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# **ABBREVIATIONS**

AIDS	Acquired immunodeficiency syndrome	NDHS	National Demographics and Health Survey
AMR	Antimicrobial resistance	NG	Neisseria gonorrhoea
ANC	Antenatal care	NGO	Non-governmental organization
ASEAN	Association of South-East Asian Nations	NRL	National Reference Laboratory
BHS	Barangay health station	OOP	Out-of-pocket
CDRRHR	Center for Device Regulation, Radiation	OHAT	Outpatient HIV/AIDS treatment
	Health, and Research	PBSP	Philippine Business for Social Progress
CHD	Centers for Health Development	PCR	Polymerase chain reaction
СНО	City health office	PhilHealth	Philippines Health Insurance Corporation
CPG	Clinical practice guideline	РНО	Provincial health office
СТ	Chlamydia trachomatis	PLHIV	People living with HIV
DOH	Department of Health	POCT	Point-of-care test
FDA FIND	Food and Drug Administration  Foundation for Innovative New Diagnostics	POGS	Philippine Obstetrical and Gynecological Society
FSW	Female sex worker	PrEP	Pre-exposure prophylaxis
HCPN	Healthcare provider network	PSMID	Philippine Society for Microbiology and
HIV	Human immunodeficiency virus		Infectious Diseases
нмо	Health maintenance organization	PSVI	Philippine Society of Venereologists Inc.
НТА	Health technology assessment	PWID	People who inject drugs
HUC	Highly urbanized city	RDT	Rapid diagnostic test
IAC-AMR	Inter-Agency Committee on Antimicrobial	RHU	Rural health unit
	Resistance	RITM	Research Institute of Tropical Medicine
IHBSS	Integrated HIV Behavioral and Serologic	SHC	Social hygiene clinic
	Surveillance	SLH	San Lazaro Hospital
IVD	In vitro diagnostic	STI	Sexually transmitted infection
KAP	Key affected population	ТВ	Tuberculosis
LMIC	Low- and middle-income country	TGW	Transgender woman
LGU	Local government unit	тот	Training-of-trainers
LHU	Local health unit	TPP	Target product profile
MARP	Most-at-risk population	UDS	Urethral discharge syndrome
МНО	Municipal health office	UHC	Universal healthcare
MOP	Manual of operations	VDS	Vaginal discharge syndrome
MSM	Men who have sex with men	WHO	World Health Organization
MSW	Male sex worker	WTP	Willingness to pay
NASPCP	National AIDS, STI Prevention and Control Program		

### **EXECUTIVE SUMMARY**

Neisseria gonorrhoea and Chlamydia trachomatis are sexually transmitted infections (STIs) that are a global public health challenge, with growing concerns around antimicrobial resistance (AMR), further compounding this challenge. In the Philippines, the national AMR surveillance system detects gonorrhoea strains resistant to antibiotics, with high rates of resistance to ciprofloxacin and tetracyclines. While a national STI programme exists, it is highly HIV/AIDS-centric, and gonorrhoea and chlamydia are low priorities.

A devolved public health system in the Philippines comprises of a complicated governance structure, where local government units govern primary care facilities, and some of the large and specialty hospitals are under the jurisdiction of the Department of Health (DOH). While the basic delivery of health services is a function of local government, the DOH stretches its functions by providing technical, financial and infrastructural assistance to address service delivery gaps. The passage of the Universal Health Care law and the Supreme Court ruling on the Mandanas Doctrine may be an opportunity to improve primary care in the Philippines, by reorganizing the health system and increasing the budget of local government units and primary care facilities within their jurisdictions.

STI care in the Philippines is delivered at all levels of the healthcare system. In the public sector, there are 58 specialty sexual health clinics, called social hygiene clinics, that provide most of the STI care. In areas where there are no social hygiene clinics, STI care is integrated within primary healthcare units. In hospitals, STI care forms part of their outpatient services. It is important to note that private sector healthcare is huge in the Philippines, comprising approximately 50% of hospitals. Private medical practice is highly independent from the public medical sector; care may not be standardized, especially for services that have no guidelines to follow.

Doctors in the Philippines prefer syndromic STI management over etiologic management because it is faster and more convenient. For facilities offering etiologic management, Gram staining is the most common diagnostic technique, while most tertiary hospitals also offer culture and sensitivity testing. Normally, STI care is free of charge in the public health sector; however, resource constraints (e.g. stockouts, staff shortages) can force out-of-pocket expenditure for proper diagnosis and treatment. STI care services in the private sector are paid for entirely out-of-pocket by patients. STI care, outside of HIV, is not covered by social or private health insurance schemes.

There are several areas for improvement in the current STI landscape in the Philippines, and there is value in introducing new point-of-care tests (POCTs) for gonorrhoea and chlamydia. As part of this study, interviews were conducted with key stakeholders. Interviewees highlighted affordability, high sensitivity, and convenience as important drivers for the adoption of POCTs by healthcare workers. They would also value a test that could detect AMR.

Key players who would be closely engaged in the introduction of POCTs for gonorrhoea and chlamydia include: the DOH National AIDS, STI Prevention and Control Program (NASPCP), local World Health Organization (WHO), the DOH regional offices, professional societies, academic partners, Philippine Business for Social Progress (PBSP, the local Global Fund partner), local health units, private hospitals, international non-governmental organizations private (NGOs), clinics and laboratories, other United Nations (UN) agencies, and the national AMR programme.

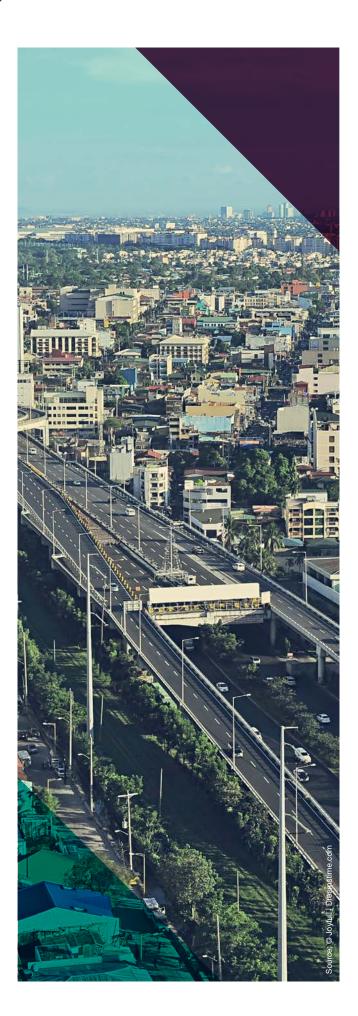
Under near-perfect market-entry conditions, which include adherence to recommended guidelines on yearly testing frequency and stricter regulation of sex workers, and assuming

the current level of STI service coverage, there is a potentially large market for a gonorrhoea/chlamydia POCT. The market potential includes testing of adolescents and youths, as well as pregnant women (approximately 2.3 and 1.7 million tests per annum, respectively). For other key affected populations (due to their behavioural risks), universal testing of commercial sex workers (approximately 610,000 tests per annum) and men who have sex with men (approximately 276,000 tests per annum) represent a further, relatively large potential market.

Between the proposed minimum and optimal target product profiles, the new molecular test for gonorrhoea/chlamydia is preferred due to its higher sensitivity and specificity, its capacity to detect asymptomatic cases, and its greater flexibility for testing more types of specimens. An initial exploration of the willingness-to-pay for the price paid per test performed revealed preferences of paying no more than 36 US dollars (1,800 Philippine pesos) on average per test result. Very few found the product's ex-work price (USD 8 per test kit) to be expensive.

The new POCTs can be integrated within existing sexual and reproductive health programmes, such as HIV screening and testing, prevention of mother-to-child transmission of HIV, and adolescent programmes. Partnerships with the national government and with professional societies, who are the national vanguards of the medical profession both in the public and private health sector, are critical.

There could be considerable first-mover advantage for any company that produces gonorrhoea/ chlamydia POCTs, as there are no existing rapid diagnostic tests (RDTs) or molecular tests on the Philippine market, despite increasing interest in RDTs for the detection of infectious diseases. To capitalize on this opportunity, a phased approach to introducing any new POCT is recommended, including both top-down and bottom-up strategies to establish visibility, generate evidence, create demand and nurture partnerships across all healthcare levels, in preparation for a large-scale rollout.



# INTRODUCTION

Sexually transmitted infections (STIs), including Neisseria gonorrhoea (NG) and Chlamydia trachomatis (CT) infections, continue to be a global public health challenge, with estimates of more than one million new infections daily.1 In the Philippines, while there are reasons to believe there is a high burden of STIs, accurate knowledge of the true national burden is hampered by inadequate surveillance and monitoring, except for HIV infections.2 Additionally, N. gonorrhoea has developed resistance to the majority of available antibiotics. In low-resource settings, providers generally use a syndromic approach for the management of patients with symptomatic STIs, which can lead to both over and undertreatment. To enable etiological case management, the World Health Organization (WHO) and FIND, the global alliance for diagnostics jointly published target product profiles (TPPs) for diagnostic tests for STIs.3 Currently, FIND is supporting the development of point-of-care tests (POCTs) for NG/CT.4 To ensure the commercial sustainability and viability of these products in high-priority low- and middleincome countries (LMICs), the Philippines included, an understanding is required of the healthcare environment, potential market size, and barriers to access, all of which are highly uncertain.

PI Health Inc. and metaHealth Insights and Innovations Inc., in partnership with FIND, conducted the project reported here. This project aimed to provide a high-level yet in-depth market assessment of potential market size, barriers to access, and opportunities for STI testing and treatment in the Philippines, with the goal of assessing the NG/CT POCT demand and supply environment.



## II METHODOLOGY

The first part of this report summarizes the clinical, health systems and market environment of STI diagnostics in the Philippines. This information was subsequently used to inform our market analysis and market entry recommendations. Supplementary information on the methodology is described in Annex 1.

#### 2.1 Phase 1: Clinical, health systems, and market research methods

#### Rapid Literature review and a documents review

A rapid literature review was conducted to investigate the burden of NG/CT in the Philippines. Academic databases were searched for peer-reviewed studies. Original research studies conducted in the Philippines and published up until 2020 were included. Grey literature was obtained from the websites of the Department of Health (DOH), WHO, and other organizations relevant to STIs.

A documents review, to complement the literature review, was conducted to investigate the national programme and regulatory framework, public and private service delivery systems, financing and resources, and stakeholders involved in NG/CT control. The DOH policy database was searched for policies, guidelines and other programme documents, using PolicyMiner.<sup>5,6</sup>

#### Key stakeholder interviews and surveys

Interview and survey tool templates were provided by FIND, then modified and locally contextualized. Interviews were conducted with 21 key stakeholders to obtain their perspectives on policy and operational concerns relevant to STI service provision, AMR prevention activities, and perceived barriers and facilitators to NG/CT POCT rollout (see Annex 4 for the list of key stakeholders). The online survey, which complemented the interviews, also included a willingness to pay (WTP) section to elicit insights into attitudes towards a range of prices for the adoption of the minimum and optimal TPPs (table 1).<sup>7</sup>

Table 1: Test descriptions used for the survey and interviews

	Target product profile	es: POC test for NG/CT		
	Minimal TPP (RDT)	Minimal TPP (RDT) Optimal TPP (POC molecular)		
Description	<ul> <li>Point-of-care test for use in primary health care settings, including health posts</li> <li>Single-use disposable diagnostic test (e.g. lateral flow assay) with a battery-powered reader</li> </ul>	<ul> <li>Point-of-care test for use in primary health care settings, including health posts</li> <li>Disposable molecular cartridge and battery-powered small instrument (with 8 hours of operation between charges)</li> </ul>		
Use	Diagnose NG in symptomatic women and men	<ul> <li>NG and CT diagnosis in both men and women who are symptomatic</li> <li>NG and CT screening to detect asymptomatic infection in both men and women</li> </ul>		
Specimen type	(f) vaginal swab (provider or self collected)	<ul><li>(f) urine, vaginal /cervical /pharyngeal /rectal swab</li><li>(m) urine, urethral /pharyngeal/ rectal swab</li></ul>		
	(m) urine			
Performance	Sensitivity: > 80%	Sensitivity: 95%		
	Specificity: > 95%	Specificity: >98%		
Time to result (TAT)	<30 minutes	<30 minutes		
Ex-works price	Targeting < USD 4-5/test kit (including swabs, consumables)	Targeting US USD 8/test kit (including swabs, consumables)		
	+ reader cost est. <usd +="" 100="" 500<="" cost="" device="" th="" usd=""></usd>			
	<ul> <li>Disposable</li> <li>Easy to use, suitable for primary level</li> </ul>	<ul> <li>Easy to use, battery-operated, suitable for primary level</li> <li>More affordable than some near-patient systems</li> <li>Faster time to results</li> <li>Can be used as a screening test</li> </ul>		
T)	<ul><li>No CT diagnosis</li><li>Reader is not universal, only works with selected RDTs</li></ul>	► Cost		

A total of 23 respondents, whose primary expertise mainly lay in HIV/AIDS, STIs, and adolescent health, completed the survey, taking on a client perspective. The survey included respondents from the government, non-governmental organizations

(NGOs), and the private sector, and who worked at all levels, from the national level down to the barangay (village) level. A copy of the survey questions, along with a summary of the results, is provided in Annex 5.

#### 2.2 Health system framework analyses

The results of the literature and document reviews, interviews and surveys were synthesized using the Health System Framework.<sup>8</sup> The policies, structures and strategies for STI control within the health

system, in terms of burden, governance, financing, service delivery, information and infrastructure, regulation, and supply chain and procurement, were described.

#### 2.3 Phase 2: Market analysis and market entry strategy methods

#### **Market-size projections**

The projected market-size for the NG/CT POCT was derived by multiplying the corresponding population sizes by the recommended number of

tests per year (which may differ for each population) and the estimated compliance rate. The following formula summarizes the approach:

Projected market-size = population size × recommended testing frequency × anticipated compliance rate

The populations considered comprised sexually active women and men, including adolescents and youths. Pregnant women were also included, recognizing their demand for antenatal care (ANC) services. Key affected populations (KAPs) were also considered separately; these included men who have sex with men (MSM), transgender women (TGW), female sex workers (FSWs), male sex workers (MSWs), people living with HIV (PLHIV), and

people who inject drugs (PWID). Recommended testing frequencies varied between one and four times per year. Anticipated compliance rates varied between 0% and 100%, according to user input. Assumptions, references, implementation of the calculations, and other details are provided through a flexible and dynamic MS Excel spreadsheet (Annex 4).

#### Market entry analysis

Various analytical frameworks, including Porter's Five Forces Analysis and the stakeholder power/interest grid, in addition to the market-size

projections, were used to generate key strategic insights and recommendations for market entry of a new NG/CT POCT in the country.

## III STI HEALTH SYSTEM LANDSCAPE IN THE PHILIPPINES

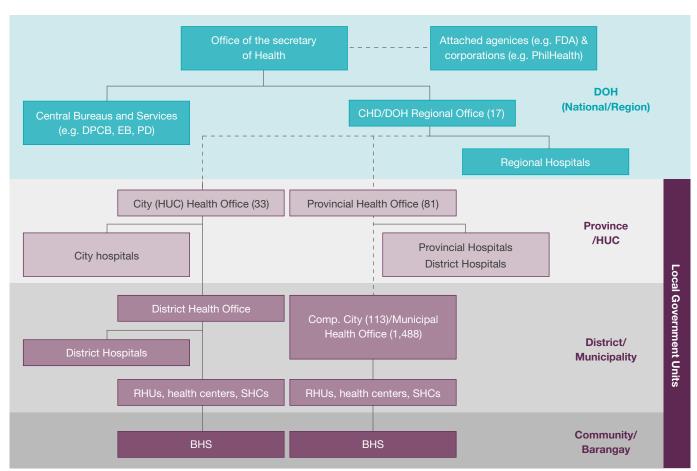
#### 3.1 The Philippine health system

The Philippine health system comprises a devolved public system and a fragmented private system. Recent rulings, such as universal health care, have also had far-reaching effects on the health system.

#### **Public-sector health system**

Health services in the public sector are provided in a devolved system by both the national government and local government units (LGUs). The latter have autonomy to finance and operate local health systems. Figure 1 shows the structure of the devolved public-sector health system in the Philippines.<sup>10</sup>

Figure 1: Structure of the public-sector health system in the Philippines



FDA, Food and Drug Administration; DPCB, Disease Prevention and Control Bureau; EB, Epidemiology Bureau; CHD, Centres for Health Development; DOH, Department of Health; HUC, highly urbanized city; RHU, rural health unit; SHC, social hygiene clinics; BHS, barangay health station

Source: Adapted from Dayrit et al. 10

The DOH is the national health policymaking and regulating agency. It sets national policies and plans, develops technical standards and enforces health regulations. The Philippine Health Insurance Corporation (PhilHealth), the national health insurance provider, is an attached corporation to the DOH. The DOH also provides LGUs and the private sector with technical assistance, capacity-building, and linkages and coordination with other national government agencies. The DOH has 17 regional offices, called the Centers for Health Development (CHD), which also provide technical assistance to LGUs and monitor field operations. The DOH provides specialized tertiary health services and specialty training to health professionals through its facilities such as regional hospitals.

At the LGU level, provincial health offices (PHOs), which report to the provincial governor, implement health programmes at the provincial level. Although the LGUs are independent of the DOH, the DOH regional offices exert considerable influence on the PHOs. PHOs also provide primary and secondary hospital services through their district and provincial hospitals. City health offices (CHOs) and municipal health offices (MHOs), which report to the city and municipal mayors, respectively, implement promotive and preventive healthcare programmes. They also provide primary healthcare and basic ambulatory clinical care through rural health units (RHUs), health centres, and barangay health stations (BHSs). PHOs have influence over the CHOs of component cities and MHOs of municipalities through the provision of hospital services. Likewise, the national programmes of the DOH are cascaded to the CHOs and MHOs through the PHOs. CHOs of highly urbanized cities (HUCs), such as the City of Manila, provide both hospital and primary care services and implement promotive and preventive healthcare programmes, thus performing the role of both PHOs and MHOs. Like PHOs, DOH regional offices communicate directly with the CHO of HUCs. The local health board is an advisory body to local chief executives

(who include the governors of provinces and the mayors of cities and municipalities) and the local legislative council. It also provides a forum to enable multi-sectoral coordination for health. It is chaired by the local chief executive, but the DOH maintains its representations.

The Bangsamoro Autonomous Region for Muslim Mindanao, which consists of five provinces and three cities, has an independent regional DOH, led by its Regional Secretary of Health, who is directly responsible to its Regional Governor. The regional DOH performs all the health service delivery functions of the national, provincial and city/municipal governments.

#### **Private health sector**

The private health sector comprises thousands of for-profit and not-for-profit health service providers, including clinics, birthing homes, infirmaries and hospitals (primary level to referral hospitals), as well as stand-alone diagnostic laboratories and drugstores/pharmacies. It also includes other actors, such as health maintenance organizations (HMOs, or private health insurance companies), pharmaceutical and medical supply companies, academic and research institutions, volunteer organizations and civil society groups. The private sector provides a significant share of health services, with 70% of health professionals in private practice and 60% of health facilities being privately owned. Private health services are generally paid for through user fees at the point-ofservice or through health insurance (i.e. PhilHealth or HMOs).

#### Financing healthcare

Several healthcare financing mechanisms exist in the Philippines. Government facilities, services and programmes are primarily financed through taxes and health insurance, and care is provided to patients for free or at minimum cost. Tiered services are also offered in public facilities, particularly in hospitals, where patients can avail themselves of better services (e.g. better rooms when admitted) if they pay a higher price. Patients may also have to purchase drugs or undergo a procedure (e.g. diagnostics) elsewhere, if supplies and/or equipment are lacking at a public facility.

The premiums paid to PhilHealth are used to finance the healthcare services availed by its members at both public and private facilities. PhilHealth membership increased from 38% in 2008 to 66% in 2017, with the goal of providing universal healthcare coverage.11 Premiums for some groups, such as senior citizens, persons with disabilities, and the very poor are subsidized by the government. Coverage is mostly limited to inpatient services, although recent benefit packages have been developed for some outpatient services.

Government expenditure, from both taxes and PhilHealth premiums, comprised 42% of the total health expenditure in 2019. The premiums paid to HMOs are also used to cover the healthcare services availed by their members, although their coverage is small, at 10.9% of total health expenditure. Lastly, out-of-pocket (OOP) expenses represent a significant mode of funding healthcare, representing 47.9% of total health expenditure in 2019.

#### **Health system reforms – the Universal Health** Care law<sup>12,13</sup>

The 2019 Universal Healthcare (UHC) Law (Republic Act 11223) aims to provide universal social health insurance coverage for all Filipinos, with PhilHealth being the national purchaser of individualbased health goods and services. It attempts to address the significant OOP expenses incurred by households for healthcare. It also institutionalizes health technology assessments (HTAs), where a positive recommendation from the HTA Council is needed to support any decisions by the DOH to make purchases of, or PhilHealth to provide reimbursement for, a technology such as an NG/CT POCT.<sup>15</sup> The law also mandates the reorganization of the health system, where provinces and HUCs will be the focal points of health service delivery and governance. Municipal governments will transfer the leadership and management of local health systems to their respective provincial governments. Healthcare provider networks (HCPNs), composed of public and/or private providers that will deliver primary, secondary and tertiary services, will be formed within provinces or HUCs. Progress on the reorganization will be reviewed in 2025 and will be fully implemented by 2030. Another feature of the UHC law includes the expansion of human resources for health deployment programmes, to address shortfalls in numbers of healthcare workers in the short-term.

The Mandanas Doctrine, which clarifies that the annual budget of LGUs will come not only from the Bureau of Internal Revenue but also from other national taxes, will increase the LGU budget by 27% in 2022.14 The DOH will reduce its workforce and transfer functions to LGUs by 2022, because the proportion of the budget for health from the national government will be reduced. 15,16 As a result, the LGUs will play a more active role in service delivery for STIs. Health services, along with hospital services and communicable and noncommunicable disease control services, will be fully devolved to the LGUs.<sup>17</sup> The DOH, however, will continue to provide resources (e.g. supplies, infrastructure and human resources) to lowerincome LGUs.

The UHC law and the Mandanas Doctrine will bring far-reaching changes to health service delivery and financing. They will strengthen the role played by PHOs and CHOs of HUCs in health service delivery and financing, making MHOs subject to the influence of PHOs and limiting the role of the DOH to providing technical assistance to the LGUs.

#### 3.2 Landscape of STI programmes in the Philippines

#### STI burden and surveillance

The HIV surveillance system in the Philippines is robust;<sup>18</sup> however, significant gaps exist for other STIs. Data on the burden of STIs among KAPs may be inaccurate due to the lack of universal STI screening and the practice of syndromic management.<sup>19</sup> Obtaining accurate STI burden

estimates is further complicated by the cultural stigma associated with testing and detection of STIs and limited access to social hygiene clinics (SHCs) in high-burden areas. Estimates for the prevalence of NG/CT infections, as well as syphilis, are shown in Table 2.

Table 2: STI prevalence estimates among KAPs

Key population	Prevalence, % (95% CI)			Ref
_	NG	СТ	Syphilis	_
General female population (15–49 years old)	0.75 (0.44–1.18)	5.75 (4.85–6.75)		20
General male population*	1.1 (0.6–1.9)	4.4 (3.4–5.8)		20
Youths (15-24 years old)	0.7 (F); 1.7 (M)	7.7 (F); 9 (M)		20
MSM Overall			4 (3.2–4.9)	22
MSM - Metro Manila	4 (Ur); 8 (Rec)	11 (Ur); 15 (Rec)		21
MSM - Baguio City	11 (Rec)	17 (Rec)		21
TGW^#			6 (4.6–7.8)	22
TGW and MSM#			4 (3.2–4.9)	22
FCW.		17–32		23
FSW	36	6.7		24
Freelance sex workers	31	31		21
Registered sex workers	3	17		21
MSW (Ho Chi Minh City, Viet Nam)**	3	2		25
Pregnant women±		17–32		23
PLHIV	7	22		00
FLNIV		4		26
PWID	2	10	2.3 in 2009 2.5 in 2011	21, 9

<sup>\*</sup>Study participants were 18–65 years old; \*\*no data were available on STI prevalence among male sex workers (MSW) in the Philippines, so data from the closest comparable setting are provided; ^KAP estimates from the DOH report a 23% overlap between MSM and TGW; ±did not disaggregate pregnant women and FSW; #weighted prevalence; F, female; M, male; Ur, urethral; Rec, rectal; CI, confidence interval.

Syndromic management of NG/CT infections may lead to improper case management and ineffective antibiotic treatment, increasing the risk of developing AMR. This has been borne out; over time, NG has developed AMR, limiting treatment

options and raising concerns for the future management of infections by this organism.<sup>27</sup> Key strategies to address AMR in gonorrhoea include enhanced AMR surveillance and improved antibiotic stewardship.

The Philippines has developed "The Philippine Action Plan to Combat AMR: One Health Approach", calling for a coordinated and comprehensive action plan amid a rising AMR burden and associated concerns, including among gonorrhoea infections.<sup>28</sup> In 2020, the Antimicrobial Resistance Surveillance Program reported the cumulative resistance of NG to ciprofloxacin and tetracycline to be 79.4% and 58%, respectively.<sup>29</sup> Tetracycline has been prescribed to treat gonorrhoea since the 1950s, especially for patients who have contraindications for penicillin. Due to the increasing resistance to tetracycline among NG cases, in 1985 clinicians began shifting to the use of fluoroquinolones (e.g. ciprofloxacin). Unfortunately, a subsequent increase in fluoroquinolone resistance was noted in the mid-1990s, initially among MSM. In 2007, ciprofloxacin was removed from the list of first-line antibiotics for gonorrhoea due to the high prevalence of ciprofloxacin resistance.<sup>30</sup> No resistance has yet been reported for ceftriaxone, cefixime or azithromycin - the current front-line antibiotics used to treat NG/CT.

Most of the studies reporting STI prevalence that have been cited in this report used purposive sampling when recruiting study participants. This may have resulted in some bias in the estimation of prevalence among KAPs. Furthermore, there seems to be an imbalance in STI testing among men and women in the general population. The Laboratory and Blood Bank Surveillance database for gonorrhoea testing includes testing data reported by multiple facilities; most of these facilities are public, although some privately certified blood banks, laboratories and STI testing facilities also report. The data show that significantly more women were tested compared with the number of men tested (Annex 5) and likely reflects a requirement for routine testing among FSWs. Overall, determination of the actual burden of symptomatic STIs in the Philippines is hindered by poor care-seeking behaviour due to stigma; a lack of training, equipment and supplies to perform laboratory diagnoses; and the failure to report cases.31

#### STI governance<sup>18,31</sup>

The national STI response is governed by the DOH through its National AIDS and STI Prevention and Control Program (NASPCP). The Health Sector Plan for HIV and STIs 2015–2020 elaborated the strategies around how the health sector will contribute to addressing HIV and STIs as public

health challenges. Figure 2 shows the vision, goals, purpose and strategies of the Health Sector Plan, which is focused on HIV. Based on our interviews, the NASPCP is mainly driven by the response to the HIV epidemic, with NG/CT as a third-tier priority after HIV, hepatitis B and syphilis.

Figure 2: HIV and STI Strategic Framework

#### Philippine Health Sector HIV and STI Strategic Framework (2015–2020)

#### **Vision**

Zero infections, zero discrimination, Zero AIDS-Related Deaths

#### Goal:

By 2020, the country will have a maintained a prevalence of less than 1% of the total population by preventing the further spread of HIV infection and reducing the impact of the disease on individuals, families, sectors and communities.

#### Purpose:

The further spread of HIV in key populations is prevented through strengthened delivery of essential prevention, treatment and care interventions

#### Strategy 1:

Continuum of HIV/STI prevention, diagnosis, treatment, and care service to key populations

#### **Strategy 2:**

Health promotion and communication on HIV and STI prevention and care services

#### Strategy 3:

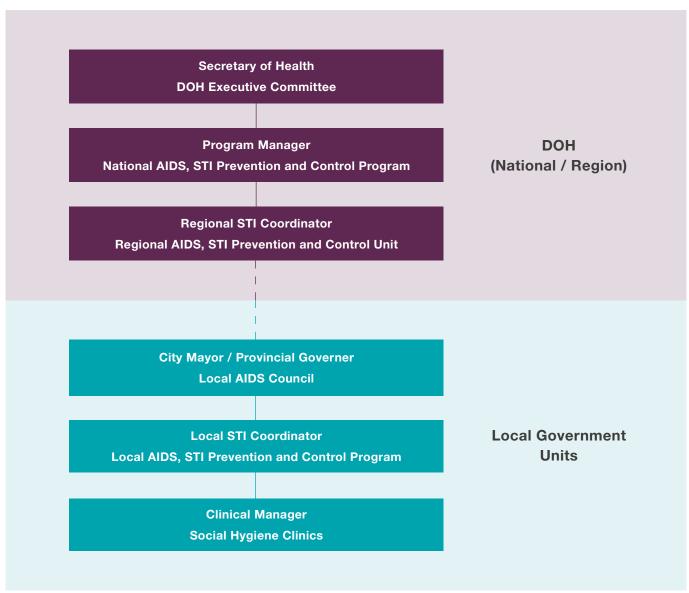
Enhance strategic information systems

#### Strategy 4:

Strengthened health system platform for broader health outcomes Other national programmes integrate STI education and services in support of the HIV/ STI response. The National Safe Motherhood Program administers activities relating to the prevention of mother-to-child transmission and encourages the testing of pregnant women for HIV and other STIs. The Adolescent Health and Development Program embeds sexual and reproductive health in its major strategies, such as advocating comprehensive education around sexuality; conducting holistic home education for healthy activities; drugs and alcohol, suicide and depression, and sexuality assessment services; and establishing adolescent-friendly health facilities

The National HIV/STI Program Managers have counterparts in the regional offices, whose main responsibilities are to cascade the programme strategies and provide technical assistance to the LGUs. At the provincial and city levels, STI programme officers supervise the SHCs. The programme officers ensure that sufficient funding is allocated to the programmes so they can continue providing services. The local response is also governed by the local AIDS Council, which is the policymaking and planning body, headed by the city or municipal mayor. Again, the emphasis is on HIV/AIDS, but STIs are also included. Figure 3 shows the organizational structure governing the national and local STI programmes in the Philippines.

Figure 3: HIV and STI public health governance structure



DOH, Department of Health; AIDS, acquired immunodeficiency syndrome; STI, sexually transmitted infection.

#### AMR governance<sup>32</sup>

The Philippine government has an Inter-Agency Committee on Antimicrobial Resistance (IAC-AMR), which was institutionalized through Presidential Administrative Order No. 42 series in 2014. The IAC-AMR is chaired by the DOH and the Department of Agriculture, recognizing the important role of the agriculture sector in the regulation of antibiotic use. The governing body issued the Philippine Action Plan to Combat AMR 2019–2023, which has the following key strategies:

- Commit to a comprehensive, financed national plan with accountability and civil society engagement.
- Strengthen surveillance and laboratory capacity.
- Ensure uninterrupted access to essential medicines of assured quality.
- Regulate and promote the rational use of medicines, including for animal husbandry, and ensure proper patient care.
- **5.** Enhance infection prevention and control across all settings.
- **6.** Foster innovations, research and development.
- Develop a risk communication plan to combat AMR.

The Philippines has been active in AMR surveillance since 1988, beginning with the creation of the Philippine Committee on Antimicrobial Resistance Surveillance Program. This program collects data from its 24 sentinel sites and 2 gonorrhoea surveillance sites. In addition to strengthening the surveillance system, the IAC-AMR also focuses on advocating the rational use of antibiotics in both the medical and agricultural sectors through its One Health Strategy. The DOH

AMR Program conducted a series of information drives and advocacy initiatives on the rational use of antibiotics. They also released a manual of operations for the Antimicrobial Stewardship Program in Hospitals for the rational and optimal use of antibiotics.

Key stakeholder interviews revealed that the AMR programme focuses on the rational use of antimicrobials in general. While gonorrhoea is a focus area for surveillance, there is limited linkage between the NASPCP and the DOH AMR Program to ensure that AMR issues are properly considered as part of the STI Program Strategy. This limited linkage is recognized as a challenge in the current AMR Program.

#### Regulatory environment

#### **Product registration**

Medical device registration in the Philippines goes through the Center for Device Regulation, Radiation Health, and Research (CDRRHR), a regulatory body under the DOH Food and Drug Administration (FDA).<sup>33,34</sup> In vitro diagnostic (IVD) device authorization is in line with the ASEAN Agreement on Medical Device Directive.<sup>35</sup> Companies who wish to market IVDs in the Philippines must obtain a License to Operate before registering their respective products with the CDRRHR.

All medical devices in the Philippines, including IVDs, are classified according to their individual and public health risk based on the ruling of the ASEAN Agreement on Medical Device Directive of 2015. Diagnostic tests for NG/CT are classified as Class C. Class B to D IVDs need a Certification of IVD Medical Device Registration, prior to their commercialization and use. This certification is valid for five years, provided there is no change in the composition, packaging, intended use, process or components of the IVD. It is subject to renewal every five years.

There are two main sets of documentation required for medical registration: legal and technical requirements. The legal requirements are standard for all applications while, the technical requirements vary depending on the class of IVD, as applications for higher-risk IVDs require more documentation regarding their safety and utility. The CDRRHR forwards the IVD applications to a national reference laboratory (NRL) for performance evaluation. Usually, a laboratory-based validation is conducted, where the new diagnostic is compared with a gold-standard test to, for instance, determine sensitivity and specificity. This is performed prior to the issuance of an initial approval or renewal. The NRL provides a report to CDRRHR regarding the performance evaluation.

Indicated fees for an initial application are 7,500 Philippine pesos (PHP; approximately USD 150), with an evaluation fee of PHP 750 (approximately USD 15). The annual retention fee for each application is PHP 5,150 (approximately USD 103). A review for the issuance of a Certification of IVD Medical Device Registration should be completed within six months.<sup>13</sup>

#### **Health technology assessment (HTA)**

An HTA is a systematic evaluation of the properties and effects of a health technology, defined as any application of knowledge and skills used to solve a health problem and improve quality of life;36 this includes the POCT for NG/CT. HTAs inform decisionmakers about the benefits and other effects of health technologies, leading to efficient allocation of resources.37 The UHC law stipulates that an HTA is a priority-setting mechanism, whereby a positive HTA recommendation is needed to support any decision by the DOH to purchase, or PhilHealth to reimburse, a health technology.<sup>38</sup> Currently, HTAs are conducted by the HTA unit of the DOH. The methodological framework for HTAs in the Philippines includes: 1) clinical assessment, 2) economic assessment, 3) ethical, legal, and social implications assessment, and 4) health systems impact assessment.

#### Other regulatory agencies

In addition to the FDA, several other agencies help to ensure strict regulation and standard maintenance in the health system. Health facilities, such as hospitals, diagnostic laboratories, and specialized outpatient facilities, are licensed by the DOH Health Facilities and Services Regulatory Bureau and must be accredited by PhilHealth to allow reimbursements and funding through the national health insurance scheme. Currently, a facility can only be reimbursed by PhilHealth if a product, such as a diagnostic test, is covered by a benefit package. The registration and licensing of health professionals is conducted by the Professional Regulation Commission. Specialty societies within the medical profession, such as the Philippine Society for Microbiology and Infectious Diseases (PSMID) and the Philippine Obstetrical and Gynecological Society (POGS), are also involved in the accreditation of training institutions, administration of qualifying examinations, and granting of certificates for Diplomas and Fellowships for medical specialists. The Commission on Higher Education regulates both public and private institutions of higher learning; this covers colleges and universities offering medical and other professional health degrees. The Insurance Commission regulates HMOs and oversees their financial viability.

#### **Government procurement**

Procurement in public health facilities follows the rules laid out in the Republic Act 9184 or the Government Procurement Reform Act of 2003, which are applicable at both national and local government levels. Procurement for primary care facilities is centralized at the provincial or municipal level, depending on the administrative jurisdiction of the facilities. There are separate procurement systems for the national, regional and DOH hospitals. To be procured for the public sector, the product must first be registered and then included in the formulary, based on HTAs.

#### 3.3 STI care-seeking behaviour

There are no nationally representative STI careseeking data. For general illnesses, household surveys indicate that most Filipinos (59%) visit a public health facility, while 40% and 1% visit private health facilities and alternative medical providers, respectively.11 Based on interviews with key informants from public facilities, individuals who are at risk of or may have NG and/or CT infection may also show poor careseeking behaviour, i.e. they are unlikely to visit health facilities to be diagnosed and treated. This is primarily due to the stigma around STIs. The 2015 Integrated HIV Behavioral and Serologic Surveillance (IHBSS) data confirmed these observations, showing that while 78% of MSM and transgender males knew which facilities were available where they could be tested for HIV and other STIs, just 29% of them felt comfortable going to these facilities, and only 14% of them tested for HIV in the past year. The data for TGW were similar, although 80% of TGW knew where HIV-testing facilities were, only 30% were comfortable accessing these facilities, leading to just 15% of individuals having HIV tested in the past year. While these data focused on information relating to HIV, they can offer insights into the accessing of care for other STIs.39

As a result of the poor care-seeking behaviour, some patients may be self-medicating, i.e. asking

other people they know about potential treatments and then buying these drugs from pharmacies. This practice is not uncommon, particularly in small, independent pharmacies, which may be less likely to follow the regulations on the rational use of antibiotics. The literature has also documented different practices of self-medication among Filipinos, especially when symptoms are clearly apparent.<sup>40,41</sup> Another factor underlying the poor care-seeking behaviour of Filipinos is the perceived cost of availing themselves of STI care, particularly with regards to diagnostics.

One strategy to address this poor care-seeking behaviour is the outreach activities conducted by public facilities and non-governmental service providers. The regular health examinations required in certain professions, e.g. those in the business process outsourcing sector, can also provide an opportunity to locate individuals who have an STI. Additionally, certain subgroups in the KAPs, for instance FSWs who work in regulated settings and MSM who are active within advocacy, tend to exhibit better care-seeking behaviour. One key informant also mentioned that care-seeking behaviour for STI infections is generally higher among patients who go to private hospitals.

#### 3.4 STI service delivery

STI care is delivered at all levels of the healthcare system. The types of services and preferred diagnostic methods vary, as the standards for STI care are not up to date with international best practices and are not strictly enforced. The health facilities providing STI care can be divided into primary care facilities, hospitals, specialty clinics, and the National Reference

Laboratories (NRLs) for HIV and STIs. Table 2 shows the different types of health facilities, including the types of NG/CT testing and management provided by the facilities. These are further described below, with a focus on the main source of STI care, the SHCs, where a set of polices is used to govern and standardize care.

Table 3: Types of health facilities in the Philippines and their roles in STI management

Level	Facility	Role in STI management	STI management	Test(s)	Public		Private	Total
					National <sup>*</sup>	ren		
	BHS	Smallest unit of public primary care	Public – syndromic	None	N/A	22,613	N/A	22,613
	Private clinic	Smallest unit of private primary care	Private – mainly etiological, but independent general practitioners may opt for syndromic	None	N/A	N/A	N/A	A/N
	RHU	Larger public primary care unit	Public – syndromic/ etiological (depends on laboratory test availability)	Gram staining	N/A	2,593	N/A	2,593
Primary	Birthing home	Integrate STI care within prenatal services	Public – syndromic/ etiological Private – etiological	Gram staining	N/A	835	1,071	1,906
	Infirmary	Clinics providing a more complex care service	Public – syndromic/ etiological Private – mainly etiological	Gram staining	o	338	336	683
	SHC	Specialized primary care facilities for STIs	Syndromic/etiological (depends on laboratory test availability)	Gram staining	N/A	28	N/A	28
	Level 1 hospital	Provides inpatient general care,	Public – etiological		36	297	418	751
	Level 2 hospital	specialized care and transition care, wherein STI care is usually part of outpatient services	Private – etiological	Gram staining/	10	33	284	327
Hospital	Level 3 hospital	End-referral and training facilities, wherein STI care is part of outpatient services	Etiological, with selected public hospitals as Gonorrhoea AMR Surveillance Units	sensitivity	43	10	29	120
	National Reference Laboratory	Provide STI care but also conduct confirmatory tests for HIV	Etiological	GS/CS (Molecular tests available, but not for NG/CT)	0	N/A	N/A	2

\* Excludes military health facilities.

RHU, rural health unit; SHC, social hygiene clinic; GS, Gram staining; CS, culture and sensitivity; N/A - No available data or not applicable.

#### Social hygiene clinics (SHCs)

STI care in the Philippines is primarily provided by specialized sexual health clinics called SHCs. There are 58 designated SHCs, which are standalone facilities, mainly located in cities across the country that have a high burden of disease. The SHCs are LGU-owned and offer a range of sexual health services and public health programmes. They employ different strategies to increase access to STI care and engage the most-at-risk populations (MARPs) in their outreach activities. SHCs also partner with brothel houses to certify a clean bill of health, or "pink card", for sex workers; this is a regulatory requirement of LGUs. SHCs conduct HIV case management, and some act as pilot facilities for the Pre-exposure Prophylaxis (PrEP) HIV Program. Despite the focus on HIV service delivery, care for other STIs is also integrated within the programme.

SHC services, including NG/CT diagnosis and treatment, are free of charge; therefore, supplies and human resources for SHC operations are paid for by the relevant jurisdictional LGU. However, whenever medicines are unavailable (i.e. stockouts), patients who can afford to do so procure treatment through their local pharmacies. Due to the budget limitations of LGUs, SHCs are usually also supported by the DOH and international NGOs, specifically the Global Fund. LGUs may request certain supplies, equipment, human resources, and health infrastructure from the DOH. In turn, the DOH, through the Health Facility Enhancement Program, assists the LGUs in the enhancement or establishment of their health facilities, including the SHCs. This programme includes the provision of equipment, provided that the LGUs have sufficient budget to maintain its operation thereafter. Our interviews also confirmed that the DOH provides laboratory supplies (but not on a regular basis) in addition to its regular health workforce augmentation programme.

#### STI care in other primary facilities

In areas with no SHCs, primary care facilities, especially BHSs and RHUs, offer STI care as part of their general health services. As these facilities are not expected to provide a wide range of STI care. variation exists around how NG/CT services are provided, especially with regards to the prescription of diagnostic tests. In settings with access to Gram staining, etiological management is prioritized. However, when testing supplies run out, syndromic management is used because ordering a laboratory test outside the facility increases the incidence of dropout. For the same reasons, independently practising general physicians prefer syndromic management, especially when a patient's symptoms are obvious.

#### STI care at the public and private hospital level

Hospitals also offer STI care as part of their outpatient services. As these are higher-level facilities, Gram staining is available, in both public and private health facilities. In public hospitals, these services are free but are dependent on the availability of supplies. On the other hand, services in the private sector are paid completely OOP. Fees for these services vary depending on the type of facility and the range of services being offered. Some facilities offer an STI care package costing around USD 50-80, which includes the following tests: complete blood cell (CBC) count, HIV test, hepatitis B surface antigen (HBsAg), venereal disease tests, Gram staining and urinalysis. On top of these fees are doctor's consultation fees, potentially ranging from USD 5-15 and the cost of treatment, at around USD 10-20. While public health facilities may be considerably more affordable, convenience and privacy are the primary factors considered by those who choose to go to private facilities. Public health facilities cater to a larger volume of patients; thus, patients must wait longer and fear meeting an acquaintance in such facilities.

It should be noted that medical doctors are independent practitioners who may be affiliated with several institutions at the same time. They are consultants with no employee-employer relationship with hospitals. While hospitals implement internal policies, medical practice is very much independent and is governed by the professional societies. Practising medical doctors may be affiliated with at least one professional society, depending on their practice and specialization. Most practitioners who take care of STIs are members of PSMID and the Philippine Society of Venereologists, Inc. (PSVI),

while in recent years the Philippine Dermatological Society has been taking an increasing interest in HIV and STI care. These professional societies issue clinical practice guidelines (CPGs) to guide and update their members on the clinical management of diseases. As of writing, no CPGs for NG/CT care were found, although there were CPGs for HIV. As there is no top-down guidance, practitioners follow their preferred standards from overseas, as discussed below.

#### **STI National Reference Laboratories (NRLs)**

The Philippines has two NRLs for STIs and HIV/AIDS: the Research Institute for Tropical Medicine (RITM) and the San Lazaro Hospital (SLH). These NRLs provide confirmatory tests for HIV and offer molecular testing services for other infectious diseases, including STIs. Despite having this capability, as posted on their website, as part of their routine work, they only offer Gram staining and culture and sensitivity tests for NG/CT.

Amid the COVID-19 pandemic, the country's capacity to conduct molecular testing has increased, which may eventually supplement the limited testing for NG/CT. Approximately half of around 200 accredited COVID-19 molecular testing laboratories are private, and 23% of them use cartridge-based polymerase chain reaction (PCR) equipment (e.g. GeneXpert or other point-of-care PCR). The DOH expects to convert some of these facilities to Subnational Reference Laboratories, targeting at least one facility in each of the 17 regions of the country. This huge increase in the availability of these molecular testing platforms is expected to augment the testing capacity for other diseases once the pandemic is over.<sup>42</sup> The optimal use of these facilities is currently being explored. In particular, the decentralization of confirmatory tests for HIV is a priority; however, the future application of these facilities for other STIs has yet to be discussed.

## Social hygiene clinic STI guidelines and Manual of Procedures

In 2014, the DOH developed a Manual of Procedures (MOP) for the SHCs.<sup>43</sup> It describes the minimum standards required for the satisfactory management of STIs in these clinics. The MOP also covers the

essential elements of setting up and managing a functional SHC in the Philippines, including ethical standards to ensure confidentiality and quality.

According to the MOP, the following services should be offered by SHCs:

- General consultation
- Physical examination
- Diagnosis and treatment
- Minimum laboratory services for STIs, i.e.
  - + Wet mounts
  - + Gram staining
  - + Rapid plasma reagin and *Treponema* pallidum haemagglutination assays
  - + HIV testing (rapid or enzyme-linked immunosorbent assays)
- STI education, counselling, and condom promotion services
- STI treatment
- Partner notification and treatment
- Family planning services
- Cancer screening via pap smear or direct cervical visualization with acetic acid; breast examination
- Linkage to tuberculosis (TB) centres

The current MOP still adheres and refers to antiquated policy issuances, specifically the DOH Administrative Order 5 s. 1998: Implementing Guidelines in STI Case Management at the Different Levels of the Health Care System and the DOH Administrative Order 5-A s. 2003: Revised National Sexually Transmitted Infections Case Management Guideline. The MOP includes a flow chart for the management of STIs involving urethral or vaginal discharge. Table 3 shows the treatment regimens for NG/CT, as prescribed in the MOP.

Table 4: Treatment regimens for NG/CT

#### Treatment for cervicitis in patients with vaginal Treatment for NG/CT in patients with urethral discharge discharge syndrome (VDS) syndrome (UDS) Cefixime 400 mg as a single dose OR Cefixime 400 mg as a single dose OR Ceftriaxone 250 mg as a single intramuscular Ceftriaxone 250 mg as a single intramuscular discharge discharge **PLUS PLUS** Doxycycline 100 mg 2x daily for 7 days OR Doxycycline 100 mg 2x daily for 7 days OR Azithromycin 1 g as a single dose Azithromycin 1 g as a single dose

The MOP prescribes three methods for diagnosing STIs:

- Etiological diagnosis utilizes specific laboratory diagnostic methods in presumptive and confirmatory testing for a specific STI pathogen. The current MOP favours Gram staining and culture sensitivity (GS/ CS) methods when performing etiological diagnoses. There are no other diagnostic methods prescribed for NG/CT POCTs. The turnaround times for Gram staining range from one hour to a day, depending on the number of clients the facility is currently serving. This long turnaround time is why clinicians prefer syndromic or clinical management because empirical treatment with antibiotics can be rapidly commenced. The clinical protocol is based on the Administrative Order 5-A s. 2003: Revised National Sexually Transmitted Infections (STIs) Case Management Guideline.
- Syndromic diagnosis is the current alternative in the absence of etiological testing and the most widely used by clinicians. It is based on the identification of a consistent group of symptoms and easily recognized signs of a disease. The algorithm for syndromic diagnosis is based on the Administrative Order No. 5 series 1998: Implementing Guidelines in STD Case Management at the Different Levels of the Health Care System.
- Clinical diagnosis involves a probable diagnosis made based on simple historytaking and physical examination. This is

mainly performed in cases of genital herpes and warts.

SHCs adhere closely to the MOP. However, variations in diagnostic and treatment protocols exist, as described during the key interviews. The availability of resources is an important consideration in the execution of diagnostic and treatment plans. When the supply of diagnostic reagents and other supplies is scarce, facilities are compelled to perform syndromic diagnosis. In other cases, patients pay OOP for diagnosis and treatment, either at another facility or in a private pharmacy, depending on their capacity to pay.

Compared with the practices in SHCs, clinical practice in other facilities varies because the current STI guidelines are outdated and there is no MOP. An informant from a private tertiary hospital shared the fact that clinicians often follow US Centers for Disease Prevention and Control guidelines for managing patients with STIs. Some clinics operated by NGOs adhere to the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine Guidelines, as well as guidelines from their mother organization, the International Planned Parenthood Federation. These international guidelines are used due to the lack of up to date, comprehensive, local CPGs. For instance, the DOH guidelines do not include guidance on when to conduct pharyngeal swabbing during the diagnosis of gonococcal infections, which is a vital consideration among MSM and sex workers. The DOH guidelines are also unclear about detecting and managing drug-resistant cases, which are prevalent among gonococcal infections. Moreover, health

professional informants confirmed that no initiatives currently exist to detect asymptomatic cases.

#### SHC outreach activities and referral system

Through the assistance of the Global Fund, outreach activities among KAPs have intensified. Priority LGUs were provided with community health outreach workers, who connected with different networks of KAPs and communitybased organizations to conduct peer education sessions, community-based HIV screening, and bring patients to the SHCs within their catchment areas. The engagement of informal networks and community-based organizations is an important strategy to increase testing uptake among KAPs. While these activities are primarily funded for the HIV programme, testing for other STIs is also integrated within this, which has operational implications. An informant shared that, even if a patient presents with symptoms of other STIs, HIV testing and counselling will still be conducted prior to undertaking other STI testing procedures.

Our interviews revealed that clients are referred to other facilities in the absence of a diagnostic test and when symptoms persist following standard treatment. While the MOP outlines some key points when referring clients, there is no established, enforceable referral system. Therefore, informal agreements exist. For example, it was disclosed that a case manager for PLHIV refers clients with recurrent STIs to a private STI practitioner instead of a higher-level public facility, because they have greater confidence in the provider's expertise than that available at other facilities. Patient navigation among facilities is a chronic issue within the Philippine health system and one of the important areas of reform under the UHC law.46 There is no interoperable information technology system that informs the originating facilities when their referrals go to a referral facility.

#### **SHC** workforce

The MOP elaborates the standard workforce requirements needed to deliver the clinical services of an SHC. SHC personnel should include: (1) a clinic manager/medical doctor, (2) a nurse/midwife, (3) a medical technologist, (4) outreach workers, and (5) a clerk/record custodian/laboratory aide. Their roles and responsibilities are outlined in Annex 6.

Human resources allocation depends on the priorities of the LGUs. Key interviewees revealed the real workforce dynamics, including gaps, and described how understaffing forced staff to stretch their capacities to provide the best services possible. While the MOP suggests that clinical personnel should comprise full-time, dedicated workers, doctors are often not full-time, as they work and are affiliated with more than one health facility. Both our interviews and surveys revealed that taskshifting is becoming the norm in most SHCs. For example, in the absence of a medical doctor and/ or a medical technologist, the clinic nurse collects and transports specimens if the laboratory is not co-located within the SHC. Some non-medical clinical staff also execute doctors' orders in the absence of clinicians. Additionally, the MOP prescribes the clinical staff necessary to run the SHCs but does not acknowledge the administrative and managerial staff required to run the backend unit, such as personnel responsible for logistics and finance. Thus, backend work is assigned to the available clinical staff, who may not possess the proper training and skillsets to do this work. These scenarios show that while specific roles are assigned to each staff member, they may assume different functions depending on the situation. Recognizing these workforce gaps, the DOH and the Global Fund Project also provide human resources. The Global Fund deploys HIV case managers and community health outreach to complement the HIV programme in their project sites. The DOH also augments health workforce gaps. In 2019, the DOH deployed around 29,000 health workers, of whom 22,590 were nurses, through the Nurse Deployment Public Health Associate Projects.

#### Financing STI care

STI care given by service providers is financed through external donor funding, budget appropriation to public facilities sourced from government taxes, OOP expenses of households and, finally, with the smallest contribution, insurance payments from PhilHealth and HMOs. Figure 4 shows the flow of finance for STI service delivery.

Funding from external donors, such as the Global Fund, constitutes a considerable proportion of STI-care financing. In the case of the HIV response, much of the programme is financed by the Global Fund,

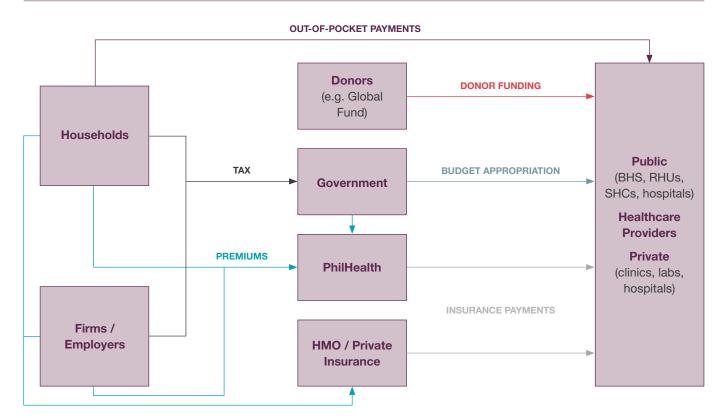
with the government funding 25% of the programme through general appropriations from taxes. The next most important contributor to financing STI care is OOP expenditure, which is particularly high in private facilities. OOP expenditure can be incurred for consultations, diagnostics and treatment.

Health insurance plays a limited role in financing STI service delivery, with most HMOs not covering STI care and PhilHealth limiting coverage. For example, utilization of PhilHealth's Outpatient HIV/AIDS Treatment (OHAT) package is expanding, although the package, that covers drugs or medications, routine laboratory exams, antiretroviral therapy toxicity monitoring exams, and professional fees, does not include STIs.47 The recent Extended Primary Care Benefit Package from PhilHealth, now called the "Konsulta Package", reimburses STI screening and treatment costs for high-risk pregnant women and adolescents. However, coverage by this package is limited due to the meagre number of accredited facilities, a result of the complex accreditation requirements. Interviews revealed that PhilHealth is waiting for the UHC implementation uncertainties to settle, against the backdrop of the COVID-19 pandemic. As a result, the opportunity to expand socialized health insurance may not be realized until the healthcare provider networks are contracted under UHC.

Private financing for STI diagnosis, treatment and care, such as from HMOs, remained at less than 1% in 2013, which may be attributable to the misperception that STIs are a consequence of a patient's deliberate risky behaviour.

With health financing being focused on HIV/AIDS, other STIs tend to receive a share of the pie owing to their co-morbidity with HIV/AIDS. For instance, current ancillary testing and treatment for gonorrhoea may be covered by excess funding received from the PhilHealth OHAT reimbursements. This happens because OHAT reimburses medicines that the government and partners already provide for free. <sup>47</sup> Medical expenses for the least well-off are also directly subsidized if availed from designated treatment hubs.

Figure 4: Flow of finance for STI service delivery



Government only appropriates budget to public healthcare providers.

Source: Adapted from Dayrit et al. 10

#### Stakeholders in gonorrhoea and chlamydia care services

The stakeholders that should be engaged in the rollout of POCTs for gonorrhoea are shown in Table 4. These include stakeholders from the DOH, LGUs, the private sector, NGOs, academia, and patients themselves.

Table 5: Roles of stakeholders in the rollout of an NG/CT POCT

	Stakeholder	Potential role(s)
	NASPCP	Provide policy and guidelines, supervise and monitor the rollout of the NG/CT POCT
	Pharmaceutical Division	Provide policy on the use of the NG/CT POCT as part of the national AMR programme
	Bureau of International Health Cooperation	Coordinate with international stakeholders, for instance FIND, and international donors, to develop the POCT for NG/CT
Ī	FDA	Evaluate and register the NG/CT POCT
рон	Regional Offices	Ensure proper rollout of the NG/CT POCT at the regional level.  Coordinate with local government units on implementation
	NRL-SLH	Conduct performance evaluations of the NG/CT POCT to support product registration
	RITM	Conduct the national annual AMR survey
	PhilHealth	Cover the expenses of all Filipinos related to the NG/CT POCT through its inclusion in benefit packages
S	Local Chief Executive and Legislative Council	Support and provide funding for the rollout of the NG/CT POCT
rgUs	Local Health Units - PHOs, CHOs, MHOs	Utilize the NG/CT POCT for case finding and surveillance at the local level.  Provide diagnostics at the local level as part of the national programme
	Professional societies (e.g. PSMID, POGS, PSVI)	Include the use of the NG/CT POCT in CPGs. Coordinate with their members to adopt the NG/CT POCT
	Private hospitals (e.g. Makati Medical Center)	Provide the NG/CT POCT to clients who prefer private service providers
Private Sector	Private clinics and diagnostic laboratories (e.g. Aventus Medical Care)	Provide the NG/CT POCT to clients who prefer private service providers
ate	Diagnostics suppliers	Manufacture the NG/CT POCT
Priva	Diagnostics distributors (e.g. MACARE Medicals Inc.)	Distribute and maintain the NG/CT POCT in the Philippines
	Private service providers	Provide the NG/CT POCT to clients who prefer private service providers
	HMOs	Cover the expenses related to the NG/CT POCT of patients who are members
	WHO Western Pacific Regional Office	Provide technical assistance to the NASPCP in relation to the NG/CT POCT
International and Local NGOs	Other UN agencies (e.g. UNAIDS, UNFPA, UNICEF)	Provide technical assistance to the NASPCP in relation to HIV and STIs for UNAIDS; population for UNFPA; and children's welfare for UNICEF
	International NGOs	Provide technical assistance to the NASPCP in relation to the NG/CT POCT
Intern	Philippine Business for Social Progress (PBSP)	Support the DOH NASPCP in implementing the national STI programme
	Non-profit service providers and local NGOs	Provide the NG/CT POCT at the local level as part of the national programme in support of the LHUs
Acaden	nia/universities	Provide evidence for the feasibility of the NG/CT POCT and technical assistance to the DOH for its rollout
Patient	S	Accept and utilize the NG/CT POCT

## IV MARKET ANALYSIS

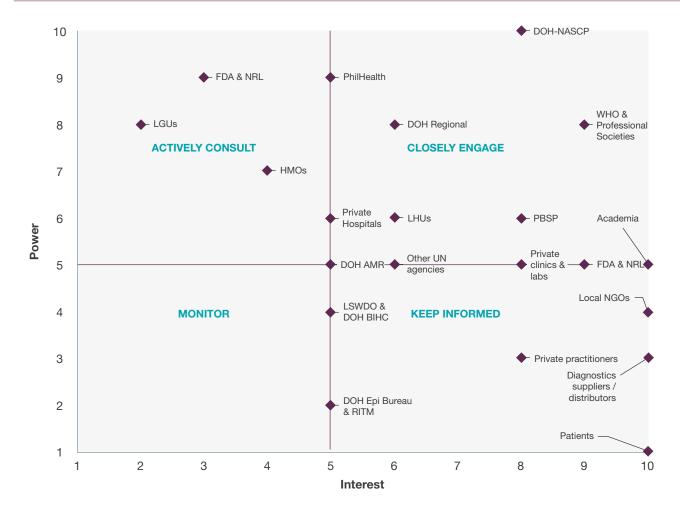
This section provides insights into the market, including potential size, preferences, and access barriers and facilitators, to provide recommendations for entry into the STI diagnostics market in the Philippines.

#### 4.1 Stakeholder engagement

Figure 5 uses the power/interest grid to map out the stakeholders who should be involved in the rollout of the NG/CT POCT. Among the key players identified who must be actively engaged are the DOH-NASCP, PhilHealth, the local WHO office, DOH regional offices, professional societies, academia, PBSP, LHUs, private hospitals, international NGOs, private clinics and laboratories, other UN agencies, and

the national AMR programme. Institutions that may benefit and thus should be kept informed include local NGOs, who may improve their services for service improvement; diagnostics suppliers and distributors, who may profit from revenue generated by the adoption of the POCT; private practitioners, who may improve their services for service improvement; and patients who may receive treatment for STIs.

Figure 5: Power/interest matrix for stakeholder mapping



The values indicated for interest and power were based on expert opinion and interview results.

#### 4.2 Cascade of market sizes

A cascade of target population sizes was estimated: (1) the overall population, (2) the infected population, and (3) the symptomatic population. Note that the infected population was based on NG/CT prevalence rather than incidence, providing a larger population eligible for testing. Incidence adjusts for duration of infection, which was deemed unnecessary due to the long mean duration of infections in untreated cases (i.e. 5–6 months for NG and 15 months for CT).<sup>48</sup>

To estimate the number of symptomatic patients presenting for care, one would optimally have data on care-seeking; however, no STI-specific data were available for the Philippines. Care-seeking behaviour was instead reflected by the best estimates of the anticipated testing coverage, differing across groups and KAPs. Note that only symptomatic NG/CT infections were considered, as there were no reliable local data available for other VDS- and UDS-causing etiologies (e.g. candidiasis, trichomoniasis, and bacterial vaginosis).

Sources of mean estimates as well as corresponding limit calculations are summarized in Table 5. Mean population sizes were sourced from official data, and the mean infected population sizes were based on the reviewed prevalence for NG/CT for each group (see Table 1), with the assumption that infection with NG or CT is mutually exclusive whenever a combined prevalence is not available. The mean symptomatic population sizes were based on the expected number of those infected who will eventually present with symptoms, following the Spectrum-STI versions 5.88 beta 23 and later modules.48 The population size limits were estimated based on probabilistic simulations such that they represent equal-tailed 95% probability intervals of the underlying distribution. For the infected and symptomatic populations, separate sex-specific simulations were generated for NG and CT. These distributions, parameterizations, and constraints differed across groups and KAPs and are further detailed in an MS Excel spreadsheet (see Annex 4).

Table 6: Summary of population size mean and limits of data sources or estimation methods

Population	Mean	Limit
Total (overall)	Men and women of reproductive age, adolescents and youths:	Population size limits (or ranges) are provided for MSM, FSWs and PWID
	<ul> <li>2020 projected population size of the Philippines.</li> </ul>	Whenever not provided, probabilistic simulations were performed from a count distribution model, accounting for
	Pregnant women:	overdispersion parameterized by the corresponding mean
	proxied by the number of live births registered in 2019. †	and variance fitted over historical data, while applying some constraints on the ratios of the populations
	MSM, TGW, FSWs, MSWs and PWID:	
	2015 size estimation of KAPs	
	PLHIV:	
	<ul> <li>2020 HIV/AIDS and Antiretroviral Therapy Registry of the Philippines.</li> </ul>	
Infected	See Table 1, with corresponding sex-specific weighting and adjustments for adolescents and youths as well as PLHIV populations <sup>‡</sup>	Probabilistic simulations were performed from a four-parameter beta distribution, separately for NG and CT by sex, parameterized by the mean (prevalence) and minimum and maximum of the truncated distribution from three potential sources of decreasing priority: (1) 95% confidence intervals surrounding the point prevalence, (2) minimum and maximum prevalence according to a closely related group, and (3) +/-25% of the point prevalence
Symptomatic	Based on the expected number of symptomatic infections according to the default sex-specific probabilities used in Spectrum-STI versions 5.88 beta 23 and later modules: for men, 0.64 NG and 0.54 CT; for women, 0.34 NG and 0.17 CT <sup>48</sup>	Probabilistic simulations were performed from a four-parameter beta distribution parameterized by the mean (default symptomatic probability) and minimum and maximum of the truncated distribution according to the following ranges <sup>49</sup> : for males, NG 22%–82% and CT 5%–54%; for females, NG 5%–40% and CT 2%–23%

<sup>&</sup>lt;sup>†</sup> This effectively assumed that one mother bore exactly one child yet was unadjusted for pregnancy losses (e.g. stillbirths, miscarriages), to which it was assumed that the differences offset each other. <sup>‡</sup> For PWID, it was assumed that everyone was male.

#### 4.3 Market size estimates

Table 7: Projected market sizes for NG/CT testing under the new recommendations

Use case/KAP	Population	Size*	Frequencyll	Coverage	Total*
General (low-risk) women (15–49-year- olds)^	Symptomatic	300K (194K–427K)	1	45% †50	135K (87K–192K)
General (low-risk) men (15–49-year- olds)^	Symptomatic	900K (543K-1.0M)	1	35% ‡51	315K (190K–358K)
Adolescents and youths	Infected	3.0M (2.5M-3.3M)	1	38% †50	2.3M (1.9M–2.5M)
Pregnant women	Total	1.7M (1.6M–1.9M)	1	100%	1.7M (1.6M–1.9M)
MSM	Total	532K (429K–730K)	2	26% § <sup>52</sup>	276K (223K–380K)
FSWs	Total	66K (46K–95K)	4	100% #	264K (182K-381K)
MSWs	Total	87K (31K-247K)	4	100% #	346K (122K–989K)
TGW	Total	123K (75K–350K)	2	29% § <sup>52</sup>	71K (44K–203K)
PLHIV	Symptomatic	14K (9K–15K)	2	100% ж	28K (18K–30K)
PWID	Symptomatic	1K (0–2K)	1	35% ‡51	<1K (0-<1K)

\*M corresponds to one million (1,000,000); K corresponds to one thousand (1,000). I Recommended testing frequencies (per year) are based on market entry recommendations and CPGs: one test for the general population and for pregnant women in ANC clinics during their third trimester of pregnancy, two tests for MARPs determined by behaviours, except for sex workers (set at four, following regulations on quarterly testing to secure a clean bill of health or pink card) and PWIDs (set at one as they are considered a very hard-to-reach population). ^ The general (low risk) population sizes and total test demands are stand-alone estimates and do not include estimates coming from other relevant populations (e.g. estimates for women do not include pregnant women or FSW populations). † Philippines NDHS 2017, where numbers reflect the percentage of those with knowledge about where to test for HIV. ‡ Published estimates and expert opinion on care-seeking behaviour for STIs among South-East Asian men. § 2015 IHBSS estimates on SHC reach coverage, which includes receiving free condoms and information on HIV transmission, prevention, testing or seminars. # FSW coverage is assumed to be 100% coverage by virtue of LGU regulations on individuals undergoing tests prior to being provided with a pink card to allow them to engage in the commercial sex trade; MSW coverage was assumed to be similar, as there are no available data to reliably inform coverage. \*\*A s the PLHIV population size is based on routinely collected data and when detected everyone is assigned a case manager, it is reasonable to assume that everyone who shows symptoms will be tested due to the influence that the case manager may exert on clients to seek proper care.

While estimating the potential market size among patients in the PrEP population was initially considered, it was later revealed that PrEP is still in the pilot stages at some SHCs, so no reliable data yet exist about how many individuals are on PrEP; this led to the decision to remove this group here to reduce uncertainties in the estimates.

Table 6 provides the most likely testing demand per year for each group and KAP under conditions of compliance with recommended CPGs on testing frequency and anticipated coverage, reflecting STI

care-seeking behaviour and intervention reach (see Table 6 footnotes for details). For general (low-risk) men and women, only symptomatic individuals were assumed to be tested once they sought care.<sup>50,51</sup>

Note that these counts are stand-alone and do not include estimates from other relevant KAPs. The infected adolescent and youth population was used. as it is believed that this reflected high-risk sexual behaviour coupled with a targeted reproductive health programme focus. All pregnant women were to be tested once, during their regular ANC clinic visit during their third trimester of pregnancy. For other KAPs, everyone was assumed to be tested under the universal screening of high-risk or vulnerable populations approach, except for PLHIV and PWID, given their very hard-to-reach status. For commercial sex workers, perfect coverage and strict compliance with regulations were assumed. For MSM and TGW populations, a once every six months testing frequency was assumed, based on recommendations and coverage as estimated by SHC reach from the 2015 IHBSS.52 For PLHIV and PWID, only care-seeking symptomatic individuals were considered. All PLHIV who were symptomatic for NG/CT were assumed to be care-seeking, given their access to HIV care providers. PWID are the hardest-to-reach population; thus, it was assumed symptomatic individuals were only tested once they sought care and that all users were male.

There is a larger potential market for low-risk men than women, which is likely to be attributable to the higher probability of men presenting with symptoms of NG/CT, despite estimating a higher number of infections among women owing to the higher prevalence. Adolescents and youths represent a very sizeable market if the interventional programme reach is wide. This is especially true if STI testing is integrated with reproductive health and/or HIV services. There may also be a huge demand for testing pregnant women.

Consistently, TGW account for 29% of the estimated MSM testing demand despite the TGW population accounting for just 23% of the MSM population, probably due to the wider reach of SHCs to TGW than MSM. There is a sizeable market among commercial sex workers. However, estimates presented here are based on perfect compliance and the regulation of all sex workers. At the time of writing, these assumptions may not represent the true situation on the ground, as only FSWs are required to undergo routine testing, to receive their pink card. With the high prevalence of STIs among PLHIV (NG/CT included), the estimated market size for this KAP is reasonably large even when considering only symptomatic infections (approximately 18% of the total PLHIV market). Testing demand among PWID is almost non-existent.

Note that these estimates are based on most-likely scenarios under near-perfect market entry conditions with regards to testing frequency recommendations and regulations. This partially explains why marketsize estimates do not yet align well with the most recently available data, especially on gender imbalance. For instance, market-sizing estimates suggest a larger potential market among men; however, Laboratory and Blood Bank Surveillance data revealed more actual testing among women (approximately 30,000 for men versus 400,000 for women per year in 2018-19, see Annex 4). This gender imbalance may be explained because women (FSWs) are more frequently targeted by HIV programmes and STI testing regulations than men, under the current CPGs.

Furthermore, the survey results revealed that microscopy kits (Gram staining) are the most used diagnostic techniques in different health facilities, yet there is a preference for syndromic management, especially in primary care facilities, because of its convenience and ease of use. While existing diagnostic methods may be preferable in several circumstances, the proposed TPPs have the potential to capture a significant market segment based on a better sensitivity while maintaining convenience and low cost.

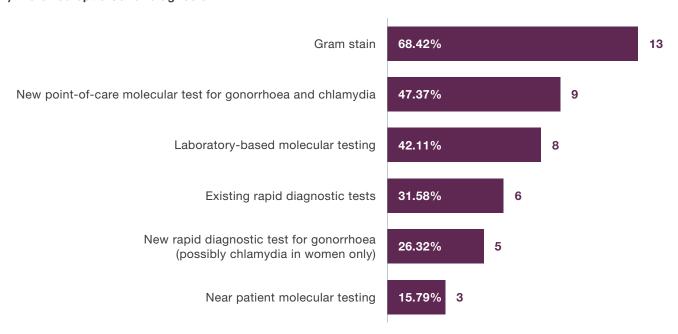
#### 4.4 Test preferences

Survey respondents were asked about their test preferences for two scenarios: (A) diagnosis of symptomatic individuals only, and (B) screening of high-risk or vulnerable populations, possibly covering asymptomatic infections (see Figure 6). For (A), Gram staining was still the most preferred method (68%), with the new POC molecular test (optimal TPP) being the second most preferred

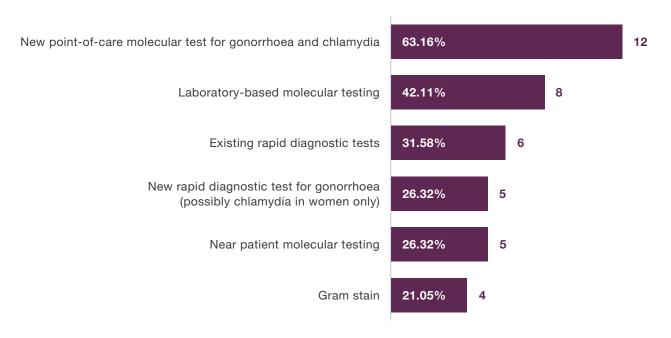
(47%). In (B), the optimal TPP was the most preferred (63%). In both scenarios, the new rapid diagnostic test (RDT, minimal TPP) was not a highly preferred option in many lists. No respondent answered "None", reflecting that everyone believed that the Philippines should be ready for a NG/CT diagnostic test, despite these infections being a third-tier STI priority.

Figure 6: Summary of survey results for testing preferences for each scenario

#### (A) Preferred option/s for diagnosis



#### (B) Preferred option/s for screening asymptomatic high-risk or vulnerable populations



These results were corroborated and explored indepth through interviews with a physician working in a private hospital, a physician in public practice working in an SHC, a municipal health officer, a manager of a local NGO and non-profit service provider, and a STI consultant.

The optimal TPP was preferred by the physicians, the STI consultant, and the manager of a local NGO and non-profit service provider because of its capacity to detect asymptomatic cases and flexibility to use more types of specimens, in addition to its greater sensitivity and specificity. They all agreed that this would be useful as part of annual screening, particularly among MARPs. The municipal health officer stressed that it should only be targeted at MARPs, considering the limited resources in primary care facilities. It was suggested that the utility of the product could be improved by reducing its cost and having the capacity to detect AMR.

The municipal health officer, on the other hand, expressed a preference for the minimal TPP, as such a test could complement syndromic management because asymptomatic individuals would not visit primary care facilities anyway. Multiple issues were raised with the minimal TPP. It might not pass the performance evaluation conducted by the NRL-SLH, which requires a sensitivity and specificity of >90% before granting a certificate of product

registration. The physicians mentioned that, as proposed, the minimal TPP does not offer much added value in practice, because they can simply adopt a syndromic approach. One advantage of the minimal TPP is its quick turnaround time.

Insights into the possible rollout of the TPPs were also provided. Deployment of the optimal TPP in HUCs and the minimal TPP in less densely populated LGUs, where there may be lower testing rates, was suggested. The rollout may only be successful if there are no OOP costs for patients, suggesting funding should be covered by the national programme, PhilHealth or HMOs. Acceptability of the test may be improved if specimens can be self-collected or collected by non-healthcare workers. Crucial in any rollout will be capacitybuilding and technical assistance on how to use the technology. Health education and promotion is also important in increasing demand for the test, especially considering the stigma attached to STIs. STI screening may be also integrated with HIV testing. A "one-stop shop" approach, which includes interventions for prevention, treatment and adherence, may be useful to maintain cohorts. Holistic services can facilitate finding and retaining clients. Physicians in both private and public practices, as well as the manager of the local NGO, expressed interest in helping with the pilot deployment of the test.

#### 4.5 Willingness to pay for a complete testing service by TPP

Figure 7 shows the maximum WTP for the entire test procedure for the minimal TPP, based on 18 survey responses. These disclosed that standard HIV testing in the Philippines, using an RDT, costs approximately USD 5 (PHP 200) per test on average, and this was used as a reference price. The elicited mean and median maximum WTP prices were USD 7.50 (~PHP 360) and USD 6.50 (~PHP 320), respectively. At least 25% of

respondents were even willing to pay as much as USD 11 (~PHP 500). These prices were higher compared with the ex-work price (i.e. factory-gate price yet to be added to other fees, such as shipping, tariff duties, distribution mark-ups and Performing the test, among other costs) in the TPP developed by FIND (~USD 4–5 per test kit). Just 15% of respondents found the ex-work price to already be expensive.

Figure 7: Willingness to pay (WTP) summaries for the minimal TPP

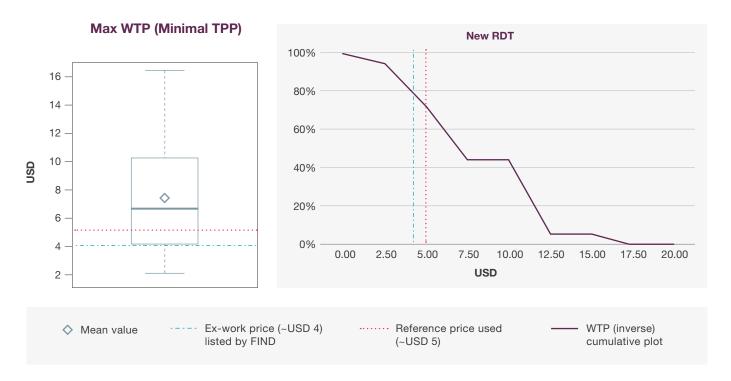
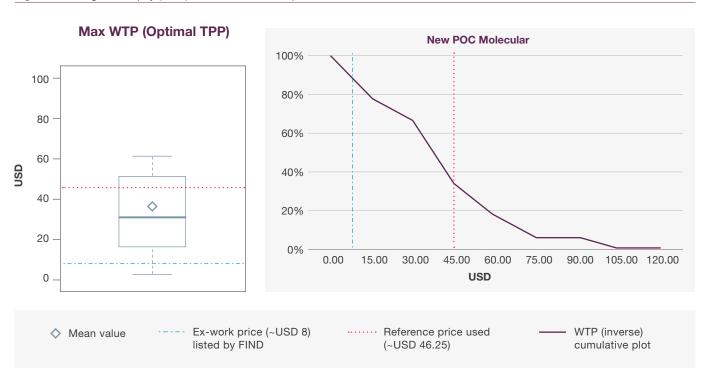


Figure 8 shows the maximum WTP for the entire test procedure for the optimal TPP following the same exercise, but using as a reference price a rapid molecular test for COVID-19, wherein all services are provided by the testing facility, for which PhilHealth pays USD 46.25 (~PHP 2,287) per test.<sup>53</sup> The mean and median maximum WTP prices were

USD 36 (~PHP 1,800) and USD 30.75 (~PHP 1,500), respectively, and around 30% of respondents were willing to pay as much as the reference price listed. Just 10% of respondents found the ex-work price in the TPP (~USD 8 per test kit) listed by FIND already too expensive.

Figure 8: Willingness to pay (WTP) summaries for the optimal TPP



In the key stakeholder interviews, only the municipal health officer expressed a preference for the minimal TPP, which was mainly driven by its cheaper cost. However, somewhat contrary to the survey results, only the physician in the SHC considered the listed price for the optimal TPP acceptable. Nevertheless, an informant who is a physician in private practice mentioned that pricing issues may only be relevant to patients who seek care from government facilities and that these issues may be less important among those seeking care at private facilities. It was reiterated in further in-depth discussions, that such pricing issues in public facilities could be resolved if any remaining OOP expenses were still much lower than those incurred when attending a private practice. Reflecting the higher maximum WTP prices in the survey, several informants expressed the opinion that increased confidence in a correct NG/CT diagnosis could justify the higher product prices. In view of the needs of several KAPs (e.g. sex workers), pricing is not an issue, especially if

required by regulations to secure a health certificate to continue engaging in the commercial sex trade.

Tiered pricing according to market segment is recommended. LGUs are unlikely to procure tests themselves; instead, it is more likely that the national government will provide LGUs with tests. Thus, a single contract could cover the entire public health market, and an attractive pricing model would promote economies-of-scale. As noted, the process for public-sector procurement requires registration, followed by an HTA to demonstrate cost-benefit potential. For the private sector, where volumes will be smaller and the market more fragmented, higher pricing can be offered. The proposed product may be of more interest to medical doctors based in large, private hospitals, whose clients may not mind paying extra for the convenience, confidentiality and certainty of results. A more targeted WTP study should be conducted to provide further evidence for potential pricing models.

#### 4.6 Barriers and drivers of adoption

#### The role of stigma in STI care

Stigma and discrimination pose significant challenges to accessing and sustaining STI care in the Philippines. There is also widespread discrimination against people with STIs and HIV. The Philippine National Demographics and Health Survey of 2017 found that 71% of women held discriminatory attitudes towards people living with HIV.<sup>54</sup>

Discrimination and a lack of awareness around HIV and STI care contributes to the Philippines having the fastest growing number of people being infected with HIV worldwide.<sup>14</sup> There are several factors that contribute to this. Consistent with recent reports,<sup>14</sup> our survey revealed that one of the most important challenges regarding STIs is the stigma that hinders affected individuals from seeking medical attention. Devi (2019) noted

that because the Philippines is predominantly a Catholic country, stigma and discrimination tend to persist. Society often associates STIs, including HIV/AIDS, with homosexuality, promiscuity and substance abuse. 15 Thus, discussion about these topics is avoided at all levels of society, and there is considerable friction between the government and conservative elements, such as the Catholic Church. 14 This is the main reason why enactment of the Parenthood and Reproductive Health Act of 2012 has been delayed. 15 The main provision of this act was to guarantee the general population access to reproductive health services, as well as to increase public awareness around sex education and include sex education in public schools. 16

Aside from the stigma, the lack of public awareness of STI symptoms and transmission contributes to the low demand for STI care.

including testing. In our survey, many respondents identified the growing need to detect individuals who have asymptomatic infections. Controversies also remain regarding the implementation of sex education in public schools, which is evident in the low-level of awareness among the general population regarding STIs, their symptoms and management. 14,15,16

#### Access to new technologies

Healthcare technology has considerable uptake in the Philippines; this was highlighted during the COVID-19 pandemic, when many healthcare professionals navigated the digital space through online consultations. This is also evident in the increased demand for the provision of healthcare-related information via digital means. Additionally, there is a demand for better diagnostic technologies, especially in terms of POCTs. Our survey revealed that the "gold standard" for diagnosing infective agents, i.e. through molecular-based testing, is only available in tertiary hospitals and a few large secondary hospitals. As there is a limited number of these institutions across the country, with most of them concentrated in state capitals, many patients in low-income brackets and those living far from urban centres may not be able to access these tests. Most of our respondents noted that a large majority of diagnostic tests for STIs are performed in SHCs, which are accessible to patients at a grassroots level. The most common diagnostic test performed is Gram staining (for NG).

We also found that access is of paramount importance for the accurate and equitable provision of quality STI testing. This implies that a novel POCT that is easy to use and distribute would have good traction across different healthcare settings.



## V MARKET ENTRY RECOMMENDATIONS

There could be considerable first-mover advantages for any company entering the NG/CT POCT space, as there are no existing rapid molecular diagnostic tests on the Philippine market, despite the increasing interest in RDTs for detecting infectious diseases. To capitalize on this opportunity, a five-phased approach is recommended: establishing visibility, creating a sense of urgency, establishing local evidence, promoting integration with the national programme and health-financing coverage, and national rollout. These phases are detailed below.

## Phase I: Establish visibility

Considering the low salience given to NG/CT in the Philippines, the first step for any potential implementing partner is to establish visibility across the three components of the health sector in the country, i.e. public, private, and non-governmental or development (local and international). A courtesy call with the key national and international players (DOH, UN, Global Fund, international NGOs, and local civil society organizations), emphasizing the challenges around NG/CT care, would spark a conversation around the issue. Further courtesy calls could be extended to professional societies, academia, and significant players in the private sector, emphasizing possible areas for collaboration. Often by asking the correct questions and presenting the care gap, the problem can be illuminated and actions sparked.

#### Phase II: Create a sense of urgency

There are two ways to create a sense of urgency to respond to NG/CT in the Philippines: through the response to HIV/AIDS and/or through the AMR lens. The former is the more obvious route. As the Philippines remains one of the few countries with a trend of increasing HIV incidence, stakeholders pay more attention to HIV, which could spill over to other STIs. As a result of this focus on HIV, local and international funding has been increasing. The AMR angle is an alternative approach, latching on to the more extensive AMR programme, which is championed by the high-level Interagency Committee on Antimicrobial Resistance (ICAMR). The 2018 AMR Surveillance Report included gonorrhoea and revealed 80% and 57% resistance to ciprofloxacin and tetracycline, respectively, meaning the current treatment regimen remains effective for the moment, but must be preserved to prevent it becoming ineffective in the future.29 For both approaches, the best way forward would be to pitch the notion to stakeholders that any effective response to HIV/AIDS or AMR would be less meaningful without an effective POCT for relevant STIs. Seeking opportunities for synergies would make the process faster, more practical and more logical than pursuing individual strategies.

Providing an evidence base serves as a cornerstone for advocacy. Research can illuminate the NG/CT burden in the Philippines. Tackling this burden does not only pertain to describing the epidemiological profile of the diseases of interest but also elucidating

the financial and economic burden on both individuals and society. Furthermore, projecting the models across various time-horizons will help visualize both short- and long-term epidemiological and economic impacts to the country. Such a strategy of translating how the disease impacts fiscal spending may help with raising awareness of the burden and impact of AMR among national and local decision-makers. Factoring the cost of STI AMR into the projections, which would be a closer depiction of the reality, may cause the estimates to balloon and hence nudge stronger actions. In the past, the 2016 National TB Prevalence survey findings showed that public health surveillance missed more than 300,000 patients; this raised the alarm within both the medical and public health communities. An approach to advocating an NG/ CT response in the Philippines could follow a similar playbook.

Dissemination of evidence and sustained discussions among key stakeholders will increase buy-in. Increasing the awareness of NG/CT requires a reframing of the mindset, such that an effective response to pressing problems like HIV and AMR can never be separated from diagnosing other STIs. Relevant actors within government, private companies, NGOs, academia, patient advocacy organizations, and activist groups should be brought on board. To accelerate change, the following steps are recommended once a sense of urgency has been created: (1) build or identify a guiding coalition, (2) formulate a strategic vision for NG/CT and relevant initiatives to achieve this, (3) communicate the vision, (4) recruit more multisectoral champions into the guiding coalition, and (5) identify actions to remove barriers to access. Maximizing virtual collaborations and workshops may be an excellent opportunity to bridge the gaps between fragmented stakeholders and bring in international expertise, with fewer cost considerations.

# Phase III: Establish local evidence for NG/CT POCT and healthcare service delivery models

Establishing the evidence base for an NG/CT POCT is a twofold process: ascertaining the accuracy of any POCT prior to it being rolled out and describing the effectiveness of POCT delivery models. Investigating the test's local accuracy would involve carrying out comparative studies with the gold-standard method to investigate at a minimum the sensitivity, specificity, positive predictive value and negative predictive value of the test. Although the international literature can yield these parameters, local experts often look for localized evidence on which to base their actions. Acceptance and buy-in is more rapid once contextualized information has been provided.

The effectiveness of various POCT delivery models should be explored through a hybrid of effectiveness and implementation research. This recommendation suggests focusing not only on the intervention (i.e. the POCT) but also on implementation of the delivery strategy (i.e. the healthcare service delivery model for the POCT). The main objective may focus on investigating the effectiveness of the POCT model in terms of finding cases compared with the standard of care and other research models. Endpoints to be measured may include the number of cases identified and successfully treated. This could also be disaggregated to syndromic versus etiological diagnosis. Ideally, a cluster-randomized, pragmatic trial, randomized at the levels of basic healthcare service units, would be adopted. If the budget is limited, non-randomized designs, such as the use of interrupted time-series analysis or regression discontinuity, could be explored. Secondary objectives may be to investigate implementation outcomes, such as feasibility and acceptability among decision-makers/programme managers, healthcare workers and patients. Utilizing Proctor's implementation science model,55 the intervention and the associated implementation strategy lead to implementation outcomes before they lead to service and health outcomes. The accuracy study would establish the local evidence base for the POCT, while the effectiveness-implementation study would elucidate real-world implementation and service data that would inform service delivery design. A final important objective to consider is establishing the cost-effectiveness, or at least the cost-benefit, of any intervention. The findings will be critical components for an HTA, which is now a prerequisite for PhilHealth reimbursement. An HTA would need to be conducted for both the test and programme, as well as the delivery mechanism. To undergo this government-led assessment, the health technology or programme should be prioritized. External stakeholders, such as implementing partners and industry members, can submit proposals and lobby for prioritization. New technologies could start to be submitted by the end of 2021; however, considering the delays in prioritizing currently implemented health technologies, external submissions may not happen this year.

In terms of delivering testing to the target clients, at least two sets of models could be explored, one public and one private. The public model could be piggybacked through the top-down SHCs. Adopting a national funding route might be challenging unless the salience of NG/CT has already been established. For an LMIC like the Philippines, such an agenda is usually donor-driven, as was the case with the successful rollout by the Global Fund of the GeneXpert for TB diagnosis. Meanwhile, private healthcare service models could explore the following three channels: (1) through NGO intermediaries, (2) through private healthcare chains, or (3) through "The Consortium" – a network of private laboratories and hospitals.

First, some NGOs are involved in direct healthcare service delivery. They could be approached to deliver the POCT. The easiest way would be to donate or lend machines to NGOs; these machines should then be operated sustainably. Some NGOs might be able to pay for these machines through innovative financing mechanisms, such as consignment or co-sharing schemes. This consignment practice involves providing the diagnostic machines for free, bundled with exclusive contract provision of reagents and related commodities for a finite period. The supplier recoups its investment by including higher margins on the commodities. The NGO may achieve further financial sustainability

by providing business-to-business arrangements with private healthcare facilities to deliver backend testing through a hub-and-spoke model.

Second, private healthcare chains are strategic targets for deployment. The Philippines has a large but fragmented private healthcare sector. Within the fragments, micro-integrations exist in the form of polyclinic chains, laboratory chains and hospital chains led by for-profit institutions. Prominent players include Ayala Healthcare Holdings (by the Ayala Conglomerate), the Metro Pacific Hospitals (by the Metro Pacific Investments Corporation), and Aventus Medical Care (Fullerton Health). These chains may be interested; however, ensuring client demand is an important consideration. Also, the availability of private financing schemes through HMOs is an essential driver of adoption, although to date. HMOs do not cover STIs.

Third, deployment of the POCT could be done through The Consortium. Inspired by the Initiative for Promoting Affordability and Quality TB Test model in India and initiated by a USAID project in the Philippines, The Consortium is a relatively new network of hospital and private healthcare institutions that primarily pools procurement for GeneXpert machines and commodities to bring down costs. For instance, the cost of testing was reduced from USD 10–20 to USD 6. While yet to scale-up beyond the metropolitan Manila area, The Consortium offers a ready opportunity to deploy the NG/CT POCT through a network of private providers.

#### Phase IV: Promote integration with the national programme and health-financing coverage

Legalization and routinization are two ways to promote integration. Legalization, or at least policy adoption, can be achieved through a top-down adoption of the national programme. Specifically, the aim is to influence the national programme to include NG/CT POCTs in the medium-term plan through the following entry points: as part of routine STI care or by integrating with the HIV Primary Care Programs (routine HIV testing, PrEP programme, prevention of mother-to-child transmission, and adolescent sexual and reproductive health). This can be achieved with the Phase I-III recommendations.

Routinization, or mainstreaming into usual practice, can be achieved by influencing healthcare providers and by securing health-financing coverage. To influence healthcare providers, specifically the prescribing physicians, NG/CT POCTs should be included in local CPGs. Professional societies that could be engaged include the PSMID, PSV, POGS, the Philippine Academy of Family Physicians, and the Pediatric Infectious Disease Society of the Philippines. Once NG/CT POCTs are included in the care algorithm, increased adoption by physicians is expected. To influence health financing, assisting PhilHealth in developing STI benefit packages or strengthening the existing Extended Primary Care Benefit Package (Konsulta Package) are recommended short- to medium-term solutions. A long-term solution would require prioritizing the NG/CT POCT for an HTA, as well as proving its superiority, or at least equivalence, to Gram staining. A successful HTA evaluation is required for eventual financing reimbursement once the UHC law takes full effect. This will also entail service delivery shifting to the LGU-contracted HCPNs. Private HMOs may follow suit once they have seen the level of market demand, which may increase as an indirect consequence of CPG inclusion and PhilHealth coverage.

#### Phase V: **National rollout**

It may be too early to discuss nationwide rollout at this point, but deliberately thinking about its general principles at the outset may help the eventual transition to scale. Three guiding principles are recommended for a national rollout: (1) conducting training-of-trainers (TOT) using a waterfall approach, (2) following a phased wave sequence spread for geographic scale-up, and (3) implementing concurrent operations research.

First, the Philippines has considerable experience in terms of conducting the TOT approach. Given the hybrid vertical and horizontal health governance structure, in which technical expertise is often cascaded vertically while the actual programme implementation is implemented horizontally, training the national DOH and its regional counterparts would be a useful strategy. The regional DOH would then train trainers at the LGUs, often starting with PHOs, CHOs, and DOH-retained (tertiary and specialty) hospitals. In turn, these would train the trainers from downstream levels such as MHOs, district hospitals, and RHUs/BHSs, ultimately creating a waterfall effect. For NG/CT testing, prioritizing the staff from the DOH national STI programme, their regional counterparts, and from NRLs, such as SLH and RITM, could be key. Staff from health offices in high-disease burden areas could then follow. External support could be provided by assisting in the development and supporting the conduct of capacity-building initiatives across all healthcare levels.

Second, the wave sequence spread approach suggests a need to create pilot implementation nodes in each region or cluster, such as the UHC healthcare networks. Again, NG/CT POCT scaleup can follow from the model of the Global Fund's successful rollout of GeneXpert for TB diagnosis. Deployment of procured GeneXpert machines and related commodities, such as cartridges, began in key high-burden cities and municipalities. Ramp-up then followed by a wave sequence spread within the wider province or region, with initial sentinel sites acting as the model, mentor and enabler for the newer rapid TB diagnostic laboratories. In the past five years, budget allocation has started to shift from the Global Fund to the government. A percentage of the commodities, such as the cartridges and human resources, are already funded by national and district government units. This resulted from combined lobbying and local stakeholder commitment on seeing the impact of testing on local TB incidence. In the era when the Philippines is moving away from verticalization to integration, piggybacking delivery through the rapid TB diagnostic laboratories could harness economies-of-scale and maximize the existing public physical and soft infrastructure.

Third, coupling operations research – a subset of implementation science – with the nationwide

rollout will help in the continuous improvement of the model. Using models, such as the popular RE-AIM framework (reach, effectiveness, adoption, implementation and maintenance), can guide the implementation towards sustainable adoption. Such studies may use routine monitoring and evaluation data, supplemented by qualitative data from patients, healthcare workers and programme managers. Strategies can then be calibrated to respond to the evolving needs on the ground. Evidence-informed iterations of the model could be achieved to optimize its delivery. With well-documented operations performance, additional funding can be sought for further scale-up.

#### The Story of GeneXpert by Cepheid

A good example of a success story of first-mover advantage through a government partnership is that of the GeneXpert TB assay, by Cepheid. The Philippine government deployed many GeneXpert machines across the country for the detection of TB cases. When introduced to the market, the GeneXpert TB assay was revolutionary in its ability to accurately detect both the disease and drug resistance. AMR is a growing concern among the TB community; thus, a more reliable test was heavily advocated by both local and international experts, as well as local NGOs, which ultimately pressured the government to adopt this new diagnostic strategy.

### **ANNEXES**

## ANNEX 1: SUPPLEMENTARY INFORMATION ABOUT THE METHODS USED

#### **Porter's Five Market Forces Analysis**

Porter's Five Market Forces Analysis was used to provide a comprehensive overview of the industry environment for an NG/CT POCT. It also examined the market forces relevant to the introduction of any new diagnostic test.

#### Stakeholder mapping

A stakeholder power/interest grid was developed to visualize each stakeholder's power to affect decision-making and their interest in adopting an NG/CT POCT. The current and potential roles of each stakeholder were also described.

#### Data management, processing and analysis

All data collected were stored in a multiple-authentication secure cloud environment, accessible only to the client, consultants and project staff members. External copies of the data, as a backup, were stored and only shared within a multiple-authentication external storage system owned by metaHealth Insights and Innovations, Inc.

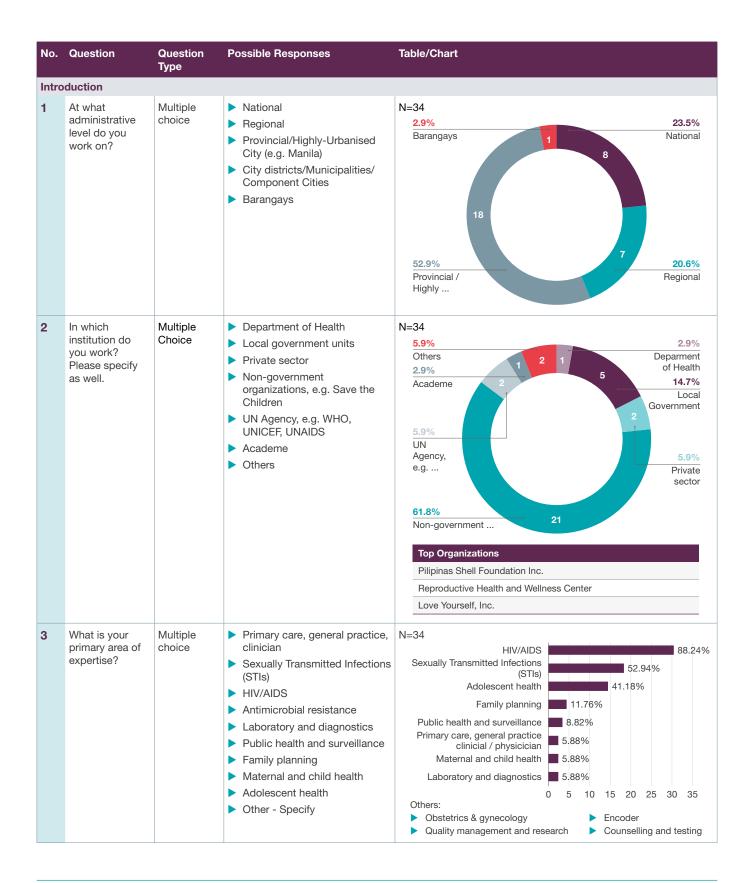
For the desk review, all relevant literature was stored in a single EndNote X8.2 library. Formal and informal web-based databases and repositories were searched. This supplemented the formal, structured literature search strategies conducted within academic databases (e.g. MEDLINE, HERDIN).

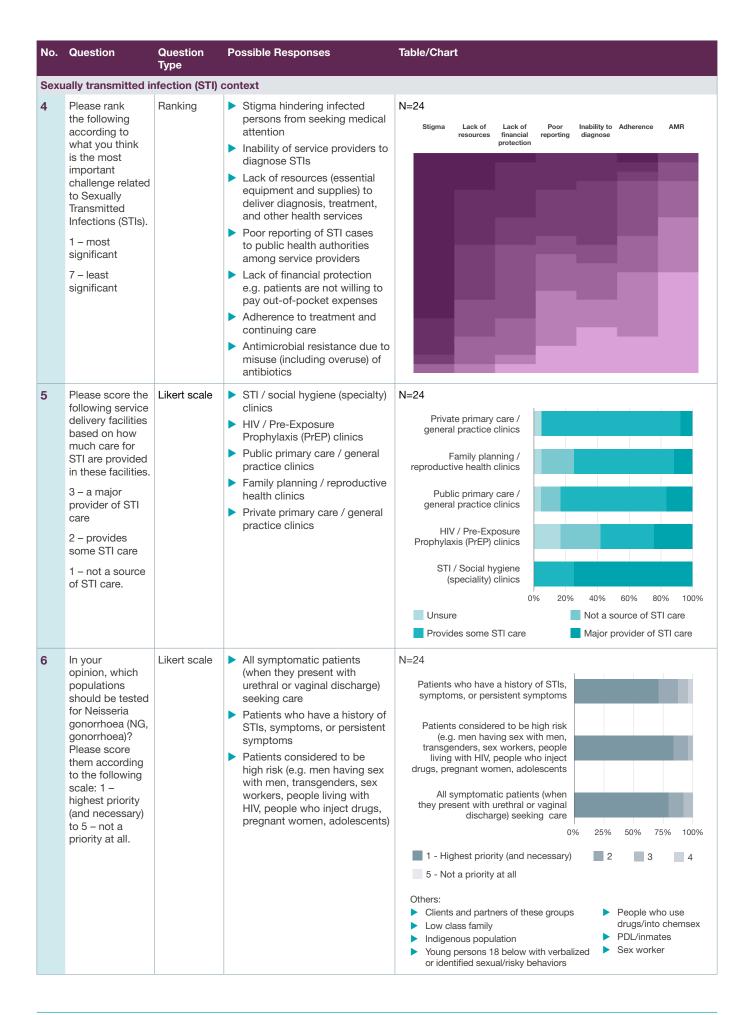
Surveys and questionnaires were administered and stored within SurveyMonkey. Key interviews were largely conducted via Zoom and were recorded as mp4 files. All statistical analyses of disease burden and mathematical projections of market size were performed using the R 3.6.3 statistical programming platform. In consideration of one of the key deliverables of this project, Microsoft Excel-365 worksheet templates were developed to make the processes and results, especially the market-sizing methodology, transparent and accessible to the client.

## ANNEX 2: ORGANIZATIONS INCLUDED IN THE KEY INFORMANT INTERVIEWS

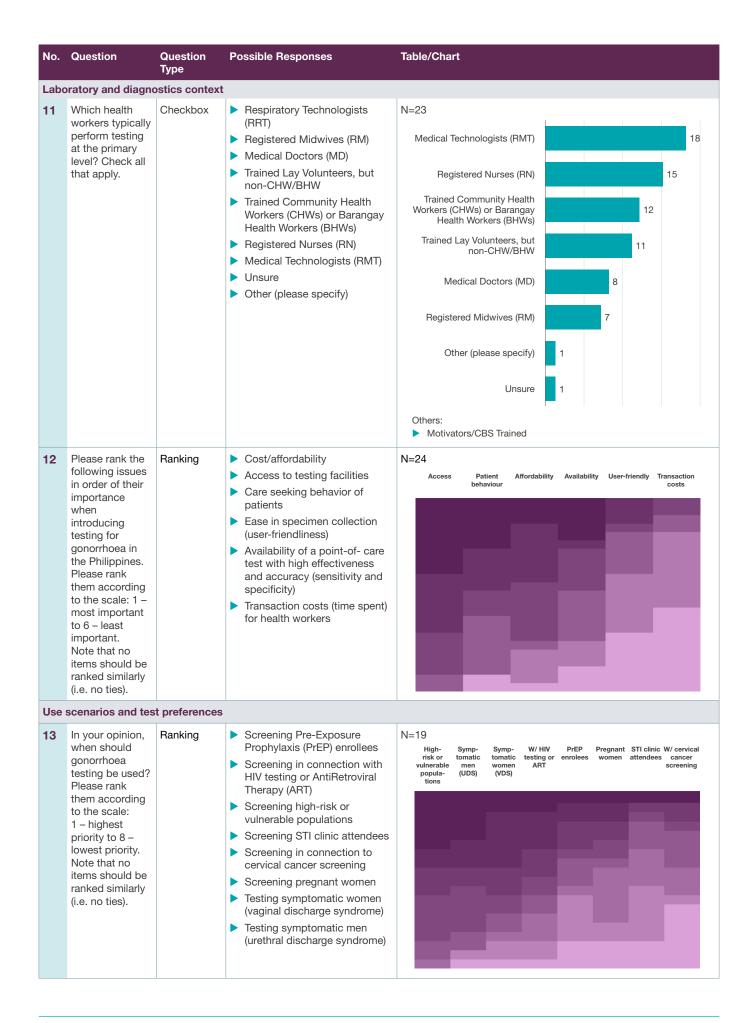
Key interview category	Organization	
National AMR Program	DOH National AMR Program	
Regulatory	Center for Device Regulation, Radiation Health and Research, Food and Drug Administration	
	UNAIDS Philippines	
	UNICEF Philippines	
International NGO and UN Agency	UNFPA Philippines	
	WHO Western Pacific Regional Office	
	Women's Global Network for Reproductive Rights	
Donor Agency (i.e. Global Fund partner)	Philippine Business for Social Progress (Global Fund Local Partner)	
	Klinika Bernardo Social Hygiene Clinic (SHC), Quezon City Health Department	
Provincial and city (HUC) STI programme manager	Cebu City SHC	
	Las Pinas City SHC	
City (component city) and	Cainta, Rizal SHC	
municipal health unit	Glan RHU, Sarangani	
Outreach worker	Talisay City SHC	
Non-profit service provider	AIDS Society of the Philippines	
and local NGO	Family Planning Organization of the Philippines	
Private hospital	Makati Medical Center	
Private diagnostic laboratory	Aventus Medical Care/Singapore Diagnostics (clinics, polyclinics and laboratory chains)	
Professional society	Philippine Society for Microbiology and Infectious Diseases	
Diagnostic supplier	Cepheid Diagnostics (GeneXpert manufacturer)	

## ANNEX 3: SURVEY SUMMARY OF RESULTS





No.	Question	Question Type	Possible Responses	Table/Chart
7	What STI testing method/s is/are currently used Level 3 (tertiary) hospitals? Check all that apply.	Checkbox	<ul> <li>None of the above</li> <li>Microscopy / gram staining</li> <li>Rapid diagnostic test (RDT)</li> <li>Culture</li> <li>Molecular testing</li> <li>Unsure</li> <li>Other (please specify)</li> </ul>	Barangay   Health   Health   Health   Health   Hygiene   (primary)   hospitals
Antir	nicrobial resistand	ce (AMR) con	ext	
8	Are you aware of the national Antimicrobial Resistance (AMR) strategy in the Philippines?	Multiple Choice	▶ Yes ▶ No	N=23  10 43.5% Yes
9	Please rank the following according to what you think is the main priority and/or activity around Antimicrobial Resistance (AMR). Please rank them according to the scale: 1 – highest priority to 6 – lowest priority. Note that no items should be ranked similarly (i.e. no ties).	Ranking	<ul> <li>Strengthening surveillance and laboratory capacity</li> <li>Ensuring uninterrupted access to essential medicines of assured quality</li> <li>Regulation and promotion of rational use of medicines and antibiotic stewardship</li> <li>Infection prevention and control (IPC) measures</li> <li>Innovation, research, and development</li> <li>Risk communication</li> </ul>	N=23  Access to Surveillance Regulation IPC Risk R&D measures Communication
10	On a scale of 1 (not at all concerned) – 5 (extremely concerned), how concerned are you with drug-resistant gonorrhoea and chlamydia?	Likert scale		N=23  4.3% 3  7 30.4% Extremely concerned



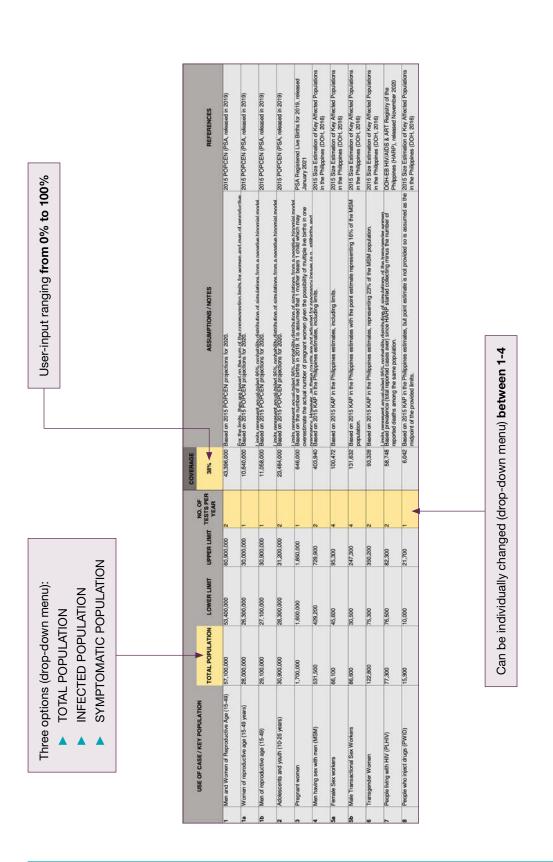
Assume that the Department of Health has of hallons guidelines and replaced syndromic management of vagnaria and ruerbral	No.	Question	Question Type	Possible Responses	Table/Chart
F100 F200 F300 F400 F300 F600 F700 F600	14	the Department of Health has a new set of national guidelines and replaced syndromic management of vaginal and urethral discharge with a strategy that requires testing for gonorrhoea before treatment. In your opinion, what is the maximum price (in PHP) that the Department of Health should pay for a point-of-care gonorrhoea test given the following characteristics? As a reference value, you may consider that standard HIV rapid diagnostic test (RDT) in the Philippines costs PHP 200 on average per		provider-collected vaginal swabs for women, or urine for men. It is a lateral flow test (similar to HIV and malaria rapid diagnostic tests) but it requires a special reader to see the results. The reader is a simple battery-operated device. It is relatively easy to operate, the needed training will only be similar to an HIV rapid test or a HemoCue.  b) In addition to the previous characteristics, it is known to have a <30 min turnaround time.  c) Furthermore, it is known to have the following diagnostic performance. Sensitivity: It can correctly diagnose more than 80 out of the 100 gonorrhoea-positive patients Specificity: It could correctly identify more than 95 out of the 100 gonorrhoea-negative patients i.e. Can diagnose gonorrhoea in both symptomatic men and women, but chlamydia only in	New RDT    Ease of specimen collection only

15 Assume that the Department of Health has a new set of national guidelines and decided to screen certain high-risk or vulnerable populations (e.g. men having sex with men, transgenders, sex workers, people living with HIV, people who inject drugs, pregnant women, adolescents) for gonorrhoea and chlamydia. For this scenario, some of the population will be asymptomatic, and therefore a highly sensitive test (i.e. can correctly identify positive patients) is needed. In your opinion, what is the				
a) It can use a variety of samples (urine, genital swabs) in men and women and cacided to screen certain high-risk or vulnerable populations (e.g. men having sex with men, transgenders, sex workers, people living with HIV, people who inject drugs, pregnant women, adolescents) for gonorrhoea and chlamydia. For this scenario, some of the population will be asymptomatic, and therefore a highly sensitive test (i.e. can correctly identify positive patients) is needed. In your opinion, what is the	No. Question	Question Type	n Possible Responses	Table/Chart
(in PHP) that the Depart-	Assume the the Depart of Health he new set of tional guide and decide screen cerhigh-risk of vulnerable lations (e.g., having sex men, transing ders, sex vers, people with HIV, people with a highly set test (i.e. care correctly ic positive pais needed. your opinic what is the maximum (in PHP) the the Depart ment of He should pay a point-ofgonorrhoeal and chlamitest given in following cacteristics reference we you may consider the HIV	at ment las a na- elines ed to tain r population men with gen- vork- eliving eople drugs, yom- cents) noea ydia. enar- f the will omat- refore nsitive an elentify titients) In pon, elentify titients in the for care at - ealth of for care a ydia the har- ? As a yalue, ponsid s PHP apid test 19 vices are and y the orato- uiring y 2	<ul> <li>a) It can use a variety of samples (urine, genital swabs, extra genital swabs) in men and women. It is a heat stable, disposable molecular test cartridge that runs on a battery-operated, rechargeable, portable instrument. It is relatively easy to operate, i.e. "sample in, answer out".</li> <li>b) In addition to the previous characteristics, it is known to have a &lt;30 min turnaround time.</li> <li>c) Furthermore, it is known to have the following diagnostic performance. Sensitivity: It can correctly diagnose more than 95 out of the 100 gonorrhoea-positive patients Specificity: It could correctly identify more than &gt;98 out of the 100 gonorrhoeanegative patients i.e. Can diagnose both gonorrhoea and chlamydia in both symptomatic men and women and can further detect asymptomatic gonorrhoea and</li> </ul>	N=18  New POC Molecular

No.	Question	Question Type	Possible Responses	Table/Chart	
16	For each of the following statements, please indicate your level of agreement.	Likert Scale	<ul> <li>Syndromic management is not ideal, but it is okay. It does not need to be replaced urgently; there are other more pressing priorities.</li> <li>If we had more funding, we</li> </ul>	N=19  It is critical that we replace syndromic management of male urethral discharge with test-based treatment.	
	Please score them according to the following scale: 4 –		would prioritize testing for gonorrhoea; however, with limited funding, we have to focus on other priorities.	Syndromic management is not ideal, but it is okay. It does not need to be replaced urgently; there are other more pressing priorities.	
	strongly agree; 3 – agree; 2 – disagree; 1 – strongly disagree.		➤ The burden of asymptomatic gonorrhoea is a higher priority than replacing syndromic management with test-based treatment.	If we had more funding, we would prioritise testing for gonorrhoea; however, with limited funding, we have to focus on other priorities.	
			► I am concerned that meaningful levels of resistance to first-line gonorrhoea treatments exist in our country, and these are currently not being detected.	The burden of asymptomatic gonorrhoea is a higher priority than replacing syndromic management with test-based treatment.	
			<ul> <li>Over-diagnosis of gonorrhoea should be a top priority for our STI program.</li> <li>Concerning etiological</li> </ul>	I am concerned that meaningful levels of resistance to first'line gonorrhoea treatments exist in our country, and these are currenlty not being detected.	
			diagnosis of STIs, it makes sense to focus first on gonorrhoea testing, given the threat of drug resistance.	Over diagnosis of gonorrhoea shold be a top priority for our STI program.	
			It is critical that we replace syndromic management of vaginal discharge with test- based treatment.	Concerning etiological diagnosis of STIs, it makes sense to focus first on gonorrhoea testing, given the threat of drug resistance.	
			It is critical that we replace syndromic management of male urethral discharge with test-based treatment.	It is critical that we replace syndromic managment of vaginal discharge with test-based	
			A test that detects gonorrhoea only has limited utility. We need a test that detects, at a minimum, gonorrhoea and oblamudia.	treamtment.  It is critical that we replace syndromic management of male urethral	
			chlamydia.  It is critical to have a point-of-care test for gonorrhoea that is easy to use, widely deployable, and rapid (<30	A test that detects gonorrhoea only has limited utility. We need a test that detects, at a minimum,	
			min).  It is critical to have a point-of-care test that can detect drug resistance to gonorrhoea.	It is critical to have point-of-care test ofr gonorrhoea, that is easy to	
			The asymptomatic burden of STIs should be an urgent priority in our country.	use, widely deployable, and rapid (<30 min).	
				It is critical to have a point-of-care test that can detect drug resistance to gonorrhoea.	
				The asymptommatic burden of STIs should be an urgent priority in our country.	
				1 - Strongly Disagree 2 - Diasagree	
				3 - Agree 4 - Strongly Agre	ee

No.	Question	Question Type	Possible Responses	Table/Chart	
17	Which of these test options is your most preferred option to use for diagnosis of symptomatic individuals only (based solely on syndromic management of vaginal and urethral discharge)?	Checkbox	<ul> <li>None. Our country is unlikely to perform any gonorrhoea diagnostic testing in the near future.</li> <li>Other (please specify)</li> <li>Near-patient molecular testing</li> <li>New rapid diagnostic test for gonorrhoea (possibly chlamydia in women only)</li> <li>Existing rapid diagnostic tests</li> <li>Laboratory-based molecular testing</li> <li>New point-of-care molecular test for gonorrhoea and chlamydia</li> <li>Gram stain</li> </ul>	N=19  Gram stain  New point-of-care molecular test for gonorrhoea and chlamydia  Laboratory-based molecular testing  Existing rapid diagnostic tests	68.42% 9 47.37% 9 42.11% 8
				New rapid diagnostic test for gonorrhoea (possibly chlamydia in women only)	26.32% 5
				Near-patient molecular testing	15.79% 3
18	Which of these test options is your most preferred option to use for screening asymptomatic high-risk or	Checkbox	<ul> <li>Other (please specify)</li> <li>None. Our country is unlikely to perform any gonorrhoea diagnostic testing in the near future.</li> <li>Gram stain</li> <li>Near-patient molecular testing</li> </ul>	N=19  New point-of-care molecular test for gonorrhoea and chlamydia	63.16 12
	vulnerable populations?		<ul> <li>New rapid diagnostic test for gonorrhoea (possibly chlamydia in women only)</li> <li>Existing rapid diagnostic tests</li> <li>Laboratory-based molecular testing</li> </ul>	Laboratory-based molecular testing  Existing rapid	42.11% 8
			New point-of-care molecular test for gonorrhoea and chlamydia	diagnostic tests	31.58% 6
				New rapid diagnostic test for gonorrhoea (possibly chlamydia in women only)	26.32% 5
				Near-patient molecular testing	26.32% 5
				Gram stain	21.05% 4

# ANNEX 4: FLEXIBLE AND DYNAMIC MS EXCEL SPREADSHEET FOR MARKET SIZING

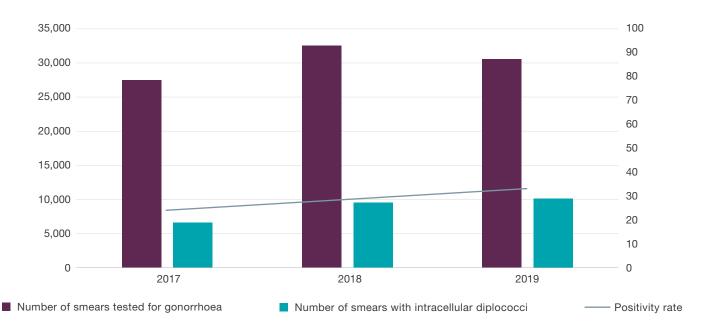


► The ASSUMPTIONS/NOTES column details the sources and/or calculations of the population size (including limits) estimates.

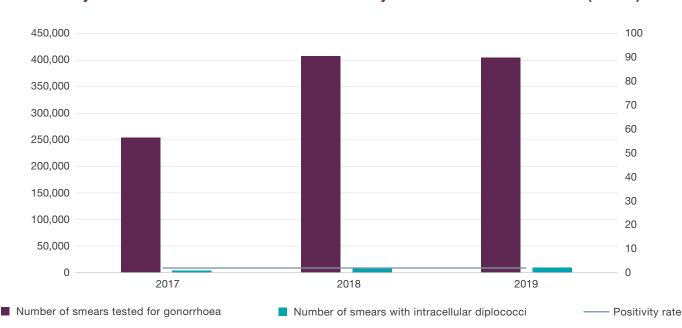
The COVERAGE column provides projected mean (point estimate) of the market size for the corresponding population according to the selected number of tests per year and the user-input coverage. Lower and upper limits for the projected number of tests are not provided in this table but can be computed in a similar way to the mean market-size estimates but applied to the corresponding population size limits.

## ANNEX 5: LABORATORY AND BLOOD BANK SURVEILLANCE DATA ON GONORRHOEA TESTING

Smears tested for gonorrhoea and smears positive for gonorrhoea among males from January 2017 to December 2019 from the Laboratory and Blood Bank Surveillance (LaBBS).



Smears tested for gonorrhoea and smears positive for gonorrhoea among females from January 2017 to December 2019 from the Laboratory and Blood Bank Surveillance (LaBBS).



## ANNEX 6: ROLES OF HUMAN RESOURCES IN STI SERVICE DELIVERY

Human resource	Roles and functions	Training requirements
Clinic manager/ medical doctor	<ul> <li>Acts as overall administrator of the clinic</li> <li>Supervises and assists clinic staff</li> <li>Conducts history-taking and physical examination</li> <li>Collects necessary specimens</li> <li>Provides effective and appropriate diagnosis, treatment and counselling</li> <li>Coordinates with the city/LGU coordinator in planning, implementing and monitoring STI/HIV control programme</li> <li>Advocates for support</li> <li>Coordinates with referral agencies for cases outside the scope of expertise of the SHC</li> <li>Provides technical assistance to peripheral RHUs and BHSs on syndromic STI management</li> <li>Updates self with the latest technology/developments</li> </ul>	<ul> <li>Comprehensive STI/HIV/AIDS management for doctors</li> <li>HIV counselling and testing</li> <li>Behaviour change communication</li> <li>Continuing medical education related to STIs/HIV/AIDS</li> </ul>
Nurse/midwife	<ul> <li>Ensures acceptable and appropriate physical clinic set-up</li> <li>Assists the doctor in history-taking, physical examination and specimen collection/labelling</li> <li>Performs routine biomedical checks (blood pressure, weight, temperature)</li> <li>Ensures specimens are transported to and processed in the laboratory immediately after collection</li> <li>Dispenses medicines correctly based on a doctor's prescription</li> <li>Ensures that instructions given by the doctor are understood by the client</li> <li>Provides counselling</li> <li>Ensures accurate entries in clinic forms and logbooks</li> <li>Supervises reporting and record-keeping</li> <li>Assists the doctor in clinic logistics inventory, e.g. supplies/materials and other consumables</li> <li>Manages the flow of clients during consultations</li> <li>Ensures infection control measures and adherence to universal precautionary practices</li> <li>Updates self with the latest technology/developments</li> </ul>	<ul> <li>Comprehensive STI/HIV/AIDS management</li> <li>HIV counselling and testing</li> <li>Behaviour change communication</li> <li>Continuing medical education related to STIs/HIV/AIDS</li> </ul>

Human resource	Roles and functions	Training requirements
Medical technologist	<ul> <li>Conducts laboratory testing</li> <li>Ensures proper handling, storage and labelling of specimens</li> <li>Ensures the accuracy of the tests</li> <li>Ensures standardized performance of tests and procedures</li> <li>Performs quality control procedures for all laboratory tests</li> <li>Ensures adequate reagents and supplies and optimum functionality of equipment</li> <li>Ensures proper sterilization and disinfection of laboratory and clinic equipment</li> <li>Adheres to manufacturer's instructions or protocols regarding equipment and supplies</li> <li>Updates self with the latest technology/developments</li> </ul>	<ul> <li>Proficiency training in HIV and other blood-borne diseases</li> <li>Refresher course on basic STI laboratory testing</li> </ul>
Outreach worker	<ul> <li>Conducts outreach, prevention, education and contact tracing</li> <li>Accesses MARPs or liaises with NGOs tasked by the LGU to track hard-to-reach MARPs</li> <li>Serves as link between clients, clients' partners and health providers</li> <li>Recruits, trains and supervises peer educators</li> <li>Advocates for community support</li> <li>Updates self with the latest technology/developments</li> </ul>	<ul> <li>Peer education</li> <li>HIV counselling and testing</li> <li>Behaviour change communication</li> </ul>
Clerk/record custodian/ laboratory aide	<ul> <li>Takes care of all documents once they have been completed by relevant SHC staff</li> <li>Ensures that all medical records/files/logbooks are kept confidential and well-maintained</li> <li>Maintains the cleanliness and hygienic condition of the laboratory and examination room and the overall satisfactory condition of the SHC</li> </ul>	► Data management

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