. Pharmacists and pharmacy assistants often prescribe treatment regimens or sell drugs to customers without prescription, as no legal sanctions for such practices are in place. These prescription practices can lead to relatively poor treatment outcomes and contribute to the development of antimicrobial resistance (AMR).

Key populations (KPs) include men who have sex with men (MSM), female sex workers (FSWs), and people who inject drugs (PWID). Because their behaviours are not socially accepted, KPs tend to be wary of public sector institutions since they are viewed as invasive, unfriendly, and time consuming. Instead, KPs tend to seek treatment in small private clinics and especially pharmacies where they can receive treatment more quickly and face lower risks of recognition.

Of the two tests evaluated, the POC NG RDT is by far the most promising for point-of-care (POC) diagnosis of NG. This is because the lateral flow NG RDT has a sensitivity level (80%) that is too low for clinical use. The NG RDT may be appropriate for use in low-tier facilities or for academic research, but little else. The POC NG RDT is more promising thanks to its 95% sensitivity and >98% specificity. Still, Level 1 and Level 2 hospitals require that both the specificity and sensitivity of their diagnostic kits exceed the “gold standard” of 98%. Unless the sensitivity of the POC NG RDT can be boosted to 98% or above, it has little chance of gaining regulatory approval in large public Vietnamese hospitals.

Conversely, gaining access to the private sector is substantially easier. To enter the market, the most promising route may be to gain regulatory approval sufficient to distribute molecular RDTs in private hospitals and clinics and lateral flow RDTs in

private clinics. These are also the locations where legal distribution encounters the fewest regulatory hurdles. Even this route, however, will likely entail significant interaction with the central bureaucracy, as the Vietnamese government requires clinical trials of all newly imported tests. Such trials are most easily conducted in partnership with Level 1 and Level 2 facilities.

As POC tests, molecular RDTs and lateral flow RDTs can be carried out outside the laboratory environment by any healthcare workers with minimal training. Another advantage of these tests compared with existing methods (e.g. culture, polymerase chain reaction [PCR], etc.) is their self-sampling feature, which provides patients more privacy, potentially increases test adoption, and lessens the burden on healthcare workers. Training will be needed on the operation of the POC NG RDT device and lateral flow RDT reader, as well as on how to read test results. However, there are concerns about the low clinical usefulness of the POC tests due to their inability to produce antibiograms indicating susceptibility to key antibiotics. Key stakeholder interviewees (KSIs) believe that the two test kits are acceptable for large national screening programmes, but external funding is likely needed for test adoption. In addition, acceptance is high among symptomatic patients (except for men) toward the NG RDT, and is feasible among certain groups of asymptomatic patients, such as pregnant women, MSMs, FSWs, and PWIDs.

In recent years, Viet Nam's social health insurance (SHI) coverage and revenue have been increasing, contributing to the rise in public health expenditure. While SHI covers at least 80% of treatment costs for 83% of the Vietnamese population, STI services (except treatment) are not included in the scheme. Thus, prevention programmes for KPs (e.g. pre-exposure prophylaxis [PrEP], STI screening and testing services) still rely on international organizations. Although external subsidies make up a large share of the funding for disease programmes, support for STIs, with the exception of HIV/AIDS, is very limited. Going forward, external financing will be phased out. Of the two largest donors, the United States President's Emergency Plan for AIDS Relief (PEPFAR) has no further grants beyond the current transition grant, while the Global Fund (GF) has stated that low- and middle-income countries (LMICs) like Viet Nam would receive less funding. Thus, Viet Nam must transition towards expanding government financing and decrease dependence on external sources.



OBJECTIVES AND METHODS

In LMICs, due to insufficient resources, healthcare providers generally use the syndromic approach recommended by the World Health Organization (WHO) to manage symptomatic patients suspected of having an STI. These practices lead to both under- and overtreatment. To enable etiological case management, FIND is supporting the development of POC tests for NG and CT.

A high-level market assessment conducted by FIND in 2019 showed that while the potential target population for an NG/CT diagnostic test in LMICs is estimated at more than 70 million people,¹ there is significant uncertainty around the actual demand. Moreover, major access barriers are likely to impede launch and roll-out of NG/CT diagnostic tests in high-priority LMICs. As such, FIND is undertaking a more in depth market assessment in selected countries, including South Africa, Thailand, Papua New Guinea, Philippines, Zambia, Kenya and Viet Nam.

The market assessment for the launch of a POC test to distinguish NG from CT at primary care in Viet Nam, following previous country assessments, covered the following topics:

► **Understanding the current national STI context, including:**

- + the STI/NG public health burden, epidemiology, surveillance, and awareness on STIs in Viet Nam;
- + current national healthcare system structure and stakeholder mapping;
- + current clinical practices, country guidelines and algorithms, and STI/NG funding mechanisms.

► **Determining the potential use case scenarios and market for a NG/CT POC test, including:**

- + key use case scenarios for POC NG/CT tests;

- + target populations and channels for each use case;
- + key considerations for introducing a POC NG test in Viet Nam; and
- + Estimating the market size for a POC NG test in the country.

► **Understanding the regulatory environment, and test selection, procurement and distribution processes for a new POC test kit entering the Viet Nam market.**

Methods used to achieve the objectives included:

1. Extensive desk review of possible STI-related reports and official studies; national health statistics yearbooks; national guidelines and policies on prevention, management and control of STIs in Viet Nam.
2. Review and analysis of STI-related data, including new STI case reported data; STI prevalence estimates; size of target populations; and average duration of infections to estimate STI incidence rate.
3. Interviews with 16 key stakeholders, conducted from October to November 2020 in-person and by video call.

I STI BURDEN AND EPIDEMIOLOGY OF GONORRHOEA IN VIET NAM

1.1 STI burden in Viet Nam

Except for HIV/AIDS, STIs have been largely overlooked by the Vietnamese healthcare system. Official data on the STI burden is only available for the period 2006–2016 (Table 1), while data on HIV/AIDS are updated regularly.² The most recent statistics on STIs are provided in the Health Statistics Yearbook, which reported 292,528 new STI cases in people aged 15–49 in 2016 (including 2,004 cases of syphilis, 5,018 cases of NG, 6,595 newly reported cases of HIV/AIDS and 278,911 cases of other venereal diseases); 75%³ of these new cases were women.

STI-related data have not been published officially since 2017 due to insufficient funding and human resources, among other factors. Viet Nam has recently gone from being a low-income country to a lower middle-income country. From 2006 to 2016, Viet Nam's National HIV/AIDS prevention programme had a STI-related component named "Program 7: Prevention of STIs, STI/STD management and treatment"⁴, so data on new STI cases were reported each year. From 2017 onwards, Program 7 was cut from the National HIV/AIDS prevention programme.⁵ To the present day, there has been no separate nationwide surveillance system for STIs, only sporadic monitoring.⁶ Annual national HIV sentinel surveillance, implemented by the MoH, integrates surveillance for STIs other than HIV only in certain key cities (An Giang, Kien Giang, Can Tho and Ho Chi Minh City [HCMC]).⁷

Moreover, it is likely that STI case report data significantly underestimates the true number of infections that occur each year. The actual number of new cases is likely five times higher than reported, at around one million cases per year,⁸ of which about 50,000 to 100,000 are NG infections.⁹ The discrepancy between the actual numbers and

case report data is due to a lack of diagnosis: STI patients are often asymptomatic and may go undiagnosed and untreated. Moreover, not all cases of infection detected at healthcare facilities, especially in the private sector, are reported. The number of STI patients seeking care in private healthcare facilities or undertaking self-treatment is often undocumented and remains unreported to the MoH. The MoH has approved nationwide regulations that require healthcare facilities (both public and private) to report all patients to the national health information management system. However, actual data remains problematic because reporting is incomplete and inconsistent.

The prevalence of STIs (excluding HIV/AIDS) has been increasing for the last ten years, a trend that is expected to continue.¹⁰ The estimated average prevalence of STIs per year in Viet Nam is approximately 18%. This estimate includes over 30 different bacteria, viruses and parasites known to be transmitted through sexual contact, which cause more than 20 types of STIs. The prevalence of STIs has tended to increase gradually each year.¹¹ One of the reasons for this increase is the lack of treatment for sexual partners of people infected with STIs, which can lead to serial reinfections. Although the MoH mentions treatment of sexual partners in the National Guidelines, there are no detailed treatment guidelines for sexual partners of STI-infected patients. Moreover, as HIV patients on antiretroviral drugs (ARV) tend to rely on ARV as their exclusive means of HIV prevention, they do not use barrier methods such as condoms when having sex. As a consequence, they bear a higher risk of STI infection and transmission than some populations not receiving ARV therapy.¹² While the ARVs used to treat HIV have been effective in preventing HIV transmission, such prophylaxis

is not generally applicable or available for other STIs. As a result, ARV use may have paradoxically increased the infection and transmission rates of other STIs.

The prevalence of STIs in urban areas and megacities is increasing due to modern lifestyles, international travel, and migration.¹³ HCMC is the major hotspot of STI infection, with 2% of adults (15–49 years old) infected. The city also accounted for 37% of all people with HIV/AIDS in 2016 in the country.¹⁴

Rates of STI coinfection are also quite high, which increases the disease burden and complicates epidemiological reporting. Various studies have explored the rates of coinfection between different types of STIs. For example, CT is detected in 10–40% of people with NG.¹⁵ A 2010 study of 162 FSWs in Hoa Binh Province demonstrated that the

rate of STI coinfection was 29%, high compared with the average of 17% for Asia.¹⁶ Additionally, non-HIV STIs facilitate the sexual transmission of HIV.¹⁷ It has been estimated that ulcerative STIs in particular increase the risk of HIV transmission by as much as 10–50 times for an HIV-positive man transmitting to women and 50–300 times for an HIV-positive woman to men. Even non-ulcerative STIs could increase HIV transmission risk by as much as 2–5 times the standard risk associated with sexual contact.¹⁸

The proportion of STIs self-reported¹⁹ across Viet Nam's provinces was different among KPs. In 2013, cross-sectional surveys were conducted from June to September among PWID, FSWs, and MSM across nine provinces. The percentage of self-reported STIs coming from PWID was lower than that of FSWs and MSM, as shown in Table 2.²⁰



Table 1: Number of new STI cases reported in the 2006–2018

Indicators	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total STIs													
Total	N/A	N/A	N/A	N/A	348,134	312,315	305,220	220,918	280,588	316,326	292,528	N/A	N/A
Of which female	N/A	N/A	N/A	N/A	293,676	266,255	246,231	181,826	205,050	240,719	218,366	N/A	N/A
Under 15 y/o	N/A	N/A	N/A	N/A	927	1,567	1,919	2,813	3,956	1,782	2,111	N/A	N/A
<i>Of which female</i>	N/A	N/A	N/A	N/A	695	1,415	1,255	1,853	3,265	935	1,154	N/A	N/A
15–49 y/o	N/A	N/A	N/A	N/A	317,467	297,699	292,203	214,951	262,439	283,720	269,937	N/A	N/A
<i>Of which female</i>	N/A	N/A	N/A	N/A	266,193	254,511	235,863	177,243	191,820	213,413	202,588	N/A	N/A
≥ 50 y/o	N/A	N/A	N/A	N/A	29,740	12,750	10,121	7,123	14,193	30,803	21,532	N/A	N/A
<i>Of which female</i>	N/A	N/A	N/A	N/A	26,788	10,311	8,127	6,067	10,563	26,333	15,624	N/A	N/A
NG													
Total	5,526	5,419	6,148	5,639	6,544	5,906	6,625	4,122	4,743	5,184	5,018	N/A	N/A
Rate per 100,000	6.57	6.45	7.13	6.56	7.53	5.19	7.46	4.03	5.17	5.66	5.41	N/A	N/A
<i>Of which female</i>	N/A	N/A	N/A	N/A	1,958	1,622	1,760	880	1,207	1,398	1,381	N/A	N/A
Under 15 y/o	N/A	N/A	N/A	N/A	58	18	52	16	35	23	15	N/A	N/A
<i>Of which female</i>	N/A	N/A	N/A	N/A	19	13	12	7	11	7	6	N/A	N/A
15–49 y/o	N/A	N/A	N/A	N/A	6,104	5,574	5,574	4,043	4,414	4,819	4,770	N/A	N/A
<i>Of which female</i>	N/A	N/A	N/A	N/A	1,844	1,516	1,647	846	1,096	1,292	1,299	N/A	N/A
≥ 50 y/o	N/A	N/A	N/A	N/A	382	310	303	188	294	332	233	N/A	N/A
<i>Of which female</i>	N/A	N/A	N/A	N/A	95	87	99	27	100	90	78	N/A	N/A
HIV/AIDS													
New cases of Infected HIV	30,149	30,456	19,900	15,713	13,815	17,780	14,127	11,567	11,680	10,195	9,912	9,920	5,700
<i>Rate per 100,000 inhabitants</i>	N/A	N/A	N/A	N/A	211.3	224.4	237.4	242.2	250.2	220.7	243.3	223.3	222.3
New cases of AIDS	13,010	12,761	7,909	8,049	6,501	9,138	6,734	5,493	6,183	6,130	5,876	5,216	N/A

AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus ;y/o, years old.

Sources: MoH's Health Statistics Yearbook 2006–2018.

Table 2: STI self-reported across Viet Nam's provinces, in 2013

Type of group	Indicators: STI self-reported	An Giang (%)	Can Tho (%)	HCMC (%)	Hanoi (%)	Hai Phong (%)	Nghe An (%)	Quang Ninh (%)	Yen Bai (%)	Dien Bien (%)
People who inject drugs (PWID)	Reported unusual genital discharge in the past 12 months.	2.1	3.7	1.4	1.9	1.5	5.3	2.7	0.4	2
	Reported genital pain/ulcers in the past 12 months.	3.5	5.8	2.1	1.5	0.6	4.7	2.4	0.2	0.9
	Reported ever having been jaundiced in the past.	5.5	13.9	7.7	4.2	19.7	17	9	1.7	2.1
Street-based sex workers	Reported unusual genital discharge in the last 12 months.	38.7	42.4	33	18.1	31.4	N/A	N/A	N/A	N/A
	Reported unusual genital pain/ulcers in the last 12 months.	52.9	44	43	54.2	77.5	N/A	N/A	N/A	N/A
Venue-based sex workers	Reported unusual genital discharge in the last 12 months.	33.7	33.9	39.1	24.7	25.5	N/A	23	N/A	N/A
	Reported unusual genital pain/ulcers in the last 12 months.	44.7	34.7	54.1	50.5	61	N/A	51.2	N/A	N/A

HCMC, Ho Chi Minh City.

Sources: HIV/STI integrated biological and behavioural surveillance (IBBS) in Viet Nam, 2013.

Table 3: Journal findings of NG/CT prevalence in Viet Nam

No.	Authors	Article	Year of publication	City/Province	Population type	Sample selection site	NG prevalence (%)	CT prevalence (%)	Proportion asymptomatic (%)
1	Nguyen, T.V., Khuu, N.V., Le, T.T.T., Nguyen, A.P., Cao, V., Tham, D.C., & Detels, R.	STIs and Risk Factors for Gonorrhoea and Chlamydia in FSWs in Soc Trang	2008	Soc Trang	406 FSWs	Hospitals & Clinics	14.9	48.4	N/A
2	Colby, D., Nguyen, N.N.T., Lan, H.T.X., Nguyen, T., Thien, D.D., Mai, T., ... & Mimiaga, M.	Prevalence of sexually transmitted diseases, HIV, and hepatitis among MSWs in HCMC	2012	HCMC	300 MSWs	City health departments	3	2	N/A
3	Le, T.K.A., & Bui, T.M.	The disease is transmitted through sex among prostitutes in Healthcare Centre for Healing - Education - Labour and Social Affairs of Hoa Binh Province	2009	Hoa Binh	162 FSWs	Healthcare centres	24.1	9.9	N/A
4	Masala, B., & Fiori, P. L.	Prevalence of Trichomoniasis in Hue City, Viet Nam: A Serological Study	2010	Hue City	249 symptomatic women & 534 asymptomatic women without vaginitis symptoms	Gynaecological Clinic, Reproductive Healthcare Centre	N/A	N/A	0.7
5	Nguyen, V.T., Nguyen, T.L., Nguyen, D.H., Le, T.T.T., Vo, T.T.N., Cao, T.B.V., & O'Farrell,	STIs in FSWs in five border provinces of Viet Nam	2005	Five border provinces: Lai Chau, Quang Tri, Dong Thap, An Giang, and Kien Giang	911 FSWs	Healthcare clinics & Hospitals	10.7	11.9	N/A
6	Lan, P.T., Lundborg, C.S., Phuc, H.D., Sihavong, A., Unemo, M., Chuc, N.T.K., ... & Mogren, I.	Reproductive tract infections including sexually transmitted infections: a population-based study of women of reproductive age in a rural district of Viet Nam	2008	A rural district of Viet Nam	1012 married women aged 18–49 years	Healthcare centre	0.7	4.3	50%: Fifty per cent of the STI cases were asymptomatic.

No.	Authors	Article	Year of publication	City/Province	Population type	Sample selection site	NG prevalence (%)	CT prevalence (%)	Proportion asymptomatic (%)
7	Phan, K.A., Nguyen, T.N.K., Dinh, T.H., Do, T.C., Pham, T.T., Pham, H.L., Klimarx, P.H., Wongchotigul, V., Kitayaporn, D., & Rowe, P.J.	Prevalence of lower genital tract infection among women attending maternal and child health and family planning clinics in Hanoi	2003	Hanoi	1,000 women, aged between 18–44 years	Obstetrics and Gynaecology Hospital & Hai Ba Trung Maternity Hospital & Thanh Nhan Hospital.	0.5	4.4	TV: 1.60; NG: 0; CT: 3.80
8	Viet Nam Ministry of Health	HIV/STI Integrated Biological and Behavioural Surveillance (IBBS) in Viet Nam, Results from Round III 2013 and trends across three rounds (2005–2009–2013) of surveys	2014	Hanoi	500 MSMs	Governmental, provincial or district health centres	RG: 3.40 G(NG): 0	RC: 10.00 GC: 4.40	N/A
9	Viet Nam Ministry of Health	HIV/STI Integrated Biological and Behavioural Surveillance (IBBS) in Viet Nam, Results from Round III 2013 and trends across three rounds (2005–2009–2013) of surveys	2014	Can Tho	347 MSMs	Governmental, provincial or district health centres	RG : 3.20 G(NG): 0.90	RC: 5.80 GC: 3.50	N/A
10	Viet Nam Ministry of Health	HIV/STI Integrated Biological and Behavioural Surveillance (IBBS) in Viet Nam, Results from Round III 2013, and trends across three rounds (2005–2009–2013) of surveys	2014	Hai Phong	400 MSMs	Governmental, provincial or district health centres	RG: 0.30 G(NG): 0.30	RC: 2.00 GC: 5.00	N/A
11	Clatts, M.C., Goldsamt, L.A., Le, M.G., & Yu, G.	Sexual practices, partner concurrency and high rates of sexually transmissible infections among male sex workers in three cities in Viet Nam	2015	Hanoi, Nha Trang and HCMC (2009–2011)	654 MSMs	Health centres & medical schools	29	17	N/A
12	Goldsamt, L.A., Clatts, M.C., Le, M.G., Le, M.G., Colby, D.J., & Yu, G.	HIV and other STIs in male sex workers: Findings from a sexual health promotion intervention in Viet Nam	2017	Hanoi, HCMC	668 MSWs	Healthcare centres	10.5	11.5	N/A
13	Nguyen, M., Le, G.M., Nguyen, H.T.T., Nguyen, H.D., & Klausner, J.D.	Acceptability and feasibility of sexually transmissible infection screening among pregnant women in Hanoi, Viet Nam.	2019	Hanoi	800 pregnant women	Healthcare centres	0.13	6	N/A

CT, Chlamydia trachomatis; FSW, female sex worker; G, genital; GC, genital Chlamydia; HCMC, Ho Chi Minh City; MSM, men who have sex with men; N/A, not applicable; NG, Neisseria gonorrhoea; RC, rectal Chlamydia; RG, rectal gonorrhoea; STI, sexually transmitted infections; TV, Trichomonas vaginalis.

1.2 HIV epidemiological context

Viet Nam has a relatively high HIV burden. In 2018, there were 230,000 people living with HIV (PLHIV), 90.4% of them between the ages of 15 and 49.²¹ The HIV prevalence among the same age group was 0.3%. The number of AIDS-related deaths has almost been halved since 2010, from 8,500 deaths per year to 4,700 deaths in 2018.²³

From 2010 to 2018, Viet Nam managed to reduce new HIV infections by 65%, the greatest reduction achieved in the Asia-Pacific region. Nearly 60% of PLHIV are receiving antiretroviral therapy (ART) and the number is continually increasing. However, this number is still behind the global average of 67% of HIV-infected people (25.4 million) who received treatment in 2019.²⁴

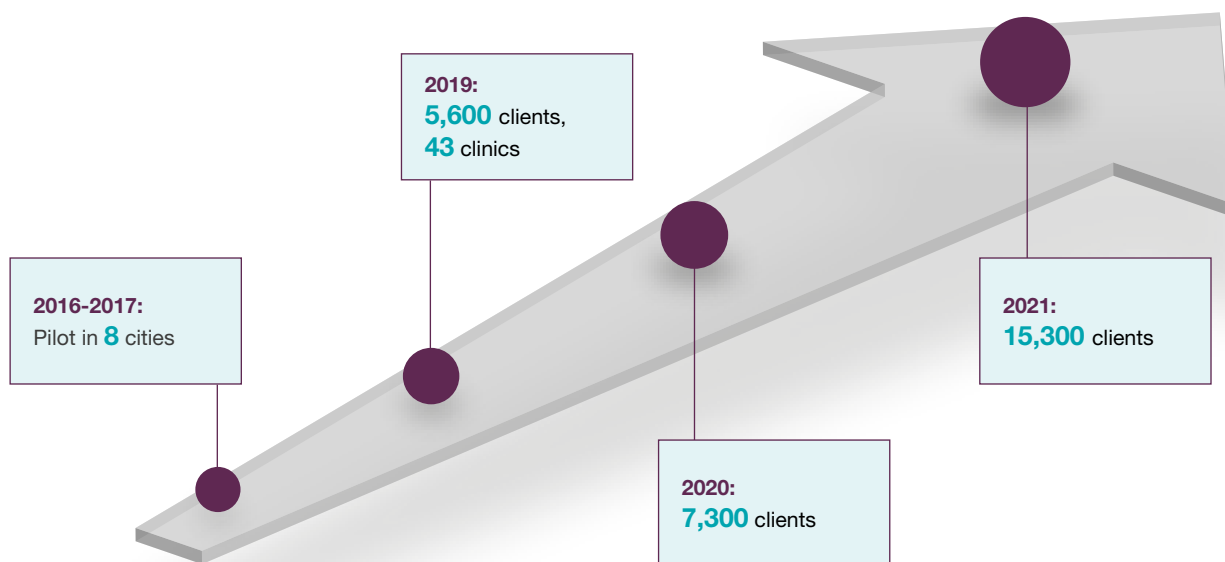
In the past, ART in Viet Nam was covered by international funding, but such funding was cut in 2016. In March 2019, the country's social health insurance (SHI) started to fully cover the cost of ART.

However, many PLHIV have not taken advantage of this free treatment: as of October 2019, only one third of PLHIV receiving ART (42,000) were covered by SHI.²⁵

Pre-exposure prophylaxis (PrEP) has been available in Viet Nam since December 2018,²⁶ but the scale of coverage is still relatively small. Services are only available in 11 provinces, including at 38 public and 7 private sites.²⁷ Figure 1 shows the envisioned PrEP scale-up. PEPFAR's target was to have 13,923 users by the end of 2020, but at the writing of this report, there were only 9,500–10,000 PrEP users in the country.²⁸ The plan is to expand the coverage of PrEP services to 27 cities/ provinces (equivalent to 327 healthcare facilities) in 2021 and nationwide (covering 358 facilities) by 2025.²⁹ PrEP services include STI diagnosis and treatment (for syphilis, NG, CT), as well as monthly and quarterly follow-ups.³⁰ Publicly reported data on STIs from PrEP services are still lacking.

Figure 1: PrEP scale-up plan in Viet Nam (donor and domestic funding)

Objective: Reduction of new HIV infections among key population (MSM, TGW, FSW, etc.)



Sources: Decision No. 5866/QĐ- BYT; Viet Nam Authority of HIV/AIDS Control

There has been some success in the implementation of PrEP in Viet Nam. As of October 2019, there was one ongoing and two completed PrEP demonstration and implementation projects. In

the same year, PEPFAR Viet Nam expanded PrEP services to all those at substantial risk of getting an STI, including PWID, FSWs, and serodiscordant heterosexual couples.

1.3 STI key populations

Certain KPs experience higher STI prevalence and incidence than the general population due to high-risk behaviours.³¹ KPs, as identified in Decision No. 2691/2002 / QD – BYT³², include PWID, MSM, and FSWs. KPs face many forms of stigma and discrimination, which limits their access to STI prevention and treatment services.

KPs account for a high proportion of new and existing HIV infections. The number of HIV infections was estimated at 174,994 among MSM (2017), 226,900 among PWID (2016),³³ and 85,600 among FSWs (2016). HIV prevalence among MSM, PWID, and FSWs was 12% (2017), 13% (2019), and 4% (2017) respectively.³⁴

The estimated infection rate of all STIs among these groups is around 12–16% per year.³⁵ Among MSM, the prevalence of NG, CT, and syphilis was estimated at 17%, 19%, and 33%, respectively (2017).³⁶ Other high-risk behaviour groups include non-injecting drug users (non-IDU) and male sex workers (MSWs) who face significantly higher risks than FSWs.³⁷

According to several studies and the WHO guidelines for STI management, age is an important factor for contracting NG/CT.³⁸ Younger people tend to be more sexually active, have more partners, and have less knowledge and experience with STI prevention than older age groups.³⁹



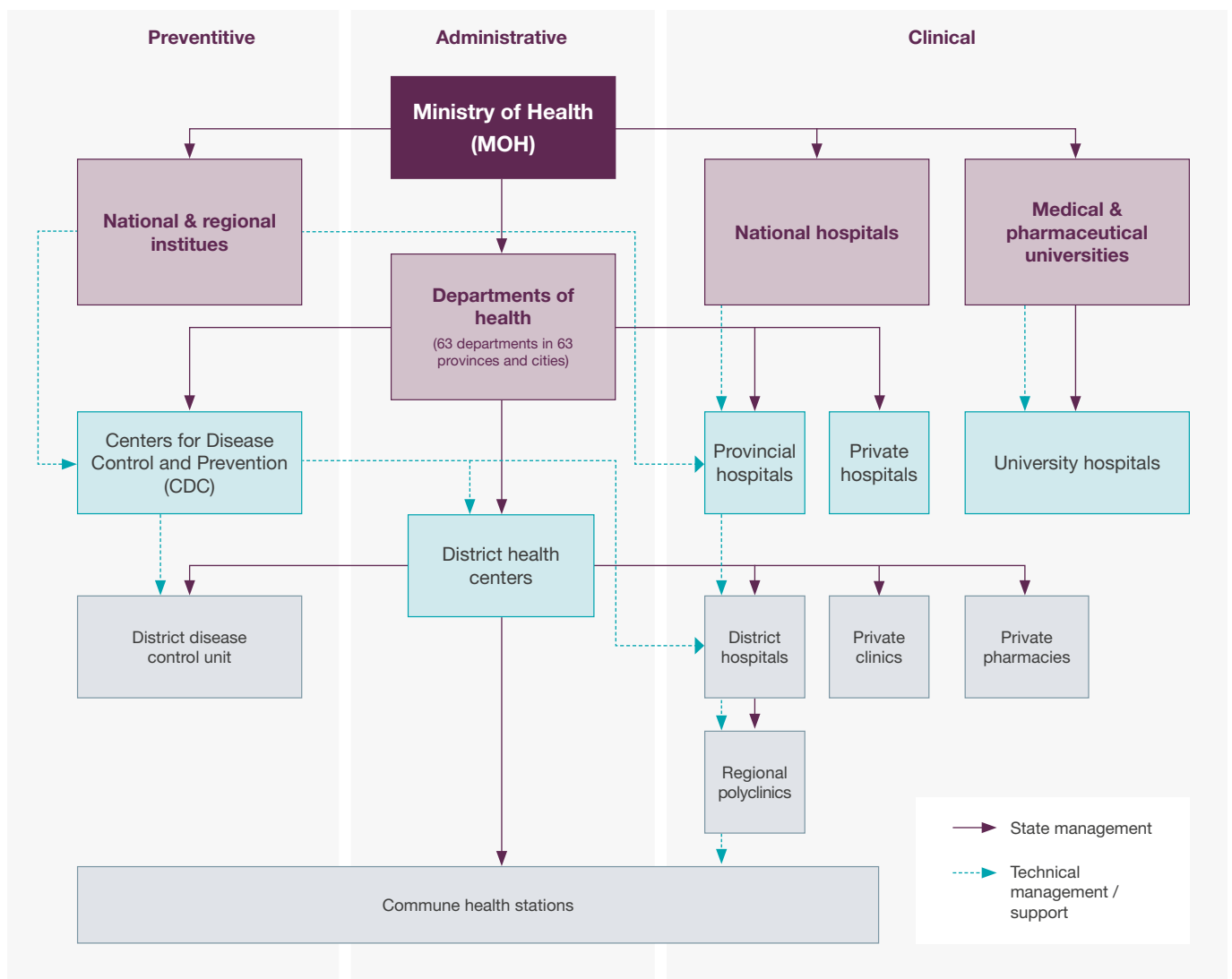
Source: © Hoxuanhuong | Dreamstime.com

II STRUCTURE OF THE HEALTHCARE SYSTEM

Viet Nam's healthcare system is a mix of the public and private sectors. In 2018, there were 105,547 facilities, with a total of 362,525 beds.⁴⁰ The public sector accounts for only 13% of total facilities (13,391) but 94% of total beds (341,403), while the private sector has 87% of total facilities (92,228), but only 21,122 beds (6%).

The management system of public and private facilities in Viet Nam is shown in Figure 2. Public and private facilities of the same level are managed by the same state authorities. For example, provincial hospitals and private hospitals are both supervised by the provincial departments of health (DoHs).

Figure 2: Viet Nam healthcare system (including public and private sectors)



Sources: Ipsos compilation and analysis (modified from the Department of Organisation and Manpower, Viet Nam Ministry of Health (2006) cited in Luu Ngoc Hoat (2008)).⁴¹

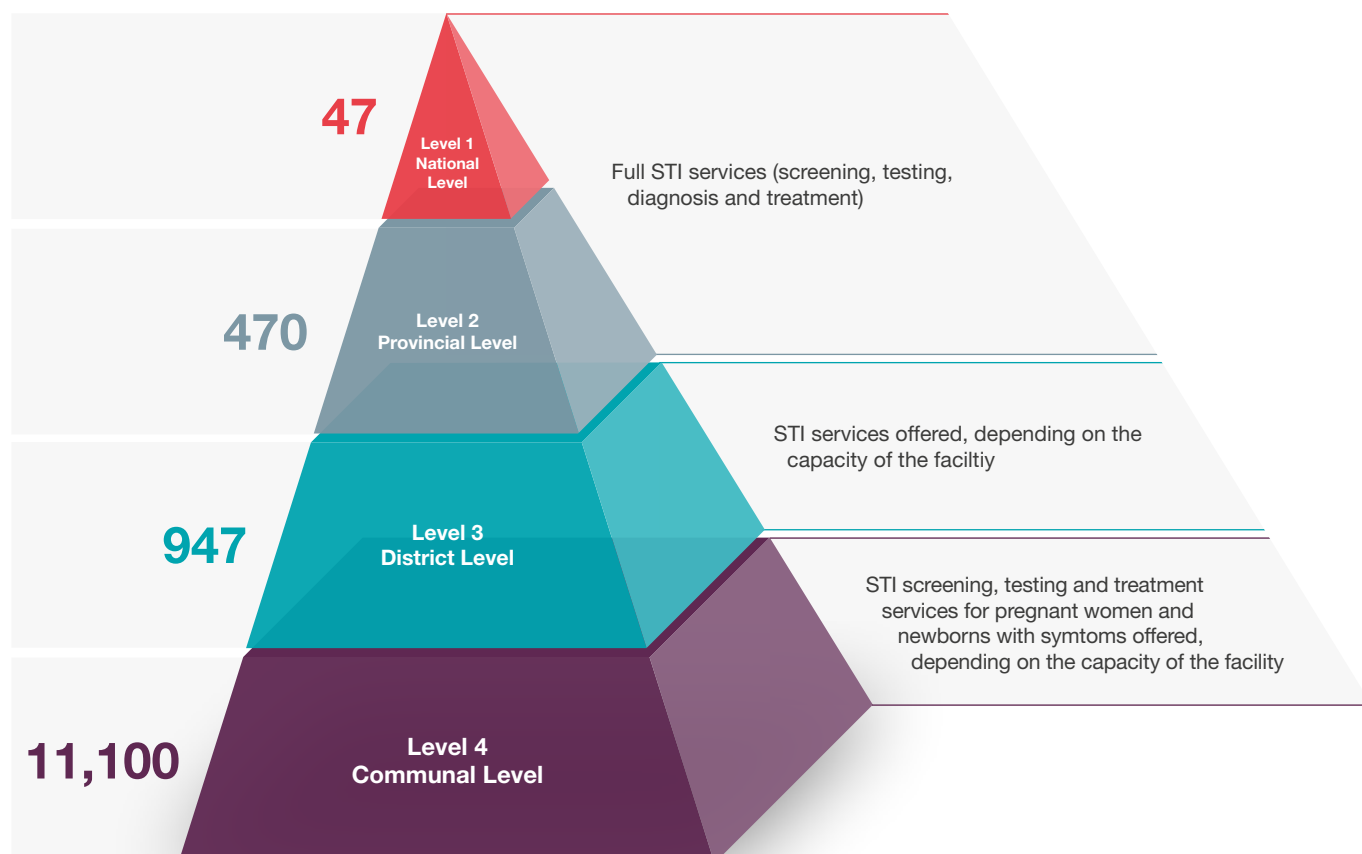
2.1 Public health sector

The public health sector has 341,403 beds⁴² spread across 13,319 health facilities.⁴³ The MoH classifies health facilities under its direct management into four levels (Figure 3). There are also 755 medical

facilities managed by other ministries, such as the Ministry of Defence (e.g. 108 Military Central Hospital) and the Ministry of Public Security (e.g. Hospital 198).

Figure 3: Viet Nam public health sector

Number of facilities



STI, sexually transmitted infection.

Sources: Ipsos Analysis (from MoH's Health Statistics Yearbook 2018)

The National/Central level (Level 1) consists of hospitals and research institutes administered directly by the MoH. In 2018, there were 47 hospitals at this level with a capacity of 31,436 beds.⁴⁴ These facilities include general and specialized hospitals, of which 70% are in either Hanoi or HCMC. The average size is 2,000–3,000 beds.⁴⁵ National hospitals are staffed with doctors, nurses, medical workers, leading professors, and healthcare specialists.⁴⁶ Hospitals at this level offer secondary and tertiary care, functioning as the highest referral points for

provincial hospitals in their regions and as teaching hospitals for nearby medical universities.^{47,48} National hospitals provide a full range of STI services such as screening, testing, diagnosis, and treatment. Since many hospitals specialize in specific diseases (e.g. National Lung Hospital, National Hospital of Odonto-Stomatology, etc.), only two-thirds of the national hospitals provide STI services including the three that specialize in dermatology (NHDV, Quy Hoa National Leprosy Dermatology Hospital and Quynh Lap National Leprosy Dermatology Hospital).

Provincial level (Level 2) facilities provide secondary and tertiary care combined with outpatient services. As of 2018, the number of provincial facilities was 470, with a total of 138,780 beds.⁴⁹ The average size is around 500 or 600 beds per facility.⁵⁰ Provincial facilities include general, specialized and traditional medicine hospitals, leprosariums, sanatoriums, and special clinics. Specialized hospitals are organized according to the population size of each province. In provinces with a large population, some hospitals serve as referral points for neighbouring district health centres. STI patients seeking access to care can go to the dermatology unit of general hospitals, specialized dermatology hospitals, or specialized clinics.

District level (Level 3) comprises 947 facilities nationwide, providing 94,045 beds⁵¹ managed by district health centres. District health centres also provide primary care, secondary care, and basic STI services.⁵² District hospitals average about 275 beds each⁵³ and offer STI testing, diagnosis and treatment services, depending on the capacity (e.g. equipment, human resources, etc.) of the hospital.

Harmonizing health activities among facilities in each district has been one of the government's targets⁵⁴ since 2004. While there have been many changes in the organization of district health facilities following Decree No. 172/2004/ND-CP, Decree No. 14/2008/ND-CP and other guiding circulars, no uniform model of service provision or governance has emerged.⁵⁵

In between the district level and the communal level are regional polyclinics managed by district general

hospitals or, if there is no general hospital in the region, by district health centres. These polyclinics represent a higher level of community health stations (CHSs), and are responsible for the construction, inspection, and maintenance of CHSs in their mission of disease prevention, food safety promotion, and provision of family planning services.⁵⁶

Communal level (Level 4) consists of only CHSs, which are largely self-administered and work to both prevent and cure diseases. On average, each CHS is staffed with seven medical workers, including one or two doctors and ancillary staffs, such as midwives, nurses, traditional medicine practitioners, and pharmacists.⁵⁷ Except for emergencies, 11,000 CHSs nationwide provide the first points of contact with the public healthcare system. CHSs deliver primary care and focus on hygiene, vaccination, prenatal care and delivery, and health education. They also refer patients to higher levels for more advanced services.⁵⁸ STIs services offered at CHSs include screening, testing, diagnosis and treatment for pregnant women and newborns with symptoms depending on the capacity of the facility.

The linkage between the two lowest public healthcare levels (district and commune) to provide primary healthcare services is called the grassroots health network. This network plays an important role in the healthcare system as it can resolve healthcare problems and alleviate overcrowding in national and provincial facilities. As a result, the government has issued many policies and regulations to strengthen and develop the grassroots health network, such as Decision No. 47/2008/QD-TTg, Circular No. 06/2008/TT-BYT, Directive No. 06-CT/TW, etc.⁵⁹

2.2 Private health sector

The private health sector, with 92,228 facilities (87%) and 21,122 beds (6%) nationwide, consists of three kinds of facilities: private hospitals, private clinics, and private pharmacies.

Private hospitals are becoming an essential part of the healthcare system. From 2010 to 2018, the number of private hospitals increased by 55%, reaching 228 hospitals with a total of 21,122 beds.⁶⁰ Most private hospitals are found

in urban areas where there is a large high-income population. In 2018, there were 36 and 56 private hospitals in Hanoi and HCMC, respectively, together making up 40% of private hospitals nationwide. Private hospitals usually have from 100 to 400 beds. Services provided depend on each hospital with general medical examination and outpatient treatment being the most common. STI services are only offered in selected private hospitals (Table 4).

Table 4: Capacity and STI services offered in key private hospitals in Viet Nam

Name	Number of hospitals	Number of beds	STI services offered
Bac Ha Hospital	1	100	✓ Has STI services but no clear scope mentioned on their website
Hanoi French Hospital	1	170	✓ Testing and treatment
FV Hospital	1	220	✓ Testing and treatment
Hoan My Hospital Group	14	100–400 (depending on the location)	✓ Has STI services but no clear scope mentioned on their website
Hong Ngoc Hospital	2	500	✓ Diagnosis and treatment
Vinmec	7	100–400 (depending on the location; Vinmec has hospitals with 600 and 1,200 beds)	✓ Diagnosis, treatment, prevention and rehabilitation

STI, sexually transmitted infection.

Sources: Hospital websites, Ipsos analysis

Viet Nam is an attractive market for **private clinics** due to the low cost of investment and operation. As of 2019, there were 35,000 private clinics,⁶¹ accounting for 33% of the country's total facilities. These clinics provide basic health advice, first-aid, examination and treatment for common diseases, screening, rehabilitation, and patient transfer to higher-level facilities as needed.⁶² Most general clinics have a dermatology department or unit that offers testing, diagnosis, and treatment for STIs. In addition, there are a few large clinics specializing in dermatology, such as Galant, Thai Ha, Hung Thinh, as well as small private dermatological clinics, which are staffed with dermatologists and provide STI testing, diagnosis, and treatment services. Most clinics outsource the tests to private independent laboratories due to cost considerations.⁶³

Private pharmacies comprise 60% of private healthcare facilities with 57,000 facilities nationwide.⁶⁴ Pharmacies need to follow certain rules and regulations, such as the Drug Law⁶⁵ and Circular No. 02/2018/TT-BYT.⁶⁶ It is reported that

55% of Vietnamese adults go directly to a pharmacy without having seen a doctor⁶⁷ and about 90% of antibiotics are sold without a prescription.⁶⁸ Half of the prescription drugs indicated for STI treatment per the national guidelines are available at big pharmacy chains. However, the prescription labelling is a formality.⁶⁹ Even though there are no official guidelines for diagnosis and treatment at this level, most pharmacies readily prescribe drugs for STIs. In a 2014 study of 60 pharmacies in Hanoi, pharmacists proposed treatment courses for 87% of urethral discharge cases, and 30% of genital ulcer cases; none of the prescriptions complied with the National Guideline for STIs.⁷⁰ One KSI indicated that pharmacists or pharmacy assistants normally prescribe drugs based on reported symptoms. However, pharmacy assistants, who receive only six to twelve months of training after college, do not have adequate knowledge to perform this task well. Pharmacists sometimes refer patients to hospitals or clinics for testing and treatment but it depends on the case and the patient.⁷¹

2.3 National STI response

Under the MoH, there are three departments in charge of controlling and managing STIs at national level: the Administration of Medical Services (AMS), the Viet Nam Administration for HIV/AIDS Control (VAAC) and the Department of Maternal Health and Children (DMHC). AMS is responsible for the state management, supervision, and monitoring of the diagnosis and treatment processes in general, while VAAC controls the National HIV/AIDS Prevention Program and publish guidelines specifically related to HIV and other STIs. In 2013, VAAC issued guidelines for diagnosis and treatment of STIs (Decision No. 4568/QD-BYT) which provide detailed information for each type of STI (syphilis, NG, CT, etc.), including an overview of the disease, causative agents, clinical symptoms, methods of diagnosis, tests, treatment, and prevention. The document also gives detailed drug regimens for each disease. For NG and CT, there is an additional guideline for screening and testing pregnant women as mandated by the MoH. These guidelines should be updated whenever an important innovation in testing, diagnosis or treatment happens.⁷² The DMHC is responsible for pre-natal care and the prevention of mother-to-child transmission of STIs. However, there is no official document indicating how these institutions manage STIs and coordinate their responses internally.

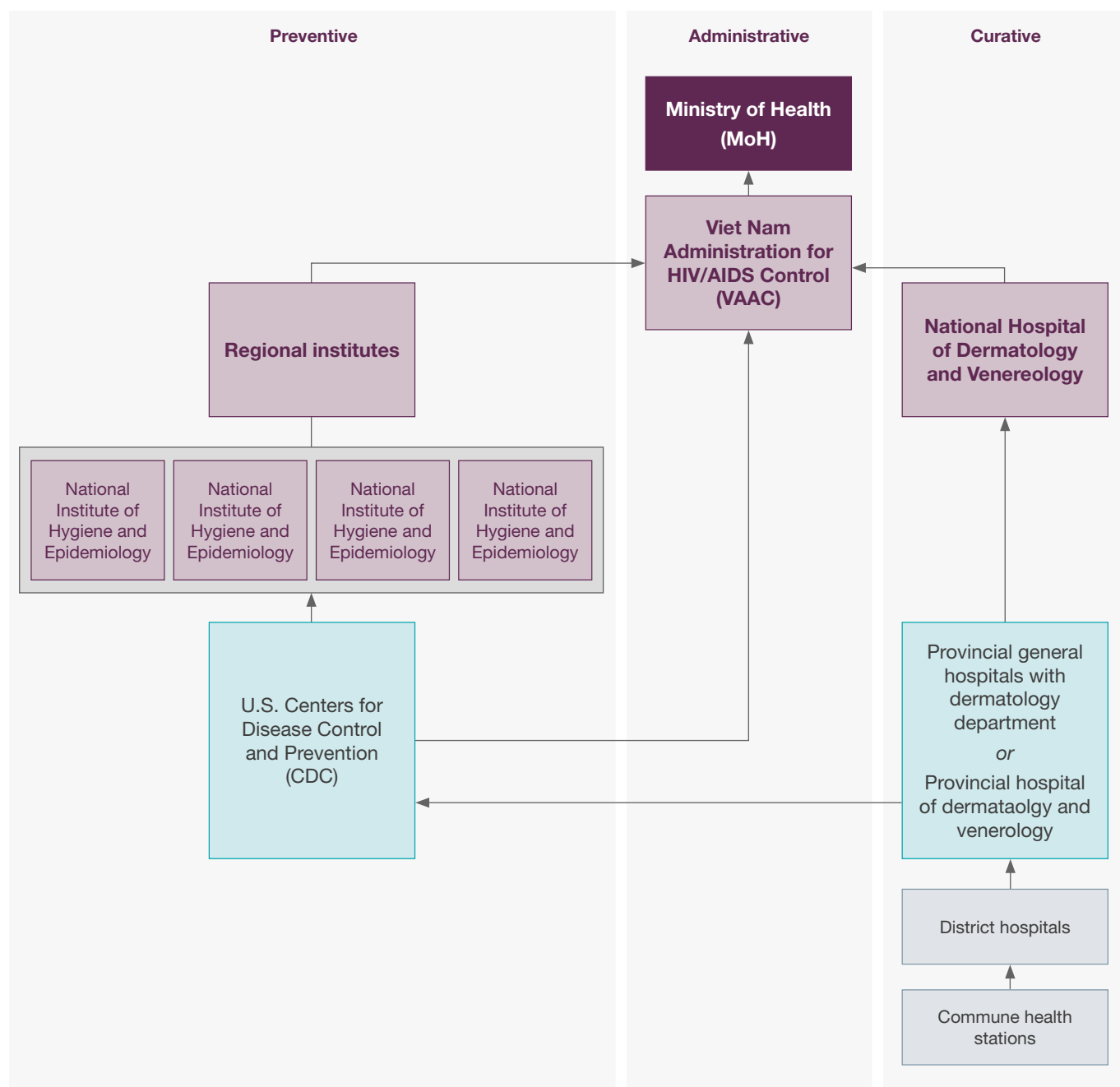
In addition to the three MoH departments that officially manage STIs, the National Hospital of Dermatology and Venereology (NHDV) is the entity leading the STI response and currently implementing all STI monitoring and surveillance in Viet Nam. AMS and VAAC support NHDV in carrying out STI activities in the country: AMS in administrative and legal issues, and VAAC in financing. The NHDV coordinates diagnosis and treatment and serves as the highest referral point for other facilities across Viet Nam. NHDV's Department of Health Activities Direction collects data on dermatology and venereology nationwide, as per MoH mandate. The department also partners with VAAC and other organizations to develop and monitor annual STI projects.⁷³

The government and MoH pay little attention to STIs (other than HIV); hence, Viet Nam's STI responses are often driven by either reproductive health programmes or responses to the HIV epidemic. Before 2017, a national STI programme was implemented by VAAC in collaboration with NHDV. The programme focused on sentinel surveillance of common STIs (e.g. syphilis, NG, CT) in KPs and pregnant women. The project was planned to continue until 2020, but it ran out of funding in 2016 and was thus cancelled.⁷⁴ Currently, the majority of STI programmes and projects in Viet Nam are funded by international organizations. Some of the notable projects include:

- ▶ NHDV's collaboration with Oxford University Clinical Research Unit (OUCRU) in an AMR in NG project, which collects monthly data in 10 cities and provinces.⁷⁵
- ▶ The Pasteur Institute in HCMC's cooperation with the Biomedical Science Association (a Japanese non-governmental organization [NGO]) in a million-dollar project training health workers to support mothers and children in preventing infectious diseases, including STIs in HCMC, Tay Ninh, Binh Duong, Kien Giang, An Giang and Can Tho. The project was projected to run from 2017 to 2020.⁷⁶
- ▶ The ongoing partnership between the U.S. Centers for Disease Control and Prevention (CDC) with laboratories in 11 cities and provinces, including Hanoi, HCMC, Hai Phong, and Tien Giang to provide free NG and CT tests.⁷⁷

Even the non-HIV STI surveillance system, which includes NG/CT surveillance, has been opportunistically integrated into the existing HIV surveillance programme. Thus, the case reporting system for STIs (Figure 4) is like that for HIV. Only VAAC is featured in the STI case reporting system, as AMS and DMHC do not directly manage patient-related issues or collect data.

Figure 4: STI case reporting system



AIDS, acquired immune deficiency syndrome; HCMC, Ho Chi Minh City; HIV, human immunodeficiency virus.

Note: Each regional health institute oversees assigned areas:

- ▶ National Institute of Hygiene and Epidemiology (NIHE): 26 Northern provinces, Thanh Hoa, and Nghe An;
- ▶ Tay Nguyen Institute of Hygiene and Epidemiology: Dak Lak, Gia Lai, Kon Tum, Dak Nong; and
- ▶ Pasteur Institute Nha Trang: 11 coastal provinces from Ha Tinh to Binh Thuan;
- ▶ Pasteur Institute HCMC: Lam Dong and 19 Southern provinces.

Sources: Ipsos analysis (Modified from MoH Decision No. 1418/2000/QD-BYT and information from interviews with KSIs).

2.4 National AMR response

Viet Nam has one of the highest rates of antimicrobial-resistant infections in the world.⁷⁸ The National Action Plan for AMR Prevention from 2013 to 2020 outlines the reasons for such high rates:

- ▶ Inappropriate use of antibiotics, due to over-dosing, under-dosing, poor self-medication, etc.;
- ▶ Limited quality control and assessment of drugs;
- ▶ Ineffective prevention of infectious diseases;
- ▶ Ineffective laws and lax regulation surrounding diagnosis and treatment;
- ▶ High percentage of antibiotics sold without

prescription (88% of drugs sold in urban areas and 91% in rural areas);

- ▶ Poor awareness of AMR, especially in the rural areas.

Despite the Drug Law, pharmacies continue to sell antibiotics to individuals without prescriptions because there is no sanction for not complying with the regulation.⁷⁹

In 2013, the MoH enacted the National Action Plan for AMR Prevention from 2013 to 2020 under Decision No. 2174/QD-BYT. The plan has six main objectives, including five concerning human health (Table 5).

Table 5: National action plan strategic objectives

Strategic issues	Strategic objectives
Public and health worker awareness and education	Improve public awareness, promote community education regarding disease prevention, in all forms and at all levels
Surveillance and monitoring	Continuously monitor and improve surveillance of antibiotic use and incidence of AMR infections through: <ul style="list-style-type: none"> ▶ developing technical guidelines for microbiological testing, and establishing standard and reference microbiological laboratories; ▶ continuous improvement of clinical microbiology testing quality and AMR research capacity; ▶ establishing an AMR surveillance system; and ▶ developing a database on antibiotic use and drug resistance.
Infection prevention and control	<ul style="list-style-type: none"> ▶ Improve management of prevention and infection-control programmes ▶ Develop legal documents regulating infection prevention and control measures to be used in healthcare facilities
Appropriate use of antimicrobials	<ul style="list-style-type: none"> ▶ Promote the appropriate use of antibiotics, ensuring the right amount of usage and safety, in healthcare, agriculture, livestock production and aquaculture, through medical and legal education on the appropriate use of medicine
Research and development	<ul style="list-style-type: none"> ▶ Upgrade microbial laboratories and research centres, invest in facilities and equipment ▶ Promote research on AMR infections, especially for multi-drug resistant bacteria ▶ Apply new technology

AMR, antimicrobial resistance.

Source: MoH Decision No. 2174/QD-BYT

The National Action Plan is a joint commitment between the MoH and the Ministry of Agriculture and Rural Development to address AMR in both humans and animals. Under the two ministries, 13 agencies and departments are responsible for implementing the action plan. There is no unit specialized in AMR specifically for STIs but such work nonetheless falls within the scope of AMS, VAAC and the provincial CDCs.⁸⁰ The current national action plan ends in 2020 and AMS is expected to publish a national report.⁸¹

Another issue is that people in Viet Nam do not take

the threat of AMR for NG seriously and assume that antibiotics can easily cure infections.⁸² To address this problem, NHDV has been collaborating with WHO and OUCRU since 2017 to implement an NG AMR project in 10 cities and provinces across the country. However, WHO withdrew from the project in 2019.⁸³

There are many other AMR programmes in Viet Nam, but their scale is small due to limited funding and human resources. Most active programmes and projects on AMR are supported by international organizations, as shown in Table 6.

Table 6: International support on AMR

Programme	International support	Aim
NAP for AMR Prevention from 2013 to 2020	US CDC, OUCRU, Association of Public Health Laboratories and PATH	Support the implementation of the national action plan for AMR prevention
Annual AMR Week Viet Nam	MoH with WHO	Raise awareness of AMR
Developing Viet Nam JANIS(*) module	AMS with AMR Research Centre of Institute of Infectious Diseases (Japan)	Develop an AMR surveillance system in Viet Nam using JANIS
AMR activities	The Fleming Fund	Improve the AMR situation in Viet Nam
AMR on NG	OUCRU collaborating with NHDV	Develop national guidelines for culture and antimicrobial sensitivity testing for NG

AMR, antimicrobial resistance; AMS, Administration of Medical Services; CDC, Centers for Disease Control and Prevention; MoH, Ministry of Health; NHDV, National Hospital of Dermatology and Venereology; NAP, national action plan; NG, Neisseria gonorrhoea; OUCRU, Oxford University Clinical Research Unit; WHO, World Health Organization.

* JANIS is a cloud-based system that can analyse data from culturing to antibiotic testing and automatically create reports on AMR and receive feedbacks from hospitals in the system.

Source: MoH, The Fleming Fund, and Information from interviews with KSIs.

In addition to general AMR investigation and prevention support, the Fleming Fund also sponsored a USD 2.6 million (60 billion Vietnamese dong [VND]) grant to the National Hospital of Tropical Diseases (NHTD) to build an AMR reference laboratory, which was opened at the NHTD branch at Dong Anh (Ha Noi) in May 2018. The laboratory's main functions are to confirm testing; to detect mechanisms of resistance and genome sequencing; to collect and analyse data on AMR, including new and special types of AMR; and to transfer technology to other laboratories.⁸⁴

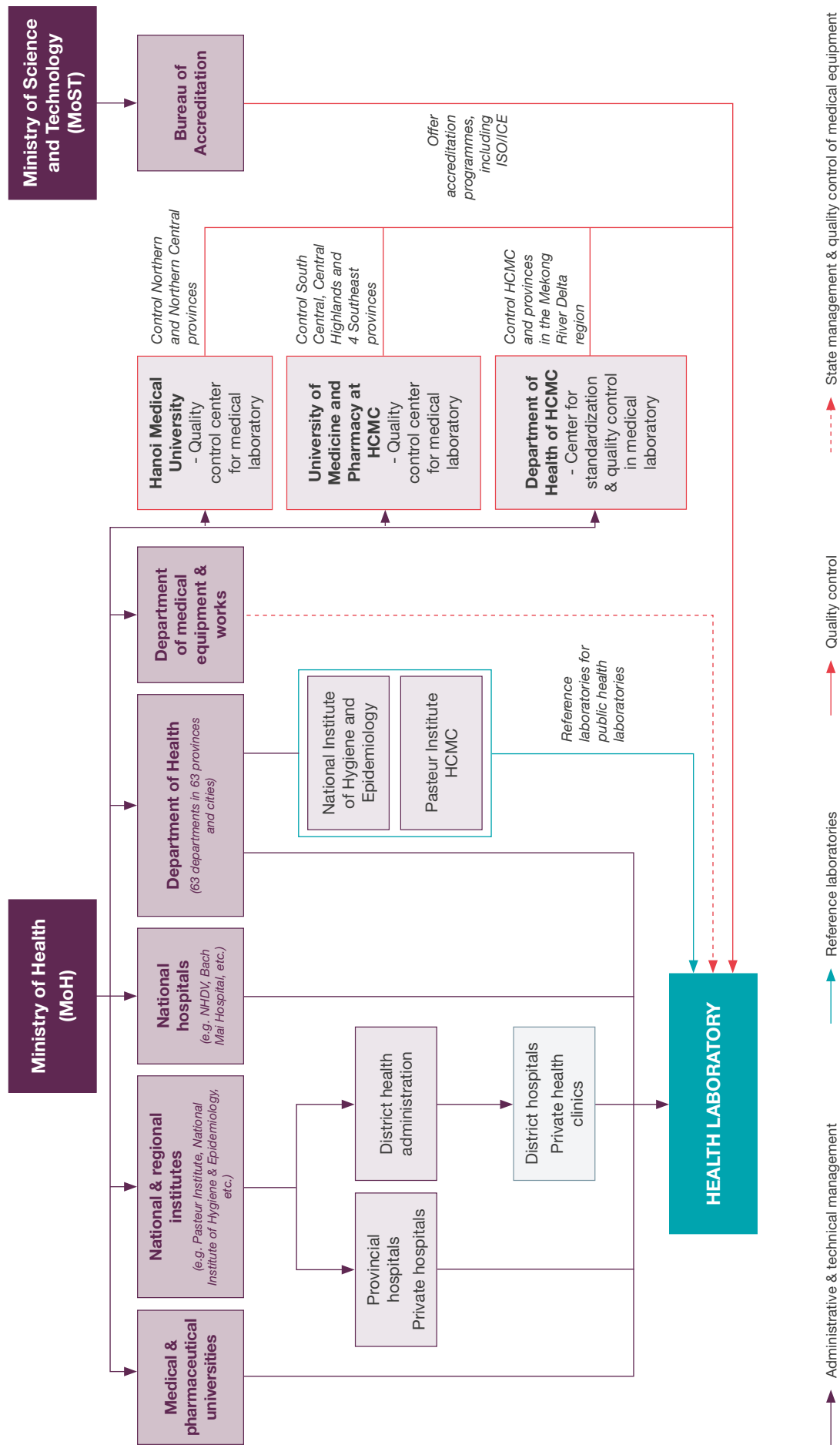
An AMR surveillance system was established under the management of AMS with the National Steering Committee on the Prevention of AMR from 2013 to

2020 (NSCPA) and the National AMR Surveillance Unit (NASU).

1. NSCPA has nine sub-committees, working on both human and animal health.^{85,86} There is a sub-committee dedicated to HIV but none for other STIs.
2. NASU focuses on AMR in human health, and oversees the Technical Group for AMR Surveillance (2017–2020),⁸⁷ the Technical Support Group on Clinical Microbiology Testing, the Sentinel AMR Surveillance Unit, and the Other AMR Surveillance Unit.^{88,89} There is no unit working for AMR specifically around STIs.

2.5 Health laboratory system

Figure 5: Viet Nam health laboratory system



HCMC, Ho Chi Minh City; ISO, International Organization for Standardization.

Source: Ipsos analysis (referred to MoH's Decision No. 5868/QĐ-BYT, Prime Minister's Decision No. 1101/QĐ-TTg, Decisions and information from the quality control centre websites)

Health laboratories are managed by multiple stakeholders (Figure 5). NIHE and the Pasteur Institute HCMC serve as two national reference laboratories for all other public health laboratories. The two institutes handle complicated cases that laboratories at lower levels cannot.^{90,91}

There are approximately 1,500 health laboratories in the country, of which 85% are government run.⁹² The number of private hospital laboratories is growing rapidly due to the rise in per capita healthcare expenditure and growth in the percentage of the population with insurance coverage.⁹³ In addition, there are independent laboratories, (e.g. SDG Life, CHEMEDIC, etc.) that provide testing and outsourcing services for both public and private facilities. Public and non-public facilities that do not have testing capacity collect specimens and outsource them to partnering, private laboratories for analysis.

Laboratories differ widely in the types of tests offered, which include haematology, parasitology, biochemistry, serology, immunology, molecular biology and microbiology tests with varied equipments and capabilities. In the public sector, laboratory capability is usually dependent on the level and size of the facility. Depending on the capacity of the facility, Level 4 CHSs can provide simple tests with simple testing machines and devices (e.g. biochemical haematology analyser, microscope, etc.) or rapid tests (e.g. blood glucose test, pregnancy test, etc.). For CHSs that do not have testing capacity, they refer patients or samples to higher levels. Thus, whether or not the CHSs are able to provide tests, patients and people who can afford to pay are likely to skip the services offered at the commune health centre and use the district- or higher-level facilities for test-based diagnosis and care.

Table 7: Health laboratory capacity

Sector	Facility type	Laboratory capacity
Public	Level 1 National level	<ul style="list-style-type: none"> ▶ General hospitals: all types of tests ▶ Specialized hospitals: limited to the hospital's specialization
	Level 2 Provincial level	
	Level 3 District level	▶ Limited capacity
	Level 4 Communal level	▶ Laboratories are not available at this level, but the infrastructure depends on the facility
Private	Private hospitals	
	Private clinics	▶ Varies widely between facilities
	Independent Laboratories	

Source: MoH and hospital websites.

Quality management certification and maintenance are serious challenges.⁹⁴ At the end of 2017, only 80 of approximately 1,500 health laboratories had received ISO 15189 Quality Management Certification. Maintenance of biosafety cabinets had not been performed for a long time at some of the sites. The government is aware of the situation. The national standard for medical laboratories, TCVN ISO 15189:2014 (ISO 15189:2012), states that at every laboratory, there must be a handbook with instructions which all personnel should strictly follow.⁹⁵ Laboratories use WHONET, the WHO management and analysis software for microbiology laboratories, to make reports. In addition, most laboratories use a laboratory information system called LABCOM.⁹⁶

To get operation licenses, health laboratories have to follow all requirements on facilities, equipment and human resources listed in Decree No. 109/2016/ND-CP. The chief physician must hold a university degree and a practice certificate specialized in testing, and have worked for a suitable laboratory department for at least 54 months or as a testing practitioner for at least 36 months. A practice certificate is also required for personnel working at the laboratory and involved in the testing process. The minimum qualification required for such a certificate is an associate degree.⁹⁷

III CURRENT STI MANAGEMENT

3.1 STI awareness in Viet Nam

Lack of knowledge and awareness about STIs is amongst the key factors underlying the current STI situation in Viet Nam. While many HIV awareness campaigns, conducted by the government or other entities, have included information on STIs, many people still lack knowledge about STIs and do not fully understand the risk of becoming infected.⁹⁸ A 2018 study conducted among 622 participants showed that a low percentage of participants had adequate knowledge about STIs and their symptoms. The number of patients who had knowledge about syphilis was the highest (57.8%), followed by herpes warts (57.7%), HIV/AIDS (57.4%), and NG (48.9%). In the study, 68% of participants were aware that not all STIs can be cured, and 35% of patients knew that vaccines were available for several STIs.¹⁰¹

A 2011 study of 455 male and female vocational school students aged 15–24 indicated that this population had little knowledge regarding STIs.⁹⁹ Particularly striking was the fact that only 3% knew about CT. There were also numerous misconceptions about STI infection methods rooted in a lack of sexual education and general understanding of biology. For example, some believed that STIs could be caught by having bad hygiene or by having sex during the menstrual cycle. Male students had a greater knowledge of symptoms and signs associated with STIs than female students. Additionally, many students lacked knowledge about the consequences of an untreated STI; for example, only 47% knew that STI infection could lead to infertility.

Attitudes towards sex remain conservative and public or frank discussions about sexual issues are still a taboo. This has led to a lack of sexual education at home and in school and contributed to a culture where it is hard to learn about or find support for the treatment of STIs.¹⁰⁰

3.2 STI care-seeking and access to care

In Viet Nam, STIs are still considered a matter of shame and stigma. People seeking care are concerned about privacy and the protection of their personal information. They typically visit facilities that are far from their workplace or neighbourhood to avoid encountering anyone they know. Moreover, patients are not willing to share their personal information (e.g. occupation, sexual activities, etc.) and may provide incomplete or incorrect personal details and avoid disclosing information. This particularly applies to FSWs who are stigmatized by the majority of Vietnamese people or other KPs whose activities are not widely accepted by society.¹⁰¹ In some cases, the fear of stigmatisation and social marginalisation causes FSWs and KPs to avoid getting proper treatment or only attempt self-treatment.

a. Public versus private care-seeking

STI treatment services are provided by both the public and private health facilities. The private sector, even though making up a smaller percentage of total facilities,¹⁰² serves the majority of STI patients.¹⁰³ STI patients prefer private facilities due to staff friendliness, less discrimination, and shorter waiting times. Moreover, they feel that their privacy and confidentiality are better respected by the private facilities,¹⁰⁴ as these are more discreet in their required disclosures of patients' personal information, including sexual histories, than public facilities.¹⁰⁵ In the private sector, private clinics tend to have more STI patients, compared with hospitals, as they offer greater flexibility for patients. These clinics offer a wider range of time slots compared with hospitals and operate outside of normal working hours, making them more accessible for patients to visit after work.

However, the relatively higher cost, rooted in the limited applicability of SHI in private facilities, is considered to be a barrier to private care-seeking. Only a small percentage of private facilities are registered as health service suppliers under the SHI scheme. For example, only around 30% of private facilities in HCMC provide health services that are covered under social insurance.¹⁰⁶

Private pharmacies are also go-to destinations for those with STI symptoms seeking STI drugs,¹⁰⁷ because they can buy these treatments without a doctor's prescription. This is a leading cause of AMR and chronic infection with the STI in question if the regimes prescribed by drug sellers/pharmacists are ineffective.¹⁰⁸

b. Men versus women

Different awareness of STIs leads to differences in STI care-seeking behaviours between men and women. Men typically have greater knowledge of STIs compared with women of the same age group and educational background.¹⁰⁹ This may lead to earlier and more active care-seeking behaviour in men, while women often wait longer before seeking consultation. Moreover, many women are reluctant to share information about their sexual history and tend to feel uncomfortable revealing their symptoms. In contrast, men tend to ask about the symptoms directly. Male patients often seek STI treatment in the early stages of disease when the symptoms are still mild.¹¹⁰

Although social factors certainly play a role, men and women also experience different signs and symptoms and this accounts for some of the differences in care-seeking behaviour. Typical signs and symptoms of many STIs are easier for men to recognize. On the other hand, in women, symptoms are often not easily discernible and go unnoticed until later stages of diseases. There is still much confusion over how much and what kind of vaginal discharge is normal.¹¹¹

Although pharmacies are popular points of contact for people of both sexes, men and women behave differently before approaching

pharmacies. For men, pharmacies are often the very first place they seek consultation or treatment. Women, on the other hand, often only go to pharmacies after consulting another healthcare provider first, or after investigating their symptoms on the internet.¹¹²

c. Under 25-year-olds versus over 40-year-olds

STI care-seeking behaviour is also influenced by age. Many doctors agree that patients in their 20s or 30s usually have access to STI treatment at the earlier stages of infection. Compared with older age groups, younger people acknowledge the risks of STIs, have received more sex education, and have accessed relevant information from a variety of sources including school, family, friends, Internet, media, etc. Middle-aged Vietnamese, on the other hand, people have not had opportunities to access STI information during their formative years. Ten or 20 years ago, sexual education was considered embarrassing and was avoided. Therefore, middle-aged people often do not know how to recognize the early symptoms of STIs.

Young people make up a larger proportion of those seeking STI-care at pharmacies compared with middle-aged.¹¹³ Other than differing social attitudes, this can also be explained by the lower cost for treatment at pharmacies and the fact that the younger population earns less than people over 40. Older people with higher-paying jobs usually choose more expensive hospitals and clinics.

d. Key populations

The care-seeking behaviours of FSWs and MSM are similar due to similar stigmatisation. In Viet Nam, prostitution is illegal and is considered a "social evil," and homosexuality is still not generally accepted. Sex workers often seek consultation and treatment in pharmacies or from private clinics rather than going to public facilities.¹¹⁴ A study conducted on over 400 FSWs revealed that most FSWs only go to see a doctor if self-medication was unsuccessful.¹¹⁵ Several studies on reproductive health in Viet Nam showed that MSM usually go to private clinics or try self-treatment due to the fear of stigma.¹¹⁶

3.3 STI guidelines and management practices

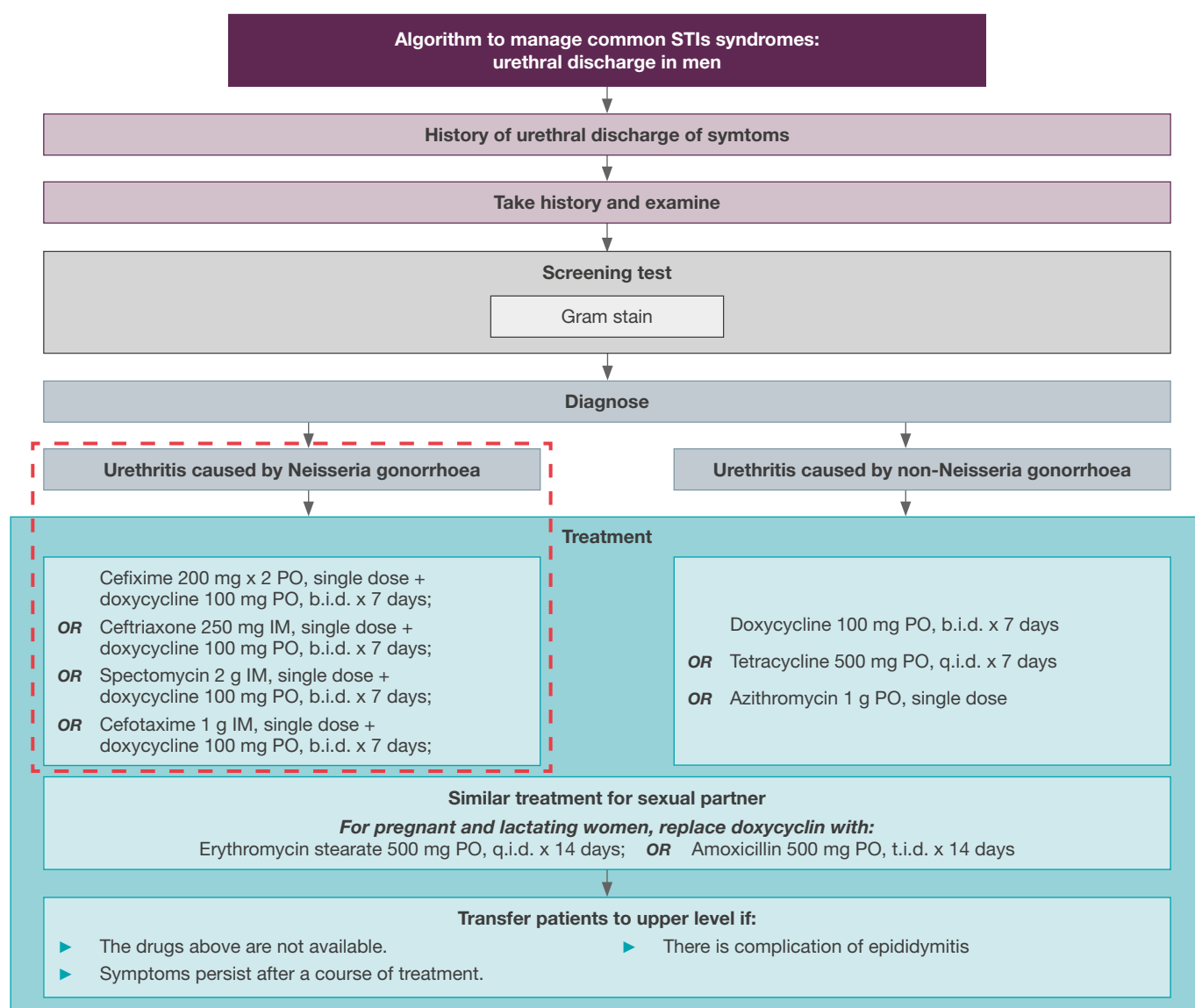
STI diagnosis in Viet Nam is both syndromic and etiological. Syndromic approaches are more common due to the lack of testing equipment at many primary healthcare facilities. Thus, the *national guidelines on STI diagnosis and treatment* indicate that facilities capable of conducting etiological tests should follow an etiological approach while others follow a syndromic one.¹¹⁷ Syndromic diagnosis is the only approach used at low-level public facilities (i.e. district and commune levels).¹¹⁸

The *national guidelines* provide detailed treatment and management processes for each type of STI for both etiological and syndromic approaches.

The disease management process for three common STI syndromes (urethral discharge, vaginal discharge, and low abdominal pain) is presented in the figures below.

Official guidelines for STIs in Viet Nam are not updated on a regular basis. However, the guidelines recommend that healthcare providers update the treatment process if they become aware of any new techniques. NHDV is often the first to update, usually based on annual AMR surveillance data or WHO recommendations.¹¹⁹ However, other healthcare providers may not follow NHDV, resulting in differences in treatment processes among facilities.

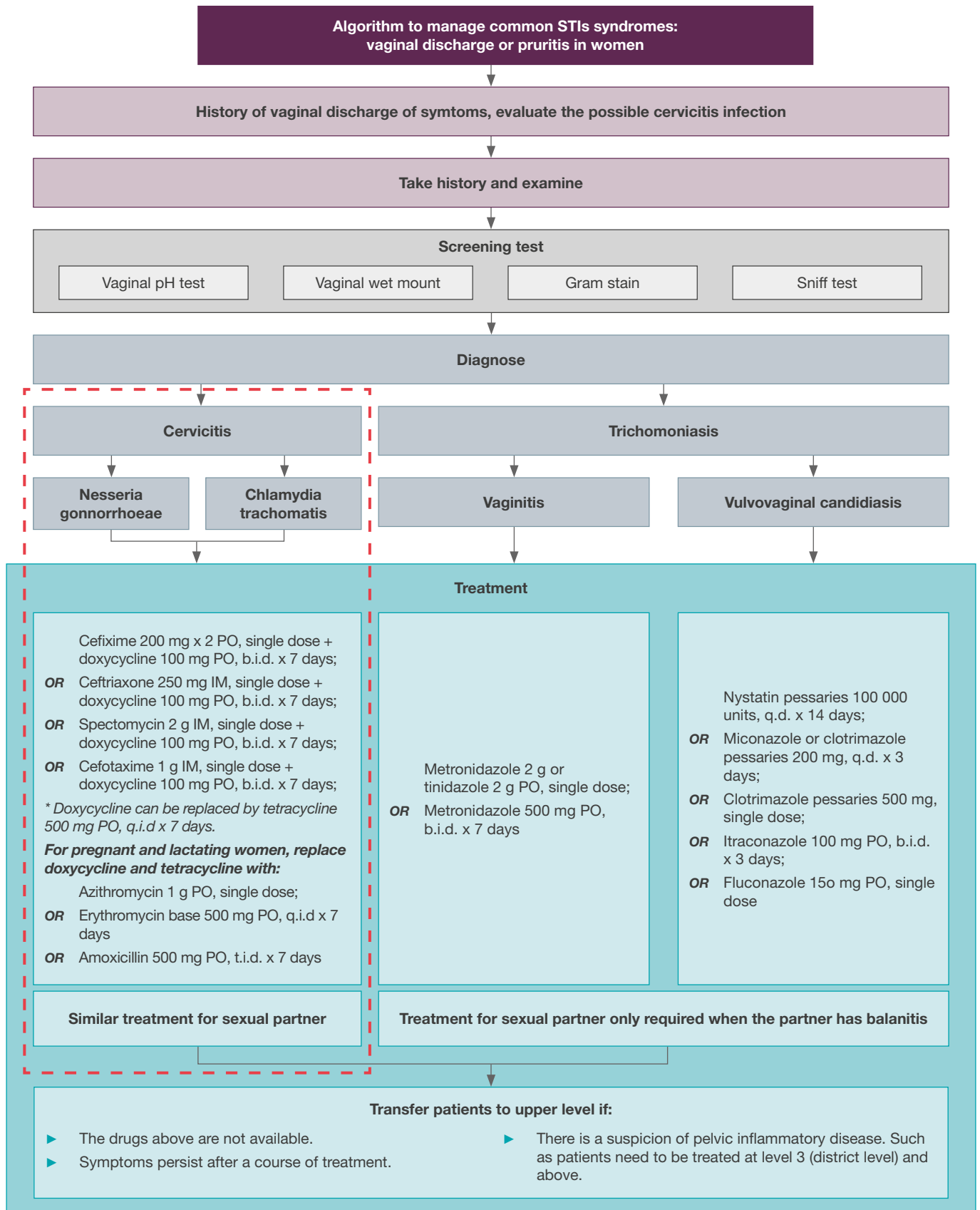
Figure 6: Flowchart for managing urethral discharge in men



b.i.d, twice a day; IM, intramuscularly; PO, orally; q.d. once a day; q.i.d, four times a day; qw, once a week; STI, sexually transmitted infection; t.i.d, three times a day.

Sources: MoH's Decision No. 4568/QD-BYT and Decision No. 4128/QD-BYT.

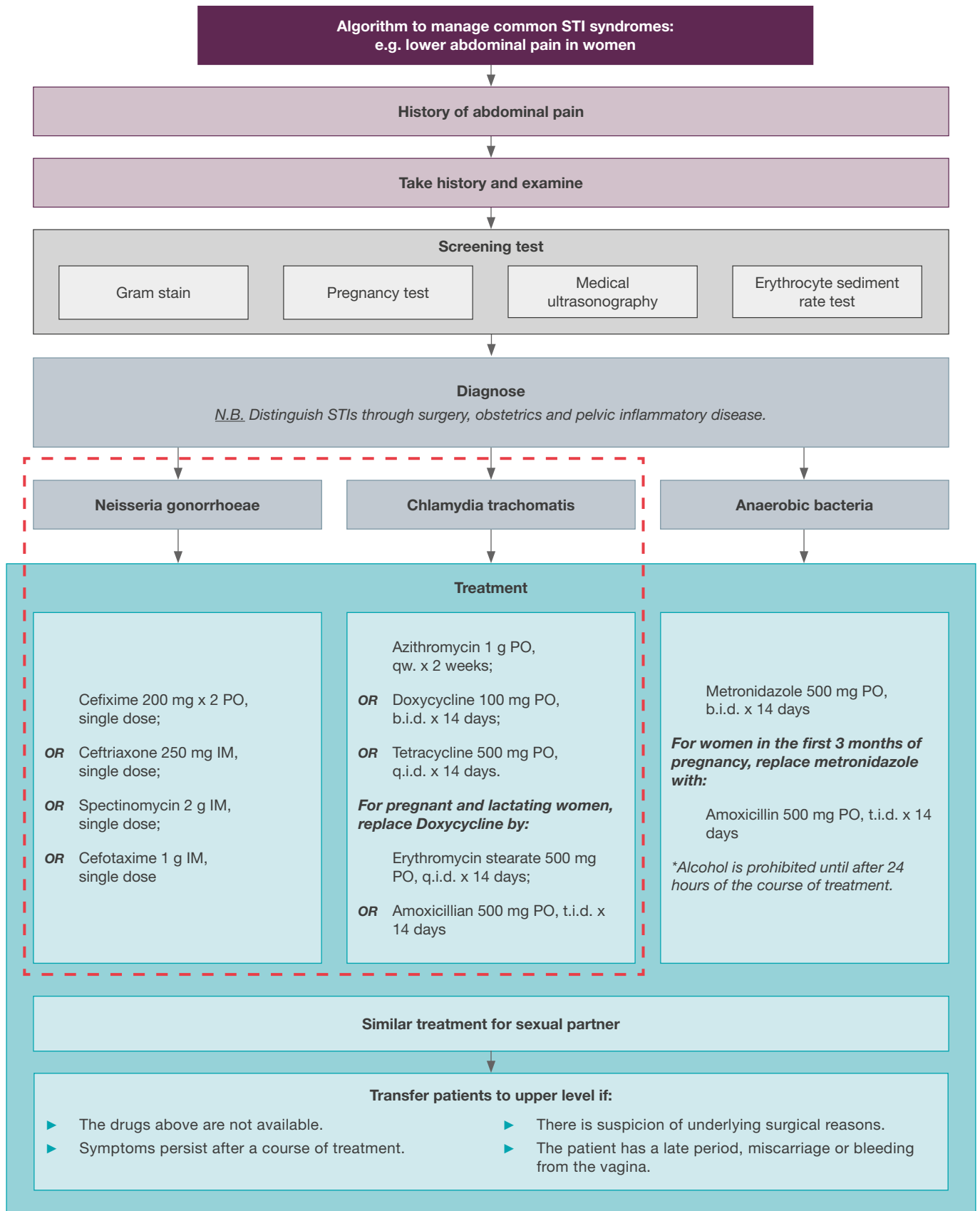
Figure 7: Flowchart for managing vaginal discharge or Puritus in women



b.i.d, twice a day; IM, intramuscularly; PO, orally; q.d. once a day; q.i.d, four times a day; qw, once a week; STI, sexually transmitted infection; t.i.d, three times a day.

Sources: MoH's Decision No. 4568/QD-BYT and Decision No. 4128/QD-BYT.

Figure 8: Flowchart for managing lower abdominal pain in women



b.i.d, twice a day; IM, intramuscularly; PO, orally; q.d. once a day; q.i.d, four times a day; qw, once a week; STI, sexually transmitted infection; t.i.d, three times a day.

Sources: MoH's Decision No. 4568/QD-BYT and Decision No. 4128/QD-BYT.

3.4 Health facility operations and diagnostic testing

a. Health facility operations

Three common STI tests (Gram stain, culture isolation and PCR) are available at public facilities of Level 1, 2 and 3. Gram stain testing is the most popular and is available at most facilities.

The variety of tests offered differs widely across

facilities (public and private), as shown in Table 8. Not all facilities offering testing for STIs have adequate equipment to analyse specimens. Therefore, many facilities collect specimens and then outsource specimen analysis to partnering laboratories.

Table 8: Types of testing provided at different facilities

Sector	Levels of facility	Types of tests available		
		Gram stain	Culture isolate	PCR
Public	Level 1 - National level	✓	✓	✓
	Level 2 - Provincial level	✓	✓	✓
	Level 3 - District level	✓	✓	✓ (Depending on the capacity of each facility)
	Level 4 - Communal level	Depending on the capacity and responsibility of each station		
Private	Private hospitals	✓	✓	✓
	Private clinics	✓	Dependent on the capacity and specialization of each clinic	

PCR, polymerase chain reaction.

Source: Ipsos analysis (Modified from MoH and from Interviews with KSIs)

b. Syndromic screening practices

Syndromic screening is an essential part of STI management in Viet Nam.¹²⁰ Syndromic screening is done at facilities that do not have testing capacity and thus is the more popular approach in Viet Nam.

Syndromic screening is conducted after gathering basic patient information. Patients are then given a physical exam, requiring examination of their genital area. This requirement often leads to abandonment of the screening due to cultural norms forbidding the exposure of genitals. Following syndromic screening, a specific treatment will be provided if the doctor can identify the causative disease. If this is not feasible, treatment will be given for all possible

diseases that can cause the symptom(s). If drugs are not available or the symptom persists after a course of treatment, the patient will be referred to upper level facilities.

Healthcare facilities are required to have adequate lights and related medical equipment, such as specula, clamps, sterile gloves, and specimen clamps.¹²¹ To help patients overcome psychological reservations, STI management needs to be discreet, private, and comfortable.¹²² Not all healthcare facilities meet these requirements. For example, there are some facilities at lower levels that examine patients in low-light conditions.¹²³

Although guidelines for syndromic screening are available, they lack specific information. For instance, there are no instructions on how to identify whether vaginal discharge is normal

or abnormal. Doctors conduct these screenings based on experience, rather than relying on national guidelines, which contributes to the variety found in observed treatment.

c. Etiological screening practices

Etiological approaches are applied at facilities that have adequate testing equipment in the following three scenarios:

- ▶ when patients have STI symptoms;
- ▶ when patients (with or without symptoms) want to verify their status; and
- ▶ when the outcome of a syndromic approach at lower levels (where no testing equipment is available) has failed to resolve symptoms after a course of treatment.

In Viet Nam, the three most popular tests used to diagnose CT/NG are Gram staining, cell culturing, and PCR. In addition, two other tests widely used in CT/NG testing are the cobas® 4800 CT/NG Test by Roche and the Abon IGO-502 RDT by ABON Biopharm.

Although unreliable (95% sensitivity for urethral specimens in men and 60% sensitivity for cervical specimens in women¹²⁴), Gram staining is often done first, especially in the public sector. The reason for this choice is that the technological requirements for Gram staining are low and results are available within two hours. More advanced methods are applied only when Gram staining fails to generate a useful result. However, in many cases, the specimen for Gram staining is collected from the wrong area of the body, the disease-causing agent is present but

not found in the area sampled, or the cells are not stained properly, leading to false negatives.

Both cell cultures and PCR testing require two to three days to return results. While the results from these tests are much more accurate, two to three days is a long time to wait for many patients. This delay, requiring patients to go home and come back for the result, sometimes causes hospitals to lose patients in the middle of the treatment path. To avoid such situations, some doctors resort to empiric antibiotic therapy.¹²⁵ While this may be curative for certain patients, excessive use of antibiotics contributes to AMR in NG/CT.

Another problem with etiological tests is that most health facilities (public and private) only collect urethral and vaginal samples. NG and CT can be found elsewhere, such as in the anal and oropharyngeal cavities, but specimens are only collected from these areas if patients indicate a history of oral and/or anal intercourse. Most patients are uncomfortable giving details of their sexual history or practices and hence avoid these questions or do not answer them completely.¹²⁶ Under such conditions, it is difficult for doctors to determine whether it is necessary to conduct oral or anal testing. Since oropharyngeal NG can account for up to 50% of total cases, this is a significant failure likely leading to underdiagnosis and incomplete treatment.

3.5 Surveillance programme

Official guidelines for STI surveillance were published in 2014 yet, the surveillance process for all STIs other than HIV has only been given nominal attention by authorities. Since 2017, when Viet Nam saw a significant reduction in development aid, there has been no national STI surveillance programme in place.¹²⁷

Currently, surveillance is carried out only in key cities, (HCMC, Kien Giang, An Giang, Dong Thap, and Can Tho), in concert with the national surveillance programme for HIV.¹²⁸ The programme has several limitations. Surveillance is conducted annually through cross-sectional studies and focuses on a group of approximately 200–400 KPs per city. However, the scope depends on each city's budget and human resources. Moreover, continuous administrative changes in the provinces and the central government make it difficult to ensure consistent data collection.¹²⁹ STI surveillance is conducted independently by local institutions in each key city and the results are not reported publicly, as it is not a national programme. Additionally, the statistics collected from this surveillance system are not representative of the situation nationwide. The scale is relatively small, and the objective is to understand trends in STI prevalence in the areas that bear the heaviest STI burden, so as to propose appropriate local interventions.¹³⁰

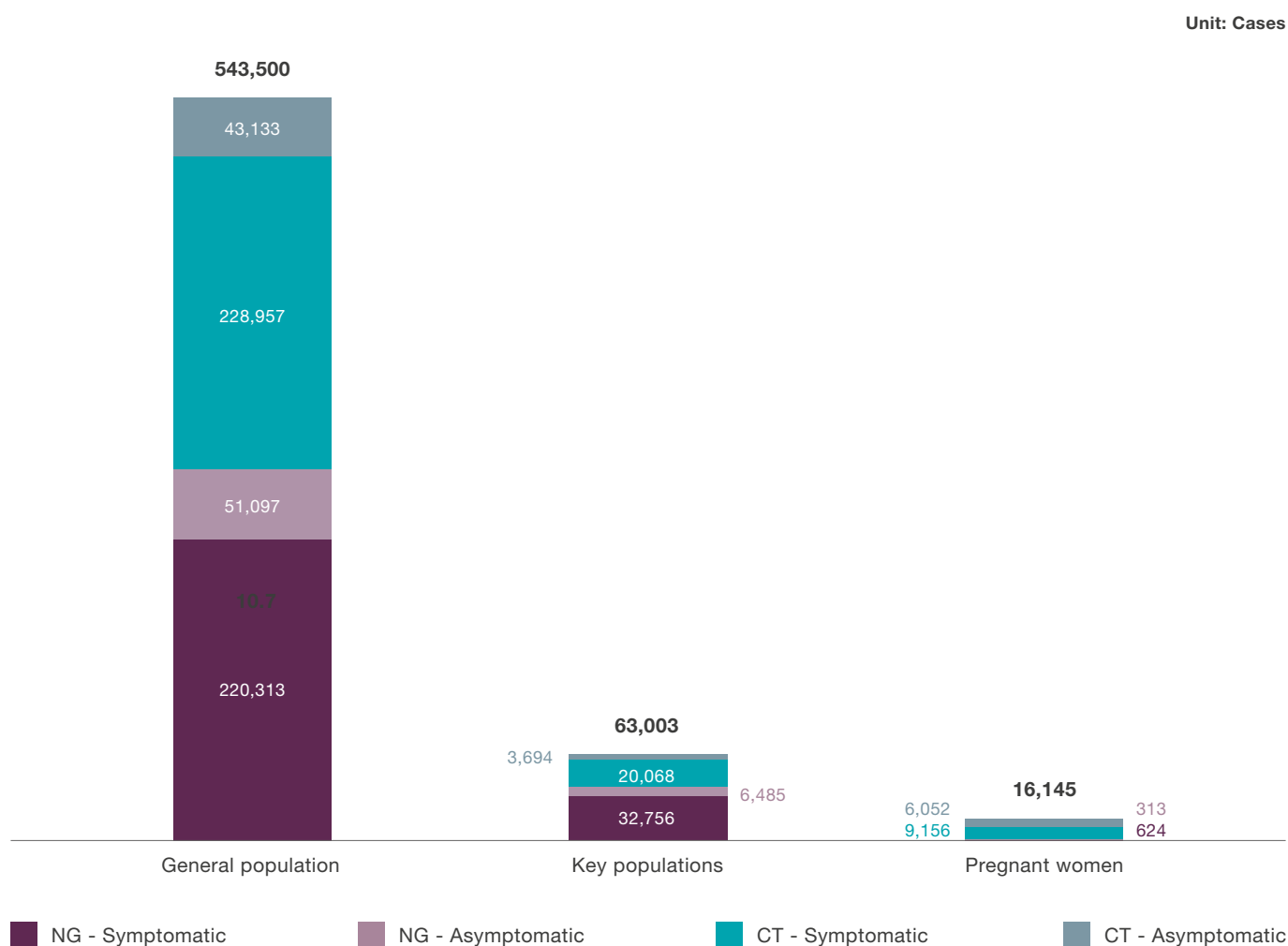
The 2014 guidelines contain provisions for case-based reporting by healthcare facilities. However, poor management and lax regulations make data collected using this approach unreliable. There is no national mechanism or official framework to regulate case reporting in the private sector.¹³¹ Many facilities, especially in the private sector, simply do not record patient information for reporting purposes.¹³²

Viet Nam has developed digital health information systems such as hospital information systems and electronic medical records (EMR).¹³³ Data collected through these systems can be transferred quickly and efficiently to all relevant connected units.¹³⁴ For instance, CDC HCMC, Pasteur Institute HCMC, and the MoH can all send and receive reports over hospital information and EMR systems. EMR is currently in practice at Level 1 hospitals although inconsistencies are observed due to technical barriers. Circular No. 46/2018/TT-BYT expects EMR to be practiced in all healthcare facilities in the country by 2028.¹³⁵

IV KEY USE SCENARIOS FOR AN NG/CT POC TEST

4.1 Market sizing and potential demand

Figure 9: Total number of tests (midpoint estimate) by population and by type of STI

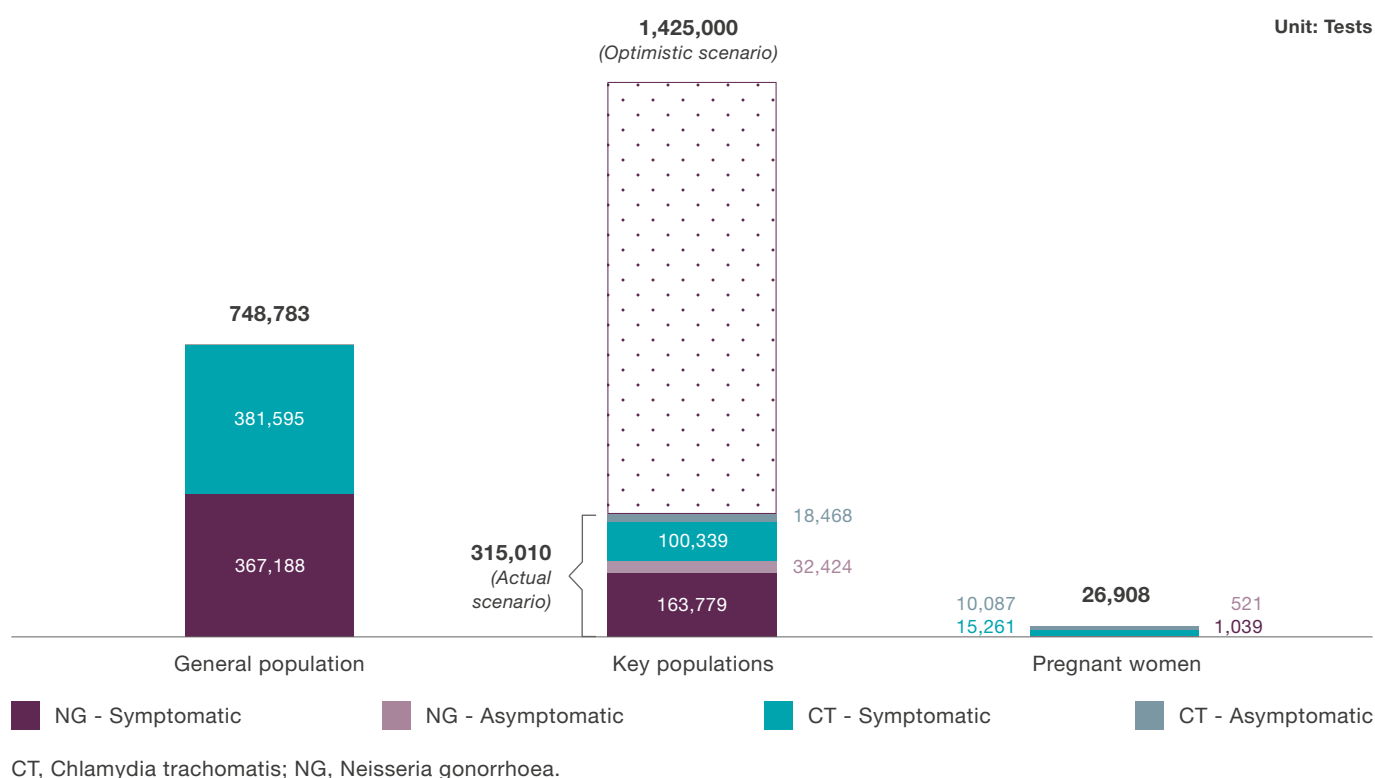


CT, Chlamydia trachomatis; NG, Neisseria gonorrhoea.

Even though the number of new KPs infected only accounts for 11.6% of total infections, the potential demand for NG/CT tests is 34.8%. On average, KPs should be tested for NG/CT every 3–6 months, equivalent to 2–4 tests per year,¹³⁶ while others (e.g. general population, pregnant women) normally to

require one test per year.

The general population tends to only get tested when STI symptoms are obvious. Thus, the demand for POC tests generally comes from symptomatic individuals in the general population.

Figure 10: Total number of new cases by population and by type of STI**Table 9:** Total number of new cases and total number of tests (midpoint estimate) by population and type of STI

		General population	Key populations	Pregnant women
New cases (case)	Total	543,500	63,003	16,145
	NG	271,410	39,241	937
	CT	272,090	23,762	15,208
Potential demand (tests)	Total (Actual scenario)	748,783	315,010 (Range: 210,000–420,000)	26,908
	Total (Optimistic scenario)		1,425,000 (*) (Range: 950,000–1,900,000)	
	NG (Actual scenario)	367,188	196,203 (Range: 130,802–261,604)	1,560
	CT (Actual Scenario)	381,595	118,807 (Range: 79,205–158,409)	25,348

CT, Chlamydia trachomatis; NG, Neisseria gonorrhoea.

* In an optimistic scenario, where POC tests could be used widely (e.g. in national screening programmes), all KPs would be tested. Thus, it is estimated that the maximum potential demand by KPs would be 1 425 000 (Range: 950 000–1 900 000) tests per year.

All KSIs believed that both POC NG/CT test kits (molecular and lateral flow RDTs) would benefit key populations, including MSM, FSWs, and PWID, the most.¹³⁷ Should these new products enter the market, KPs should be the primary targets for uptake because:

- ▶ they are the most at-risk and vulnerable populations needing to be tested;

- ▶ they require regular testing, often once every 3 or 6 months; and
- ▶ WHO identifies them as a priority group.

Hence, it is recommended that the key use scenarios for the two POC NG/CT tests focus on KPs.

4.2 Key use scenarios for the NG/CT POC test kits

KSIs varied widely in their definitions of acceptable use cases for both NG/CT POC test kits. The generally agreed use cases, as well as the most clinically and programmatically relevant use cases, are analysed

and summarized in greater depth in this section.

Detailed test descriptions used in the interviews are described in Table 10.

Table 10: Molecular RDT and lateral-flow RDT descriptions

	Molecular RDT	Lateral flow RDT
Scope of test		
Goal of test	<ol style="list-style-type: none"> 1. NG and CT diagnosis in both symptomatic men and women 2. NG and CT screening to detect asymptomatic infection in both men and women 	<ol style="list-style-type: none"> 1. NG and CT diagnosis in symptomatic women 2. NG (not CT) diagnosis in symptomatic men
Target product format	Disposable molecular cartridge and battery-powered small instrument (8 hours of operation between charges)	Single-use disposable diagnostic test (e.g. lateral flow assay) with a battery-powered reader
Target use setting	<ul style="list-style-type: none"> ▶ POC test for use in primary healthcare settings, including health posts (Level 1) ▶ To be used after initial clinical evaluation (referring to Step 2 in the WHO vaginal/urethral discharge flowchart) to guide treatment decision 	
Personnel requirement	Community health workers with minimal training and any health worker with a similar or superior training level	
Operational characteristics		
Specimen type	Women: vaginal swab (self-collected) Men: urine	
Ease of use	Number of steps: 1–3 Usability: easy Readiness: easy	Number of steps: 1–3 Usability: easy Readiness: needs a fluorescent reader
Time to result	<30 minutes Throughput: low (1 sample/instrument/30min)	<30 minutes Throughput: high (parallelization)
Cold chain requirement	Not needed in all steps	
Performance characteristics		
Clinical sensitivity	95%	>80%
Clinical specificity	>98%	>95%
Pricing		
Price per test	<ul style="list-style-type: none"> ▶ Ex works price(*): USD 8/ test kit ▶ End-user price(**): USD 10–11/ test kit (including swabs, consumables) 	<ul style="list-style-type: none"> ▶ Ex works price: <USD 4–5/ test kit ▶ End-user price: USD 6–7/ test kit (including swabs, consumables)
Ex works price for instrument	Device: USD 500	Reader: <USD 100

CT, Chlamydia trachomatis; NG, Neisseria gonorrhoea; POC, point of care; WHO, World Health Organization.

* Ex works price: Price of the test purchased and collected at the site of manufacture, excluding transport, reconditioning, import, custom, tax fees and distributor charges.

** End-user price: Price that end-users will have to pay. End-user price is marked up 20–30% over ex-works price to cover distribution charges, import and customs fees, taxes, etc.

Table 11: Summary of use cases for both POC tests kits in priority order

Use case #	Description
Molecular RDT	
1	Private clinics
2	Private hospitals
3	Community screening programmes
4	Public facilities from District (Level 3) and up
Lateral flow RDT	
1	District and commune level (Level 3 and 4)
2	Private clinics
3	National level and provincial level (Level 2 up)
4	Operational/evaluation research study

RDT, rapid diagnostic test.

a. Use of molecular RDT test kit

Molecular RDT use case 1: Private clinics

Target: KPs interested in privacy and confidentiality

Rationale

- ▶ Private clinics often look for ways to diversify their services; this makes them flexible and willing to experiment.¹³⁸
- ▶ Compared with outsourcing specimens for testing, POC molecular RDTs are seen to offer:
 - + greater flexibility and better control of testing quality;
 - + cost-effectiveness through reductions in transportation fees, mark-ups, etc.;
 - + quick turnaround times due to a less complex process (taking hours not days);
 - + Smaller risks of losing patients on the road to treatment.
- ▶ Compared with existing in-house methods (e.g. Gram stains, culture and PCR), the molecular RDT was seen to offer:
 - + high utility with low investment (no dedicated laboratory or specialized machines required);
 - + effectiveness with fewer personnel (as the patients can self-collect specimens); and
 - + lower personnel training requirements (the POC molecular RDT can be conducted by any health worker with minimal training, while other methods require more experience).

Concerns

- ▶ Testing for STIs can pile up during peak times, especially after long Lunar New Year holidays, when high numbers of STI patients visit clinics. Due to low throughput (one sample per device per 30 minutes), molecular RDT testing is slower to give results, unless large numbers of machines are deployed.¹³⁹
- ▶ In private clinics, healthcare providers tend to offer patients a variety of diagnostic test kits and there is potentially high competition against existing methods since private patients will compare the prices and characteristics of all options.¹⁴⁰

Molecular RDT use case 2: Private hospitals

Target: KPs

Rationale

- ▶ The process for procurement and circulation at private hospitals is straightforward.
 - + No bidding process is required for most private hospitals. Some big hospitals (e.g. Vinmec) might require bidding but the process is less complicated than that of public hospitals.¹⁴¹
 - + Unlike public facilities, private hospitals have the right to make decisions without having to consult with higher state agencies. It is often the head of the laboratory who decides if the testing platform will be adopted.
- ▶ Private hospitals tend to be more open to innovative solutions. They prioritize the quality of products and services and are willing to change if a new test kit meets all regulatory standards and hospital requirements.
- ▶ Private hospitals are willing to pay higher prices for high-quality tests.

Concerns

- ▶ Private hospitals, usually equipped with up-to-date equipment, have high standards for product quality. Some, for example, require the sensitivity and specificity of their tests to be 98% and above.¹⁴²
- ▶ Patients visiting private hospitals usually come from high-income demographics and are not price sensitive. They prefer to pay more for the most advanced products available on the market, such as real-time PCR.

Molecular RDT use case 3: Community screening programmes

Target: KPs in rural and remote areas

Rationale

- ▶ It would be relatively easy for molecular RDTs to reach large populations, especially people at high risk of NG/CT who are less likely to visit a hospital for a test. Its availability will increase testing frequency and coverage as well as reduce NG incidence.
- ▶ The specimen collection can be done by patients, if instruction is provided, which reduces the number of trained personnel needed.
- ▶ The molecular RDT device is small, portable, easy to use, and battery-operated, so testing can be done at the primary healthcare level.
- ▶ Molecular RDTs can detect NG/CT infections in asymptomatic patients and prevent further transmission of NG/CT in the community.

Concerns

- ▶ Insufficient funding: There is no particular programme, and very little funding, dedicated to non-HIV STIs in Viet Nam; the major STI response falls under the umbrella of national HIV/AIDS programmes. Consequently, there is a need to seek external funding or foreign aid to run large-scale POC NG/CT screenings.
- ▶ Getting the necessary government approvals and overcoming administrative hurdles may take a long time,¹⁴³ especially as many stakeholders, such as VAAC and NHDV, will be involved. This could delay the start of testing programmes in community and outreach settings.

Molecular RDT use case 4: Public facilities from the district level (Level 3) and up Target: KPs in urban areas

Rationale

- ▶ Molecular RDT reduces the risk of losing patients due to its quick turnaround time.

Concerns

- ▶ Complicated and time-consuming procurement.¹⁴⁴
- ▶ The higher the administrative level, the higher the sensitivity and specificity requirements.

Molecular RDT test general considerations

Cost

A cost of USD 10 for molecular RDTs might be high for some price-sensitive demographics (e.g. the young, those living in rural and remote areas). Cheaper alternatives (e.g. Gram staining) exist, as well as similarly priced, but more sensitive, specific, and clinically informative alternatives, such as cell culture, which both identifies the pathogen and antimicrobial susceptibility.

Turnaround time

KSIs raised concerns about the efficiency and productivity of the molecular RDT, as each device processes only one test at a time. This means that test results would be returned to patients more slowly

during peak times, for example, after holidays. This is a major drawback of molecular RDTs compared with other, higher throughput methods. One KSI mentioned that on average, there are around 150 patients with STI symptoms visiting NHDV daily.

Sensitivity and specificity

There are concerns that the sensitivity and specificity of the molecular RDT are low compared with other methods, such as cell culturing and PCR.¹⁴⁵ For large public hospital approval, test sensitivity must be greater than 98%.

b. Use of lateral flow (LF) RDT kits

Lateral flow RDT use case 1: District and commune level (Level 3 and 4) Target: KPs in rural and remote areas

Rationale

- ▶ Currently, screening tests for pregnant women and newborns with symptoms can be done at commune health stations if they have the facilities to perform such tests. District facilities are only capable of some initial STI diagnoses (using Gram staining) and often make referrals to higher levels.¹⁴⁶ Hence, LF RDT kits used at the grassroots levels are expected to increase access to care and early NG diagnosis.
- ▶ The LF RDT is affordable, especially for people living in rural and remote areas.
- ▶ The LF RDT is easy to use and does not require a high level of expertise to administer.
- ▶ During lateral flow RDT screening, patients can take samples by themselves. The limited human resources in commune health facilities (Level 4) is therefore not an obstacle to test adoption.

Concerns

- ▶ Funding: there is limited national funding for testing at grassroots healthcare facilities.
- ▶ Complicated administrative approval processes: before distribution, LF RDTs would have to receive many approvals from many different stakeholders from the central government right down to the commune level.¹⁴⁷ Aside from the normal procurement processes listed in Section 8 of this report, the supplier would also need to get approval from the provincial DoH and the district health centres.
- ▶ Test kit distribution and training can be challenging in remote areas.
- ▶ The low sensitivity of LF RDTs may underestimate actual NG and CT cases, potentially exacerbating, rather than solving, the underdiagnosis problem.

Lateral flow RDT use case 2: Private clinics

Target: KPs

Rationale

- ▶ The short time-to-result for the LF RDT is attractive to many private clinic customers. These customers value the short waiting times found at these clinics. In addition to its other advantages, a short time-to-result means that stigma- and shame-conscious patients face a smaller risk of meeting someone they know at the clinic.
- ▶ The test kit is affordable for patients such as young adolescents, factory workers, etc.

Concerns

- ▶ In private clinics, patients are often given a variety of test options, hence the competition from existing testing methods (e.g. cell culture, real-time PCR, Gram staining) is expected to be high.

Lateral flow RDT use case 3: National and provincial level (Level 2 up)

Target: KPs in urban areas

Rationale

- ▶ The short time-to-result for LF RDTs can help to resolve overcrowding in public hospitals. More than 100 people per day visit public hospitals in need of STI screening.¹⁴⁸
- ▶ Quick testing times retain patients. Lateral flow RDTs would help hospitals to retain and re-engage patients to ensure continuous treatment after diagnosis.

Concerns

- ▶ The LF RDT is at a disadvantage when compared to existing test kits. There are advanced test kits used in Level 1 and 2 healthcare facilities, which have higher sensitivities and specificities. It will be a challenge for LF RDTs to compete with existing tests, such as cell culture or real-time PCR.
- ▶ The bidding process to distribute tests at the national and provincial level is complicated by high barriers to entry. and the competition from the large number of suppliers.

Lateral flow RDT use case 4: operational/evaluation research study

Target: KPs of interest to researchers for study

Rationale

- ▶ Quick turnaround times and ease of operation make LF RDTs suitable for screening large samples for research purposes
- ▶ LF RDT kits are portable, inexpensive, and sensitive enough to be used in scientific laboratories involved in clinical trials and research and development.

Concerns

- ▶ Factors that limit the usefulness of the LF RDT are its low sensitivity and specificity, its inability to detect asymptomatic cases, and the narrowness of its scope (especially its inability to detect CT).

Lateral flow RDT general considerations

Sensitivity:

The low sensitivity of the LF RDT kit was a concern for half of the KSIs. The 80% sensitivity means that there is high probability of false negatives, especially in patients at the early stages of disease.¹⁴⁹ There were also concerns from four KSIs that the sensitivity LF RDTs does not meet the standards of provincial or national hospitals.¹⁵⁰ Such facilities typically require kits with at least 98% sensitivity.

Specificity:

Several KSIs agreed that to be widely adopted in the biggest facilities in Viet Nam, test specificity should be much higher (ideally >95%), as their existing tests (such as PCR and cell culture) already achieve 98–99% specificity.¹⁵¹

Competitiveness:

Compared with existing, higher-performing NG/CT tests, the LF RDT kit is unlikely to be a viable alternative, except for niche applications. Additionally, there are two commercial tests that are already on the market - Roche's cobas® 4800 CT/NG Test and Abon Biopharm's IGO-502 RDT. The Roche test has a higher sensitivity than the Abon RDT and is certified by Canada-IVD, CE-IVD, Japan-IVD, and US-IVD,¹⁵² while the Abon kit is considerably less expensive, selling for only USD 1–2 a kit (which includes 20 tests).

c. Prioritization of use target product profile

Among KSIs who commented on the two tests, the majority (85%) said they would prioritize molecular RDT over LF RDT for Viet Nam based on price, sensitivity, and specificity. Health is a top priority for Vietnamese people, so they are willing to pay more for better healthcare, removing the slight price advantage of the LF RDT. In addition, the sensitivity and specificity of the molecular RDT are significantly better, and its applicability is broader. As a result, the molecular RDT has a higher chance of getting widely approved and adopted than the LF RDT.

Nevertheless, there remain concerns regarding the low sensitivity and specificity of both tests relative to existing methods. One KSI expressed no interest in either test at the moment, explaining that the sensitivity and specificity were just too low. KSIs suggested that improving these two indicators and/or getting international regulatory clearances (e.g. CE-IVD, US FDA) would make the tests more attractive to healthcare facilities.

V CONSIDERATIONS FOR INTRODUCING A POC TEST FOR NG

Who will conduct the test?

Circular No. 49/2018/TT-BYT defines POC tests as those carried out by healthcare workers outside the laboratory environment and applied in cases of emergency or screening to serve patient monitoring and primary healthcare. The healthcare workers then document the test results and the doctor who ordered the test confirms and signs the results. Tests conducted in the laboratory environment (e.g. Gram staining, culture, PCR) must be done by trained professionals or laboratory technicians.¹⁵³ Hence, the molecular RDT and LF RDT have a huge advantage over existing testing methods in that the POC tests can be conducted by healthcare workers with minimal training.

Specimens can be collected by anyone (patients, healthcare workers, etc.), the only challenge being the actual sample collection itself.

Additional workload/time

KSIs were concerned about turnaround time and productivity of the two tests, especially for the molecular RDT. Some KSIs noted that these tests cannot produce antibiograms, which raised questions about their clinical usefulness, as additional methods, such as culture, would be required to determine the antimicrobial susceptibility of the pathogen. If additional testing is needed, then the LF RDT and molecular RDT would be largely redundant, adding expense but no utility.

Training

Most of the KSIs indicated the need for trainings before launching molecular RDTs and LF RDTs. Trainings would include instructions for operating the molecular RDT device and LF RDT reader, as

well as how to read test results. It was understood that such trainings would be provided by the manufacturer of the test kits. One KSI suggested that a one-hour training would be enough for healthcare workers to learn how to use the test kits.

Budget/cost

Getting the tests into a national programme would maximize test distribution and adoption. However, national programmes often face budget constraints, and so external funding from international organizations or NGOs will likely be needed.

Sustainability of supplies

At district and communal levels, medical supplies sometimes run short. This issue, however, does not affect higher-level facilities.

Sample collection

KSIs valued the self-sampling feature of the molecular and LF RDTs, as it provides more privacy. KSIs indicated that patients would feel more comfortable with the molecular or lateral flow test kits, relative to existing specimen collection methods, as they allow patients to collect specimens by themselves. As a result, the two POC RDTs would lessen sample collection burden for healthcare workers and lead to greater test adoption.

Self-sampling already exists in Viet Nam for several tests, such as blood glucose test for diabetes, or urine tests for associated diseases.¹⁵⁴ Even vaginal swab self-sampling has been in practice in Viet Nam to detect CT,¹⁵⁵ and cervical cancer.¹⁵⁶

KSIs appreciated also that the molecular and LF tests can be done with urine specimens for male

patients, as this is more convenient and less painful than taking urethral specimens.

Test sensitivity

Most KSIs (13 out of 15) agreed that the sensitivity of the LF RDT (80%) is too low to be used for diagnosis and treatment in quality healthcare facilities. In higher-level and higher-quality hospitals, the current gold standard for diagnostic test sensitivity is 98% and above. Neither the molecular RDT nor the LF RDT meet this standard. However, a sensitivity of 80% (LF RDT) and 95% (molecular RDT) is acceptable for large population screening.¹⁵⁷

Patient acceptance

- ▶ **Symptomatic patients:** patients with STI symptoms are generally open to testing, but typically want to test for all possible infections. Hence, male patients with symptoms are less likely to use an LF RDT as it cannot test for CT in men.
- ▶ **Asymptomatic patients:** certain groups of people would be open to testing as part of a screening process even if they are asymptomatic –pregnant women, or members of KPs (MSM, FSWs, PWID) who acknowledge the risks inherent in their behaviour. However, other groups are likely to resist testing recommendations from doctors if they feel judged or accused by the implications of these suggestions.

VI FINANCING AND ADOPTION CONSIDERATIONS

6.1 Public financing

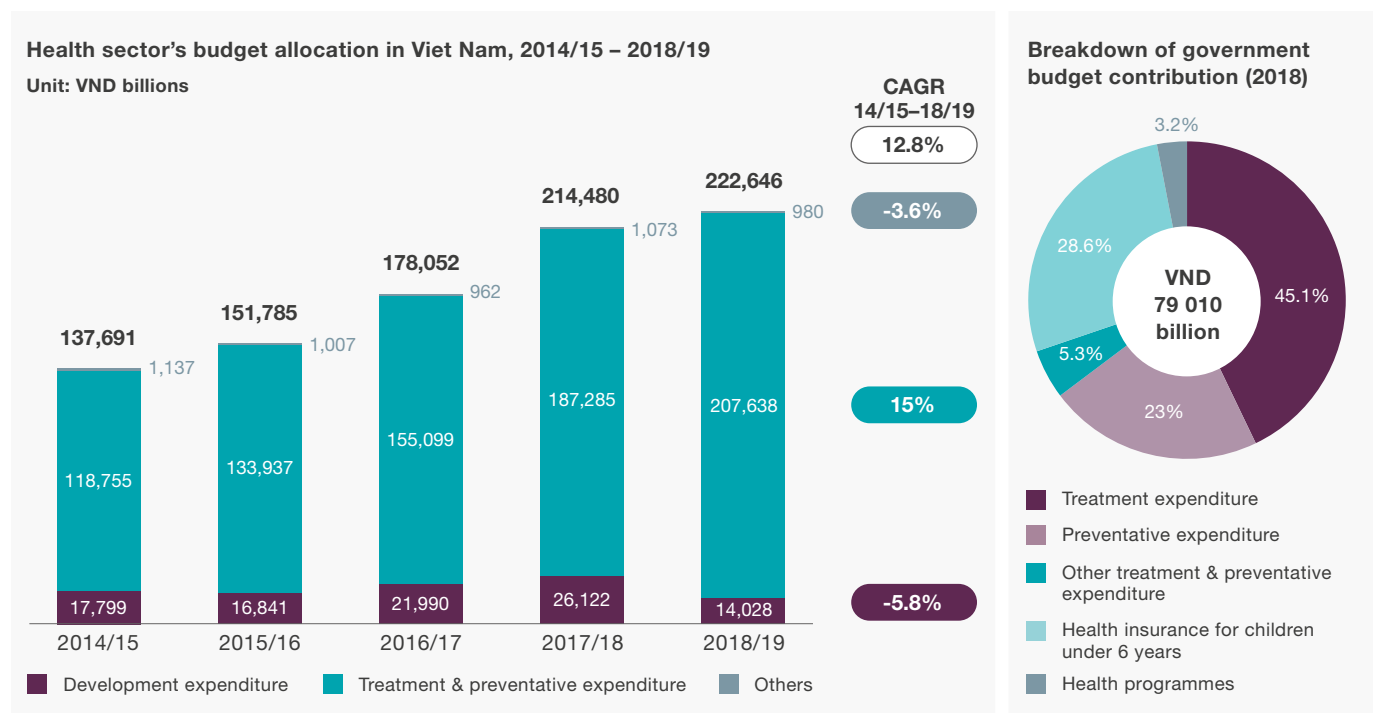
Health financing is one of key functions of a national health system. Viet Nam's total health expenditure has been increasing and is comparable to that of countries of similar income levels, with a health expenditure per capita of VND 2.8 million in 2018.¹⁵⁸ Total health spending was 5.9% of GDP while public spending on health as a share of GDP was 2.8% in 2016, both numbers being slightly higher than the average for LMICs (5.7% and 2.7% respectively).¹⁵⁹

The structure of national health expenditure has not changed much over the years. Public spending on health has increased gradually, but remains 40% of the total, while the share of out-of-pocket spending has remained high, accounting for 45% of total

health expenditure in the 2017 financial year.¹⁶⁰ The largest share of government health spending has gone to preventive care.

National public financing policies underwent significant changes in recent years. Viet Nam's government has increasingly funded the healthcare sector as it has had to be less reliant on external sources. Since 2008, the government has periodically issued health bonds to raise funds for local and provincial hospitals.¹⁶¹ As a part of the full cost recovery policy for medical services applied widely across Viet Nam, user fees for curative care have increased to cover costs that were previously funded externally and to support financial autonomy for leading public hospitals.

Figure 11: Viet Nam's Government Health expenditure during the period 2014/15–2018/19



CAGR, compound annual growth rate; VND, Vietnamese dong.

Sources: MoH's Health Statistics Yearbook 2018, Ipsos analysis.

6.2 Social health insurance

The recent increase in public health expenditures is partially due to substantial increases in SHI coverage and revenue. SHI has become an important funding source for the healthcare system and has increased access to care for the poor and other vulnerable groups. In 2017-18, 83% of the Vietnamese population was covered by SHI.¹⁶² By 2020, the goal was to obtain 90% population coverage. Private patients can register for SHI services, so that their medical expenses can be covered by SHI under the same policies applied at public facilities.¹⁶³

For most Vietnamese citizens, SHI covers 80% of treatment costs. However, there are groups that can receive higher payments. People unable to work and those who receive pensions or subsidies

from the government, members of households near the poverty line, and the relatives of war veterans can receive up to 95% coverage. Children under six years of age, members of impoverished households, and the survivors of soldiers killed in war are eligible for 100% coverage.

However, the SHI scheme only covers STI treatment services, and not prevention services, including testing. Many prevention programmes implemented among KPs including PrEP, screening, and testing services are still reliant on international organizations for support. The prices for Gram staining, cell culturing, and PCR testing are USD 2.93, USD 12.78 and USD 25.38, respectively.

6.3 External financing

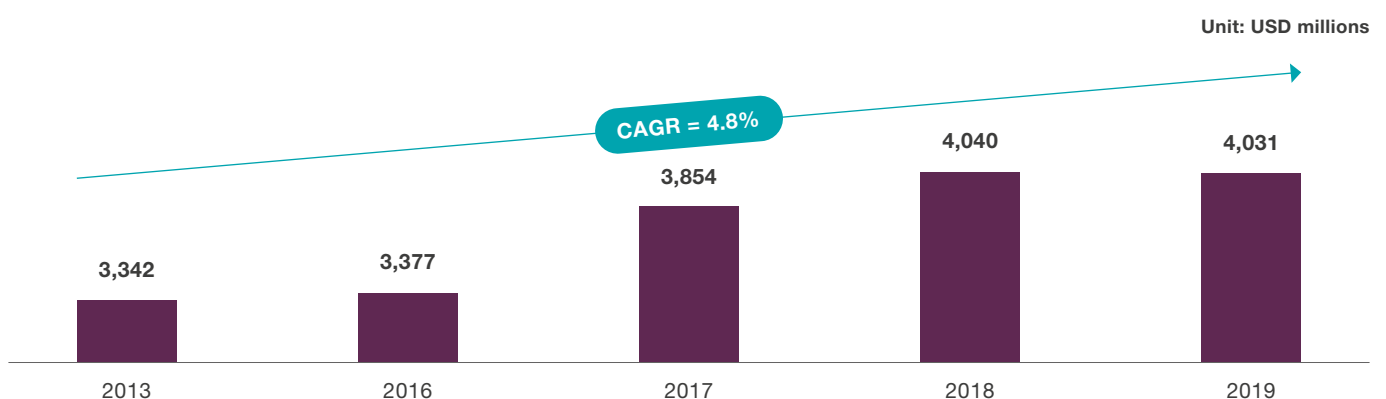
As Viet Nam has transitioned to lower-middle income status, the funding received from external donors has gradually decreased. External financing for health has recently accounted for less than 5% of total health expenditure, but it continues to comprise a large share of resources for global priority disease programmes.¹⁶⁴ For example, HIV/AIDS receives the majority of external funding, while funding for other STIs is very limited.

Even though Viet Nam has transitioned from donor-funded to locally supported HIV/AIDS prevention and treatment,¹⁶⁵ external financing comprises more than half of total funding for HIV/AIDS programmes,

as of 2019.¹⁶⁶ The two major external donor sources for HIV/AIDS are PEPFAR and the GF.¹⁶⁷

1. PEPFAR makes the greatest financial contribution to HIV/AIDS programmes. In 2018, the total spending of PEPFAR on HIV/AIDS in Viet Nam reached USD 31 million, including:¹⁶⁸
 - + USD 11.8 million for clinical care, treatment, and support
 - + USD 13.3 million for HIV sentinel surveillance, laboratories, surveys and surveillance
 - + USD 2 million for HIV testing
 - + USD 3.8 million for prevention among key populations.

Figure 12: PEPFAR expenditure on HIV/AIDS in Viet Nam (2015–2019)



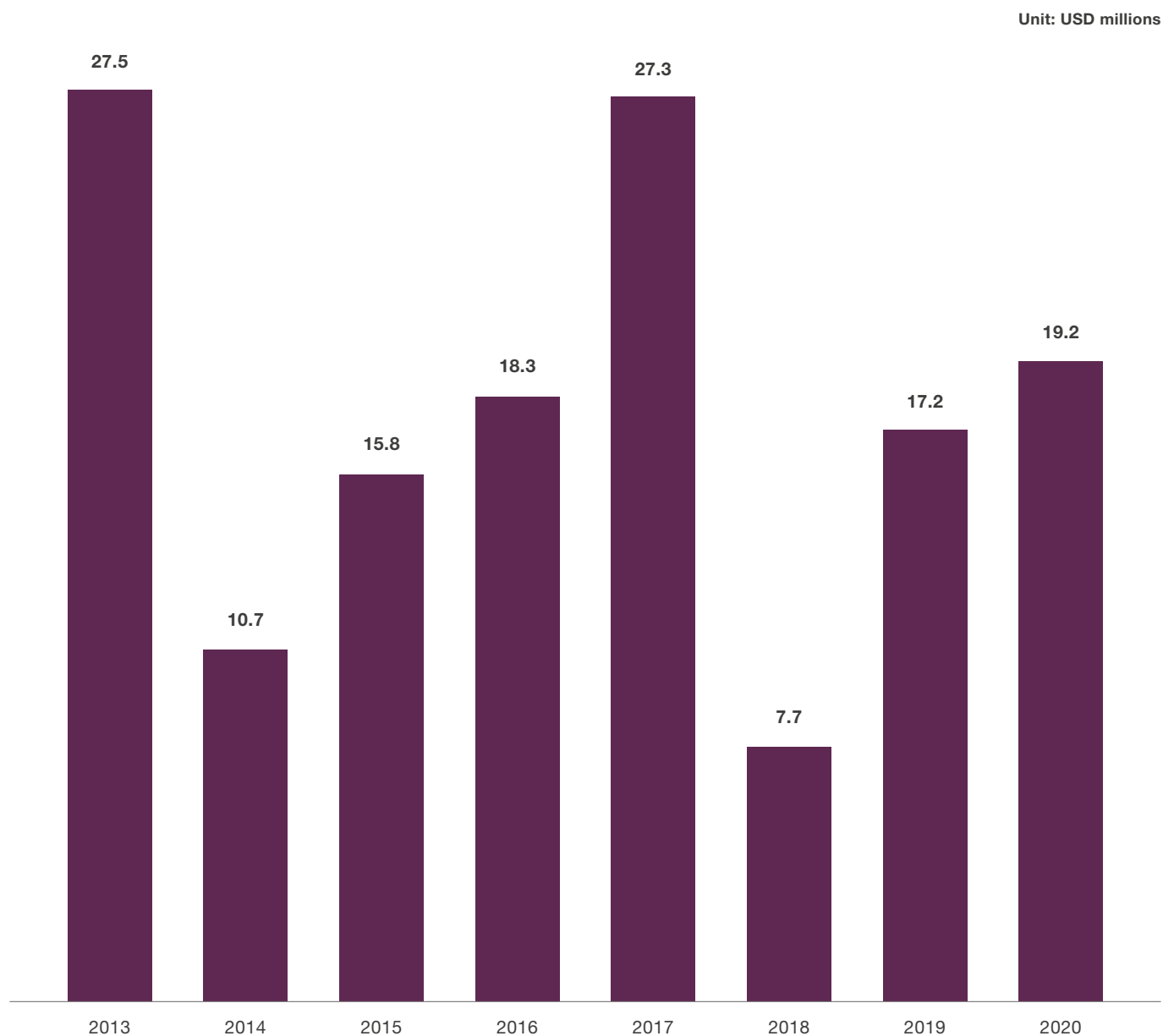
CAGR, compound annual growth rate.

Source: PEPFAR, 2020,¹⁶⁹ Ipsos analysis.

2. The GF has allocated USD 214 million on a three-year basis to support Viet Nam in the fight against social diseases such as HIV/AIDS, tuberculosis and malaria. PEPFAR is committed

to helping the healthcare system transition from relying on donor-funded ARVs to SHI-funded ARVs. However, there will be no further grants beyond the current transition grant.

Figure 13: Global Fund Grants on HIV/AIDS in Viet Nam (2013–2020)



Source: The Global Fund, 2020.¹⁷⁰

External financing is no longer a sustainable or reliable source of funds for health spending and the government needs to take greater responsibility for financing health programmes. The cost of treatment for social diseases will eventually be subsumed under SHI reimbursement. In 2019,

SHI reimbursements for HIV/AIDS services and treatment alone were estimated at USD 6.5 million, including reimbursements made to 51,090 PLHIV.¹⁷¹ Viet Nam must experience a health financing transition and further decrease dependence on external funding sources.

VII REGULATORY ENVIRONMENT

The Department of Medical Equipment and Health Works (DMEHW) under the MoH is responsible for overseeing the registration and approval of medical devices. Starting in 2017, all imported medical devices must have valid import and marketing authorization licenses. In addition, diagnostic tests must also bear a Summary of Clinical Testing Data and Certificate of Inspection, along with clinical testing research results. According to Decree No. 169/2018/ND-CP dated 31 December 2018 on medical equipment management,¹⁷² the first important step towards regulatory compliance for

new test kits is a classification assessment, which groups tests based on levels of risk. NG/CT POC diagnostic kits are classified as Group 2 – Class C tests.¹⁷³

Medical devices in Viet Nam are also regulated by the ASEAN Medical Device Directive. As of 1 July 2020, ASEAN Common Submission Dossier Templates are required in the submitted registration dossier for Class C medical devices. It is no longer necessary to submit the technical document, instructions for use, or labels previously required.

Table 12: Summary of regulatory requirements for registration of new class C products

	Regulatory parameter	Viet Nam
1	Assessment of technical data	Department of Medical Equipment and Health Works
2	Authorized representative	Required
3	Submission format	Online
4	Manufacturer's quality certificate	ISO 13485 or ISO 9001 certification CE-IVD / FDA approval
5	Quality systems conformity assessment	ISO 13485:2016
6	Validity of license	5 Years (renewable marketing authorization)
7	Labelling requirements	Article 54 of Decree No. 36/2016/ND-CP
8	Fee per application	VND 5 million (approx. USD 215)
9	Process duration	15–60 days, depending on the complexity of products, examination and evaluation process, and the number of queries
10	Certificate obtained	Certificate of free-sale registration

CE-IVD, CE-approved in vitro diagnostic medical devices; FDA, United States Food and Drug Administration; ISO, International Organization for Standardization; VND, Vietnamese dong.

Sources: MoH, Ipsos analysis.

VIII TEST SELECTION, PROCUREMENT, AND DISTRIBUTION

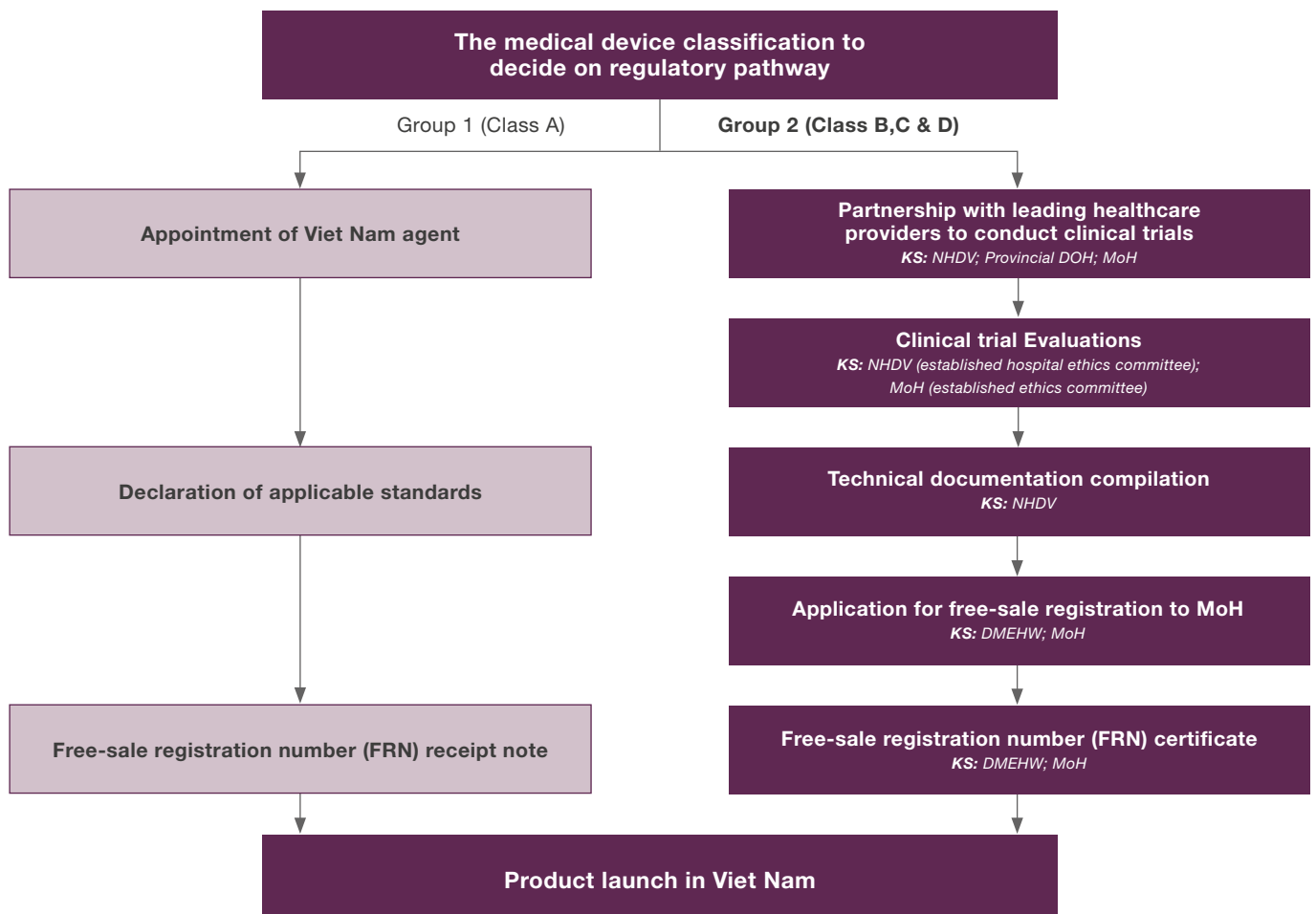
8.1 Test selection

Introducing a new test kit in Viet Nam is a long process that involves multiple stakeholders, including the MoH, the DMEHW, provincial departments of health, and leading national healthcare providers.

The MoH is the primary entity in charge of introducing new diagnostic test kits and equipment.

The government requires all new test kits to go through registration and clinical trials (carried out in Viet Nam) before they can be sold to the public. For newly imported NG/CT POC test kits, the fastest route of registration and market entry is to partner with leading STI hospitals such as the NHDV to conduct clinical trials.¹⁷⁴

Figure 14: Market entry process flow of medical devices and key stakeholders in Viet Nam



DoH, Department of Health; KS, key stakeholder; MoH, Ministry of Health; NHDV, National Hospital of Dermatology and Venereology.

Sources: DMEHW, Ipsos analysis.

8.2 Procurement and distribution

Under the law, only businesses registered in Viet Nam with a valid import license will be able to distribute and sell test kits to end-users. Foreign medical device suppliers are required to set up a local office or partner with local distributors to sell products in the local market.

a. Public sector

Public hospitals procure medical devices through a bidding process wherein bids are subject to a price ceiling per device set by the provincial DoHs. The lowest price wins the bid, and the company gets the right to supply products for a year. Foreign companies can bid, but limitations and difficulties often arise due to a lack of procedural transparency. The standards and conditions to enter this sector are high, and at high-level public healthcare facilities, more advanced and branded devices are preferred over simpler devices.¹⁷⁵ The state-owned hospital bidding process remains opaque, complex, and time consuming.¹⁷⁶

The contractor selection plan is prepared annually or whenever it is necessary. In addition to regulations of the Law No. 43/2013/QH13 on Bidding, Decree No. 63/2014/ND-CP and relevant guiding documents, the estimated supply of medical equipments, including diagnostic test kits must be based on funding sources, the estimated demand and the actual purchase and equipment usage in the previous year.¹⁷⁷ The scope/function of professional activities, infrastructure conditions and the actual number of beds and staff at the facility are also taken into consideration.

b. Private sector

Accessing the private sector is more straightforward and depends on negotiations between suppliers and the principal(s) of a given facility.¹⁷⁸ In private facilities, the Director of the Clinical Laboratory usually decides which diagnostic test kits are used. As private healthcare providers are typically open to new and innovative medical devices, they are likely willing to trial new NG/CT POC test kits if there is sufficient patient demand, if the tests add value to the hospital's offerings, and if acceptable prices and product certifications are in place.¹⁷⁹ The procurement process in private healthcare facilities is much simpler and faster than comparable processes in the public sector.

ANNEX 1: INDIVIDUALS CONSULTED

No.	Respondent type	Organization	Date of interview
1	Health organizations / associations	Light Centre	6-Oct-20
2	Private healthcare provider	Andos Clinic	6-Oct-20
3	Private healthcare provider	Tam Anh Hospital	7-Oct-20
4	Government officer	Viet Nam Ministry of Health - Viet Nam Administration of HIV/AIDS Control	7-Oct-20
5	Government officer	Viet Nam Ministry of Health - Department of Administration for Medical Services	7-Oct-20
6	Pharmacist	Pharmacy	8-Oct-20
7	Academic researcher	STI Researcher and Freelance Consultant	8-Oct-20
8	Diagnostic devices distributor	TNT Medical	9-Oct-20
9	Public healthcare provider	National Hospital of Dermatology and Venereology	9-Oct-20
10	Public healthcare provider	National Institute of Hygiene and Epidemiology	15-Oct-20
11	Diagnostic devices distributor	Hamesco Viet Nam Company Limited	16-Oct-20
12	Health organizations / associations	Lighthouse/Gtown Association	17-Oct-20
13	Public healthcare provider	Bach Mai Hospital	19-Oct-20
14	Public healthcare provider	National Hospital of Dermatology and Venereology	23-Oct-20
15	Public healthcare provider	Viet Nam Ministry of Health - Pasteur Institute Ho Chi Minh City	26-Oct-20
16	Researcher	Hue University of Medicine and Pharmacy	18-Nov-20

ANNEX 2: NG POC TEST MARKET SIZING METHODOLOGY

Introduction

We have defined the market size by following the methodology developed and improved by the WHO to quantify STI prevalence and incidence. The WHO's estimates are based upon meta-analyses of prevalence data from 2009 through 2012 among general populations for genitourinary infection including chlamydia, gonorrhoea, and trichomoniasis. To calculate total available market size for two NG/CT POC tests in Viet Nam, we utilized all available STI-related data and official studies.

Factors limiting the accuracy of sizing estimates

- ▶ Insufficient official STI-related data in Viet Nam. Data inputs have been collected from cross-sectional surveys in Viet Nam or global records.
- ▶ Limited case-report data and significant underestimation in official figures.
- ▶ Lack of recent published studies and reports on STI key population groups.
- ▶ Inaccurate tabulations of key population demographics. STI-related stigma causes KPs to remain hidden as they are reluctant to admit stigmatized behaviours.
- ▶ No available Viet Nam-specific access to care data or service coverage rates.
- ▶ Poor information and estimates of average infection duration. Average duration of infection of symptomatic and treated cases may not be representative due to the small sample size of STI inpatients at the KSI's hospital over two years (2017–2018). Besides, the majority of STI patients are outpatients, who visit the hospital for STI diagnosis or treatment but are not admitted. This makes it difficult to monitor treatment compliance and response. Moreover, many patients do not return for follow-ups.

Market sizing calculation

STI prevalence for KPs

Prevalence estimates among each KP group were based on the median value of the standardized prevalence estimates from all the related studies conducted across Viet Nam. The median was chosen because the prevalence data varied between locations.

Table 13: High/low-risk population prevalence ratios

		Prevalence among high-risk populations in Viet Nam(*) (%) ¹⁸⁰	Number of data points (studies)	Pooled prevalence among low-risk population in South-East Asian region (%) ¹⁸¹	Crude prevalence ratio (high/low risk populations)
FSW	NG	16.56	3	0.94	17.62
FSW	CT	23.4	3	1.75	13.37
MSM	NG	8.02	5	0.58	13.83
MSM	CT	9.94	5	1.4	7.1
MSW	NG	10.5	1	0.58	18.1
MSW	CT	11.5	1	1.4	8.21
Pregnant women	NG	0.13	1	0.94	0.14
Pregnant women	CT	6	1	1.75	3.43

CT, Chlamydia trachomatis; FSW, female sex worker; MSM, men who have sex with men; NG, Neisseria gonorrhoea.

* When 2 or more studies of high-risk populations were found, a simple average was calculated.

The crude prevalence ratio was calculated to compare the prevalence rates among high-risk populations in Viet Nam with the pooled prevalence rates among low-risk populations in South-East Asia. Due to the lack of STI-related data and research studies, we calculated the prevalence rates among high-risk populations in Viet Nam based on the number of STI reports that we have collected. A simple average is applied to calculate the prevalence of each type of STI in different groups. In addition, the pooled prevalence among the low-risk population in the region was extracted from the WHO report on STI surveillance in 2018.

Size of the target populations

Key population sizes were obtained from the following sources:

Table 14: Population sources

Target population	Sources of information & methodology	
Key populations (KPs)	FSW	UNAIDS Atlas of Key Population, Country: Viet Nam, 2019 data
	MSM	UNAIDS Atlas of Key Population, Country: Viet Nam, 2019 data
	PWID	UNAIDS Atlas of Key Population, Country: Viet Nam, 2019 data
General population	Male (aged 15–49 years)	Viet Nam Ministry of Health - Health Statistics Yearbook; UN Population Data, 2019 data
	Female (aged 15–49 years)	Viet Nam Ministry of Health - Health Statistics Yearbook; UN Population Data, 2019 data
Pregnant women	[Crude birth rate ¹⁸² * Total population ¹⁸³] – [# of multiple births(*)]	
Pregnant women having at least 1 antenatal care visit	[No. of pregnant women] * [% pregnant women having at least 1 ANC visit] ¹⁸⁴	

FSW, female sex worker; MSM, men who have sex with men.

* Multiple births in Viet Nam is calculated as the total number of twins and triplets per year.

	Rate of births	Sources
Twins	6.2 per 1,000 births	Smits, J., & Monden, C. (2011). Twinning across the developing world. PLoS One, 6(9), e25239.
Triplets	1 per 8,000 births	Tuoi Tre News (2017)

Average duration of infections

The average duration of infections is the average time that people have a disease (from diagnosis until they are either cured or die).

Table 15: Average duration of infections

	Asymptomatic ¹⁸⁵		Symptomatic ¹⁸⁶	
	Male	Female	Male	Female
NG	5 months	5 months	3.5 weeks	5.6 weeks
CT	1.25 years	1.25 years	5.6 weeks	8.8 weeks

CT, Chlamydia trachomatis; NG, Neisseria gonorrhoea.

The average duration of infection for asymptomatic cases was extracted from the WHO report on prevalence and incidence of selected STIs in 2005, while figures for symptomatic cases have been collected and cross-checked with our KSIs. Unfortunately, we do not have sufficient Viet Nam-specific data to benchmark and validate the applicability of global estimates to the situation on the ground in Viet Nam.

Incidence estimates

It is necessary to distinguish between prevalence and incidence.

Prevalence is the proportion of infected cases at/over a specified point in time in a given population, while incidence is the proportion of new infected cases during a specified period. Incidence can be used to estimate the future number of infections. Put another way, disease prevalence¹⁸⁷ includes all existing cases, while incidence describes only new cases in a given time frame.

Incidence estimates among KPs were generated from the estimated prevalence rates adjusted for duration using the following equation:

Equation 1:

$$\text{Incidence estimates} = \text{Prevalence rates} / \text{Average duration of infections}^{188}$$

Probability of men and women developing symptoms

	Asymptomatic		Symptomatic	
	Men	Women	Men	Women
NG	36.0%	66.0%	64.0%	34.0%
CT	46.0%	83.0%	54.0%	17.0%

CT, Chlamydia trachomatis; NG, Neisseria gonorrhoea.

Source: Prevalence and incidence of selected sexually transmitted infections, Methods and results used by WHO to generate 2005 estimates.

Addressable market size calculation

The addressable market size for the NG/CT POC tests is calculated as the total number of potential tests used by the general population, KPs (MSM, FSWs and PWID) and pregnant women in Viet Nam. Such a figure is determined through the two equations below:

$$\text{New cases infected} = \text{Target population} * \text{Incidence estimates}$$

$$\text{Total potential demand} = (\text{New cases infected} / \text{Percentage of positive tests}) * \text{Average tests used per year}$$

in which:

- ▶ Incidence estimates are calculated based on equation 1. Prevalence estimates for target populations are the median values of the standardized prevalence estimates from all the related studies conducted across Viet Nam, listed in the [Table 3. Journal findings of NG/CT prevalence in Viet Nam](#).
- ▶ Percentage of positive tests = 60%.¹⁸⁹ That is, out of 100 people taking NG/CT tests, there are 60 positive (confirmed infected cases) and 40 negative results.
- ▶ The average tests used per year: average number of times the target group would take a NG/CT POC test in a year. General population and pregnant women would take the test once a year while KPs would do so 2–4 times.¹⁹⁰

In the optimistic scenario when all KPs can be tested, either in healthcare facilities or large screening programmes, the total potential demand by KPs is calculated as follows:

$$\text{Total potential demand by KPs in optimistic scenario} = \text{Total KPs} * \text{Average tests used per year}$$

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