

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

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ABBREVIATIONS

AGYW	Adolescent girls and young women	MSW	Male sex workers
AIDS	Acquired immunodeficiency syndrome	MTCT	Mother-to-child transmission
AMR	Antimicrobial resistance	N/A	Not applicable
AMREF	African Medical and Research Foundation	NACC	National Aids Control Council
ANC	Antenatal care	NAP	National Action Plan, Kenya
ART	Antiretroviral therapy	NASCOP	National AIDS & STI Control Programme
ASP	Antimicrobial stewardship programs	NASIC	National Antimicrobial Stewardship Interagency Committee
BMGF	Bill & Melinda Gates Foundation	NCD	Noncommunicable disease
CDC	Centers for Disease Control and Prevention	NG	Neisseria gonorrhoea
CHAI	Clinton Health Access Initiative	NGO	Non-governmental organization
CT	Chlamydia trachomatis	NHIF	National Hospital Insurance Fund
DHIS	District Health Information System	NHLS	National Public Health Laboratory
DHIS2	District Health Information System 2	NMRL	National Microbiology Reference Laboratory
DHS	Kenya Demographic Household Survey	PEPFAR	President's Emergency Plan for AIDS Relief
EAC	East African Community	PHC	Public health centres
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation	PID	Pelvic inflammatory disease
FBO	Faith-based organization	PLHIV	People living with HIV
FP	Family planning	PMTCT	Prevention of Mother to Child Transmission (unit within NASCOP)
FSW	Female sex worker	POC	Point of care
GARP	Global Antibiotic Resistance Partnership	PrEP	Pre-exposure prophylaxis
HCW	Healthcare worker	PWID	People who inject drugs
HIV	Human immunodeficiency virus	SC	Steering Committee
HPV	Human papillomavirus	SRH	Sexual reproductive health
HTS	HIV testing services	STC	Special treatment centre
HVOP	High volume order processing	STI/STD	Sexually transmitted infection (Sexually transmitted disease)
ICRHK	International Centre for Reproductive Health Kenya	TB	Tuberculosis
KEMRI	Kenya Medical Research Institute	TPP	Target product profile
KEMSA	Kenya Medical Supplies Authority	TV	Trichomonas vaginalis
KP	Key populations	UNAIDS	United Nations Programme on HIV/AIDS
KSI	Key stakeholder interviewee	UNFPA	United Nations Population Fund
LFA	Lateral flow assay	WHO	World Health Organization
MEDS	Mission for Essential Drugs and Supplies		
MOH	Ministry of Health		
m2m	mothers2mothers		
MSM	Men who have sex with men		

EXECUTIVE SUMMARY

In Kenya, national estimates for sexually transmitted infections (STIs), specifically gonorrhoea, are mostly unknown, as there is no routine reporting done by facilities nor are broadly representative prevalence surveys being performed. Available estimates for the general population come from the 2014 Kenya Demographic Household Survey, while scientific journal articles only offer estimates for targeted populations. Despite the lack of data, Kenya's generalized HIV epidemic and documented vulnerable populations indicate that STIs are a public health concern.

STIs are managed by the Prevention of Mother to Child Transmission (PMTCT) unit within Kenya's National AIDS and STI Control Programme. Although HIV is both a biological and behavioural risk factor for STIs, the country has recently started to recognize the importance of strengthening STI services as a whole, following new guidelines (2018), and is in the process of developing an HIV and STI surveillance strategy. However, STIs are still overshadowed and deprioritized compared with HIV due in part to PMTCT prioritization of the triple elimination of mother-to-child transmission of HIV, viral hepatitis, and syphilis.

Currently, only syndromic management of STIs is being practiced in Kenya. As per the 2018 STI guidelines, patients are to be prescribed four different treatments, and must have symptoms for 14 days before they are referred for diagnostic testing. There are no recent records of this occurring within the public sector. Facilities cite long test turnaround times, weak referral networks, and a perceived lack of capacity within the National Public Health Laboratory (NPHL) system as the reasons why etiological testing is not being done. Costs are also a barrier to such testing, all of which explains why syndromic management is considered an effective and cost-efficient practice.

To determine the market accessibility for a point-of-care (POC) *Neisseria gonorrhoea* and *Chlamydia trachomatis* (NG/CT) test, a mixed methods research design was used, which included an extensive desk review of STIs, antimicrobial

resistance (AMR) reports and documents, analysis of available prevalence data, and 14 interviews with 17 key stakeholders. Building upon a methodology established by the World Health Organization (WHO) to quantify STI prevalence and incidence¹, the potential market size for the two test profiles, and their use cases, are summarized in this report.

Of the two potential POC test profiles, TPP1 Minimal (sensitive enough to confirm NG/CT within symptomatic patients) and TPP1 Optimal (sensitive enough to confirm NG/CT within asymptomatic patients), TPP1 Minimal judged to be the most feasible to introduce in Kenya. Twenty different use cases for the two test profiles were discussed by the key stakeholder interviewees (KSI), with potential market size for six uses cases forecasted, based on the frequency the use cases were recommended.

The potential demand for TPP1 Minimal ranged from ~197,000 tests/year targeting pregnant women presenting with symptoms, to ~1.7 million tests per year should the test be available for anyone presenting with symptoms of NG/CT. This likely represents the upper bounds of the potential market size; an influential interviewee from the Ministry of Health (MOH) suggested that, due to cost and limited human resources capacity, testing would occur only at higher-level facilities for individuals whose symptoms persist after initial syndromic management.

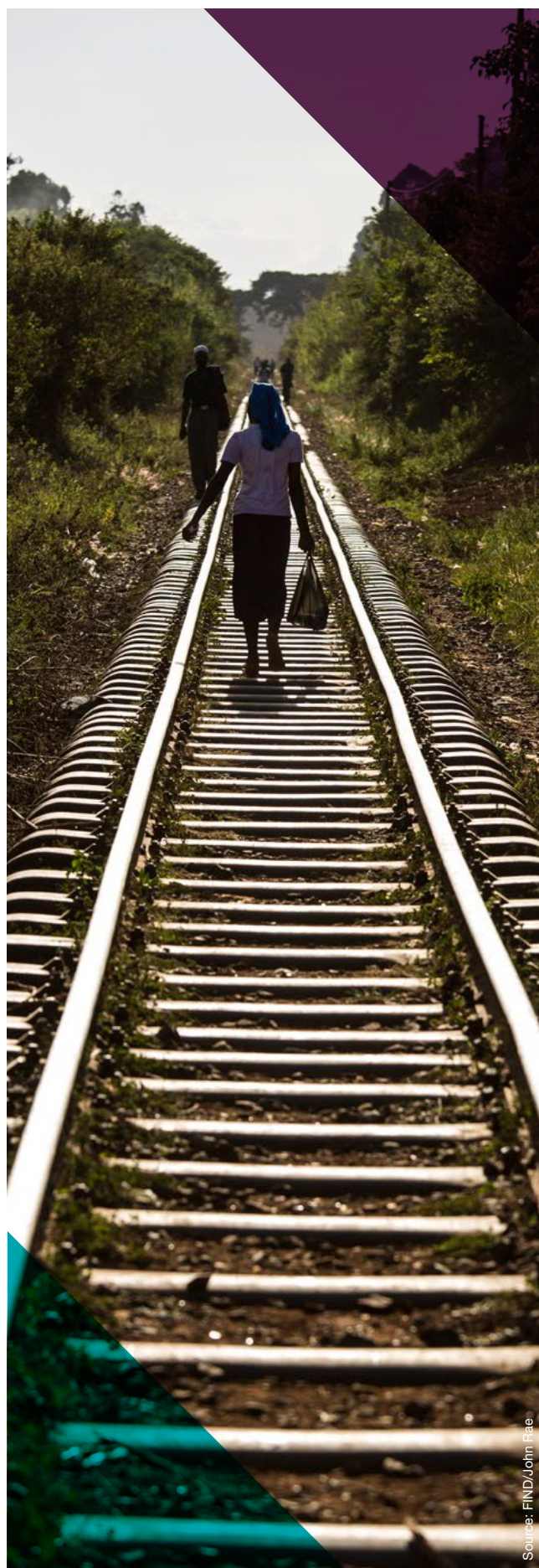
The potential market size for TPP1 Optimal ranged from ~200,000 tests/year reaching pregnant women to ~1.7 million tests a year if funding is available for screening high-risk populations. While the use case discussed among the KSIs explored specific facility-level implementation, the market sizing methodology only considered total potential demand, without taking into consideration other factors such as adoption of etiological testing and implementation management. When evaluating the estimated market size for such a test, it is essential to note that the use cases discussed have overlaps within the populations, and so they cannot be considered cumulatively. Additionally, these figures reflect a potential total market size; actual demand would likely be much lower.

For both test profiles, KSIs cited concerns about the cost of the tests, sample collection methods, integration into the workflow of a health facility, and had questions regarding which cadre would conduct the testing.

Additional data regarding the prevalence of STIs and evidence of emerging AMR are needed to facilitate the country's adoption of a POC test for NG/CT and shift the country's STI management preference from syndromic to etiological. Additionally, significant resources would be required to introduce the new test, as the STI guidelines have generally not been well disseminated, and the skills of health providers and, to a lesser extent, laboratory technicians need to be refreshed. Overtreatment of STIs and linkages to drug resistance are not immediate priorities in Kenya, although there is a dearth of data to inform these opinions. Similarly, the asymptomatic burden of STIs is not a major concern for the MOH.

A new study (the East African Community Boresha Huduma STI study) promises to fill some of the evidence gaps on the STI situation in Kenya. Phase 1 is being led by the Swedish International Development Cooperation Agency (Sida), and phase 2 includes prevalence by syndrome and the conduct of antimicrobial susceptibility testing. Updating WHO guidance might also promote NG testing in Kenya. However, the cost of this testing was deemed prohibitive, and the scope will be limited without donor support, which is unlikely, given decreasing funding for HIV/STI programmes.

For now, gonorrhoea diagnosis is low on the list of MOH priorities, as illustrated by its exclusion from the STI framework currently in development, a strategy that will focus solely on syphilis and hepatitis. Kenya also lags in AMR programming at the health facility level and as such the MOH is unlikely to prioritize NG testing for antibiotic stewardship reasons in the near term. Adoption of etiological testing, beginning with NG, will be a hard sell in Kenya, and one that first requires significant investment in expanding the evidence base, i.e. conducting nationally representative prevalence surveys, etiological surveys to assess syndromic management, and NG drug resistance monitoring. From there, pilot studies would be needed in different settings to look at outcomes, acceptance, and cost effectiveness.



Source: FIND/John Hae

OBJECTIVES AND METHODS

In low-resource settings where clinical diagnosis is often unavailable, providers generally rely on syndromic management of symptomatic patients with suspected STIs, which leads to both under- and overtreatment. It should be noted that WHO recommends expanding syndromic management of NG/CT to etiologic testing where feasible and cost-effective². To enable etiological case management, FIND is supporting the development of POC tests for NG and CT.

In early 2019, FIND completed a high-level global market assessment to size and understand the potential market for such tests. Despite the substantial need for testing (i.e. a high volume of people eligible for NG testing), there is significant uncertainty around the magnitude of actual demand for a new test, as well as concern about potential access barriers to the launch and roll-out of the two POC tests in high-priority LMICs. For these reasons, FIND is undertaking a more in-depth market assessment in selected countries - South Africa, Thailand, Vietnam, Papua New Guinea, Philippines, Zambia, and Kenya.

The Kenya assessment, following previous country assessments, was structured around the following objectives:

- ▶ **Understand the current national STI context**
 - + STI/NG public health burden, epidemiology and surveillance, current clinical practices, country guidelines and algorithms, stakeholders mapping, and NG funding mechanisms
- ▶ **Determine the potential use scenarios and market for an NG/CT POC test**
 - + Key market access challenges, potential market interventions to be done by FIND and partners, and identify drivers of demand and build demand forecast
- ▶ **Estimate the market size for an NG POC test in Kenya**

Methods used to achieve these objectives included:

1. extensive desk review of reports, strategic STI and AMR documents, and selected literature on STIs, HIV, and AMR in Kenya and East Africa;
2. review and analysis of data, including STI incidence estimates, etiological and resistance survey data, and recent household survey data; and
3. fourteen interviews (11 in person and 3 by phone) with 17 key stakeholders conducted between January and April 2020

GONORRHOEA AND SEXUALLY TRANSMITTED INFECTION BURDEN AND EPIDEMIOLOGY IN KENYA

Available STI estimates come from the 2014 Kenya Demographic Household Survey (DHS) among the general population, or from scientific journal articles among targeted populations³. From the 2014 Kenya DHS⁴, 2% of both men and women self-reported⁵ having any STI in the past 12 months (~560,000 adults). Participants were also asked if they had experienced any symptoms of an STI in the past 12 months, to which 2% of men, and 6% of women

responded yes (~1.1 million). Among key populations (KPs), approximately 20% of sex workers in Mombasa presenting for care at drop-in centres have at least 1 STI as defined by self-reported abnormal vaginal discharge, or genital ulcer/sore⁶.

Scientific journal articles targeting several different populations and settings have reported a range of NG prevalence, from 0% to 15%, as shown in Table 1.

Table 1: Journal findings of *Neisseria gonorrhoea* prevalence in Kenya

Study author	Year of publication	Location	Population type	Sample selection site	NG prevalence	CT prevalence	TV prevalence	Proportion asymptomatic
Maina et al. ⁷	2016	Nairobi	Women seeking family planning	Family planning clinics	0%	13%	0.4%	64% (vaginal discharge)* 67% (lower abdominal pain)*
Masha et al. ⁸	2017	Kilifi County	Pregnant women	ANC clinics	1%	14.9%	7.4%	76% (abnormal vaginal discharge)** 57% (lower abdominal pain)**
Masese et al. ⁹	2017	Mombasa	Female high school and university students	High schools & universities	1.6%	3.6%	0.7%	Not available
Warr et al. ¹⁰	2019	Nyanza	Pregnant women	ANC clinics	2%	6%	5%	66%**
Musyoki et al. ¹¹	2015	Nairobi	FSW	Snowball sampling	2.30%	3.10%	N/A	Not available
Deese et al. ¹²	2019	Kisumu	Women seeking family planning	Family planning clinics	3.0% at baseline 3.3% at end line	9.3% at baseline 11.4% at end line	N/A	Not available
Muraguri et al. ¹²	2015	Nairobi	MSM	Snowball sampling	6.90%	4.10%	N/A	Not available
Muraguri et al. ¹³	2015	Nairobi	MSM	Snowball sampling	10.30%	5.90%	N/A	Not available
Winston et al. ¹⁵	2014	Eldoret	Male street children	Snowball sampling	0%	3%	2%	
Winston et al. ¹⁵	2014	Eldoret	Female street children	Snowball sampling	15%	16%	10%	95–98%**

NG, *Neisseria gonorrhoea*; CT, *Chlamydia trachomatis*; TV, *Trichomonas vaginalis*; ANC, antenatal care; FSM, female sex workers; MSM, men who have sex with men; N/A, not applicable;

* Among women testing positive for CT ; ** Among population testing positive for any STI

Broader epidemiological context

Of particular relevance to NG testing is sexually acquired HIV, as many of the factors contributing to the high HIV burden are equally relevant to STIs. In 2018, there were 1.6 million people living with HIV (PLHIV) in Kenya, with 1.4 million of them between the ages of 15–49 years¹⁶, representing a prevalence of 4.7%. In addition, there were an estimated 38,000 new HIV infections, representing an incidence of 1.62%. Sixty-nine percent of HIV-infected adults received antiretroviral therapy (ART), although this was disproportionate between men and women (59% vs 75%, respectively).

Even though Kenya has a generalized HIV epidemic, specific populations have a disproportionately high number of new HIV infections¹⁷. As identified in the Kenya Aids Strategic Framework, these include KPs, such as men who have sex with men (MSM), people who inject drugs (PWID), and sex workers (SW). Other vulnerable populations include adolescent girls and young women (AGYW), fishing communities, truck drivers, street children, people in prisons and other closed settings, people with disabilities, migrant populations (especially those that are part of a humanitarian crisis), and itinerant workers. There are an estimated 167,900 sex workers and 32,600 MSM living in Kenya, with an HIV prevalence of 29.3% and 18.3% respectively¹⁸.

As part of HIV prevention efforts, recommendations for these KPs and vulnerable populations include¹⁷:

- ▶ provision of key commodities (e.g. lubricants, condoms);
- ▶ scaling-up and sustaining needle and syringe programmes;
- ▶ initiation of medically assisted therapy for opioid dependents;
- ▶ screening and management of HPV among female sex workers (FSW)/MSM, and HBV and HCV for PWID);
- ▶ alcohol screening and addiction support;
- ▶ scaling up STI management in all health facilities; and
- ▶ provision of pre-exposure prophylaxis (PrEP) services.

PrEP services have been implemented in Kenya since 2016 with huge success. Kenya has been in the forefront of providing evidence on the efficacy, safety and feasibility of PrEP locally, regionally, and globally. As of October 2019, there were 15 ongoing and planned PrEP demonstration and implementation projects; although the majority are focused on AGYW, some projects are targeting other high-risk groups such as serodiscordant couples, FSW, and male sex workers (MSW)¹⁹. To qualify for PrEP, an individual must be at high risk for acquiring HIV. There are currently an estimated 56,000 PrEP users in Kenya, which surpasses the 2019 total of 31,047 PrEP users¹⁹. Interestingly, the provider interviewed from The Special Treatment Center in Nairobi indicated a recent drop in PrEP uptake. Some reasons for this include decreased motivation for starting PrEP (social pressure was initially high and now has waned), and side effects of the drugs.

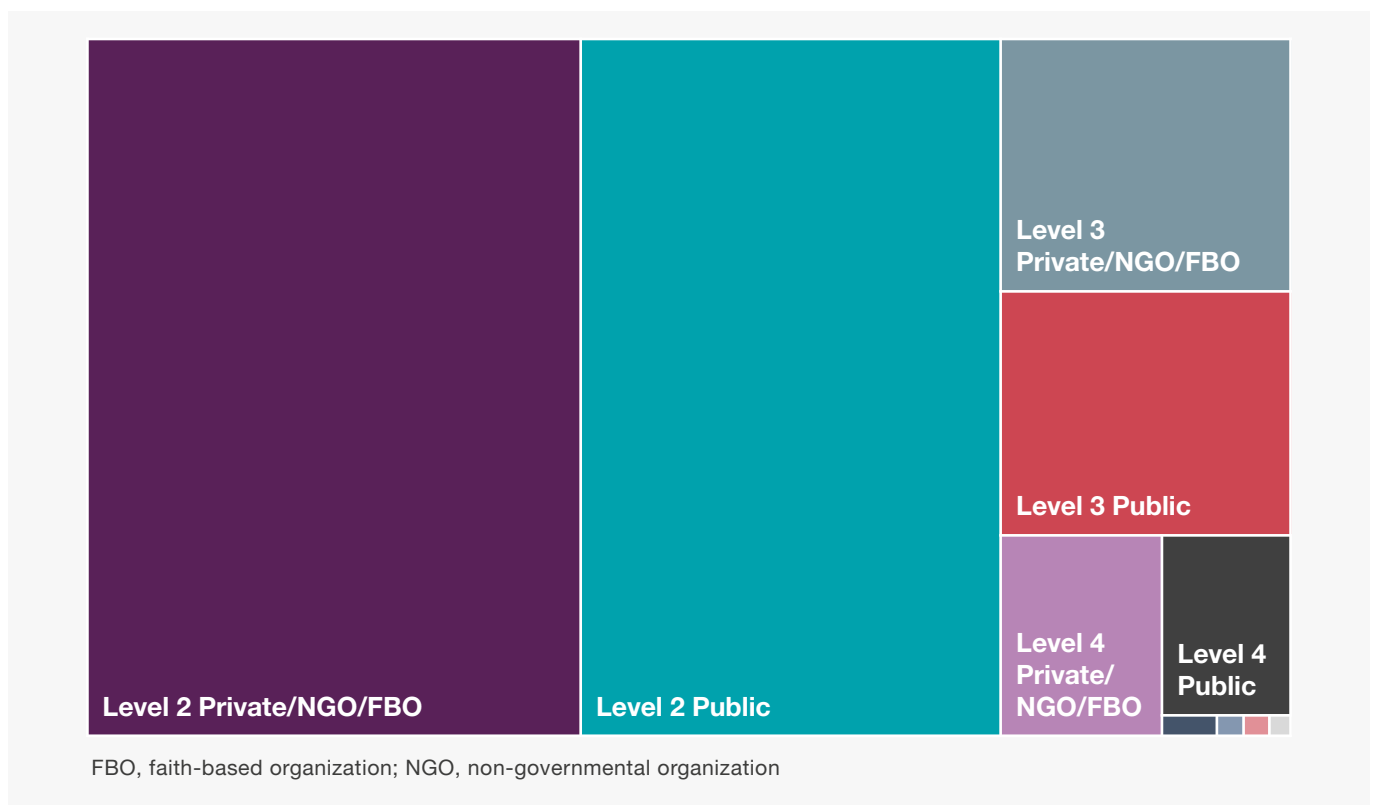
STRUCTURE OF THE HEALTHCARE SYSTEM

Public health sector

Public facilities represent the biggest potential uptake market in Kenya. The Kenyan public health sector is organized into six levels of service delivery based on the scope and complexity of services offered²⁰. Between 2010 and 2012, Kenya

devolved health and other services from the central government to 47 new county governments. County governments are responsible for service provision at levels 1–5, and the National Government is responsible for level 6.

Figure 1: Kenya health facilities structure levels 2–6



Community health services (level 1) are staffed by volunteer community health workers. Services focus on health promotion through education, treatment of minor ailments, and identification of cases for referral to primary care services²¹.

Primary care services (level 2 and level 3) offer basic outpatient care, minor surgical services, basic laboratory services, maternity care, and limited inpatient facilities. They also coordinate the

community health workers under their jurisdiction. Dispensaries (level 2) are led by nurses as the most senior member of staff. Nurses do the majority of the clinical work, although legally nurses are meant to be supervised by a clinical officer prior to diagnosing and prescribing²². STI cases are managed syndromically by nurses. If the case is too complex, they will refer to higher levels of healthcare²³. Dispensaries do not have laboratories. In 2020, there were 9,393

documented level 2 primary care facilities, 46% of which were public²⁴.

Health centres (level 3) are led by clinical officers²⁵ as the most senior members of staff. Clinical officers do the majority of clinical work, and syndromically diagnose and treat STI cases. Health centres have laboratories with the minimum required reagents and equipment. In 2020, there were 2,135 level 3 primary care facilities, 49% of which were public²⁶.

County health services offer a broad spectrum of curative services, and some are also health training centres. The County Hospital (level 4) and County Referral Hospital (level 5) are secondary referral facilities. Hospitals are led by medical officers²⁷ as the most senior members of staff. In 2020, there were 818 documented level 4, and 18 level 5 county health services, 43% and 72% of which were public, respectively²⁶.

National referral services (level 6) are tertiary referral facilities that offer specialized care and specialized training to health workers. The national government manages these facilities, but they are semi-autonomous organizations. Level 6 hospitals are also led by medical officers as the most senior members of staff. There are multiple general medical officers, in addition to specialty medical officers. In 2020, there were 6 national referral facilities, 100% of which were public²⁶ (the Kenya Master Facility List did not include the private facilities – another source indicated that in 2016 there were 12 facilities, 25% of which were public)²⁸.

Public vs private care seeking: Approximately 48% of all health facilities in Kenya are public²⁶, spread across levels 2–6 of care. However, the number of facilities doesn't directly correlate with the amount of care sought at public facilities. According to the 2014 DHS results, the majority of Kenyans seek care at these facilities (e.g. 69% of children with fever, 60% of women seeking contraception services, and 46% of births). KSIs also confirmed this claim, with some estimating that the public sector provides upwards of 80% of services²⁶.

Private health sector

Private, faith-based and non-governmental organization (FBO/NGO) facilities in Kenya are significant market segments, representing 41% (n=5309), 8% (n=1036), and 3% (n=365) of all facilities, respectively²⁶. The private sector tends to control the nursing home (level 3) and health clinic (level 2) segments, while the public and FBO/NGO sectors run most health centres (level 3) and dispensaries (level 2)²⁹.

Although private facilities account for 52% of healthcare facilities in the country, the distribution is not uniform. There are a small number of large private providers who own hospitals and clinics that offer high quality services, but they are concentrated in Nairobi, Kisumu and Mombasa³⁰; 37% of all private facilities are located in the Nairobi Metro Area and in Mombasa²⁹. Many small-scale providers offer private primary care services of varying quality. These small-scale providers are located throughout the country and serve lower- to middle-income patients; ~47% of the poorest quintile of Kenyans seek care in the private sector²⁹.

Both private and FBO/NGO facilities are generally thought to provide a better quality care compared with public facilities³¹. FBOs are run with oversight from an ecumenical partnership of the Kenya Conference of Catholic Bishops (KCCB) and Christian Health Association of Kenya (CHAK), whereas private facilities operate independently. Government agencies conduct audits of private and FBO facilities to regulate the quality of care.

The reporting of patient visits at private facilities into the Kenya Health Information System is inadequate. The Health Act requires that anyone providing health services report on the services provided; however, this reporting is not being enforced³². Therefore, it is difficult to find reliable data on the number and types of services obtained in the private health sector.

Pharmacies are another “level” of private health services where patients frequently seek care and self-medicate. Although customers are meant to present a prescription, it is quite easy to access pharmaceuticals at private facilities without one.

According to the 2014 DHS, 8% of children with fever, and 10% of women seeking contraception services presented to a pharmacy rather than seek care at a public or private healthcare facility³³.

National sexually transmitted infection response

Kenya's national STI response is split between three departments within the MOH: National Aids Control Council (NACC)³⁴, National AIDS and STI Control Programme (NAS COP), and Department of Family Health³⁵. There is no official national coordinating mechanism for these three units and programming is done in siloes.

NAS COP leads the STI response, accounting for about 80% of the country's STI programming, according to one key informant³⁵, and would be the lead if NG testing were introduced. However, in the most recent report from NAS COP, *Kenya AIDS Strategic Framework 2014/2015–2018/2019*, STIs were not included. Similarly, in the NAAC Strategic Plan, STI services are only included within the general goal of "Strengthening integration of community and health systems" and few specifics are included.

Prior to 2018, there was no STI focal person at NAS COP, and as the current Head of NAS COP, said about that time, "*the S (in NAS COP) was lost*". NAS COP was so focused on HIV that it didn't know where or how to start looking at STIs. In 2018, the current NAS COP head was the STI Program Manager at NAS COP, and STIs became a standalone unit within the programme. Recently, she was promoted to Head of Programs for NAS COP, as part of a larger NAS COP reorganization, and her former position has not been filled.

Currently, STI programming is housed under the Prevention of Mother-to-Child Transmission (PMTCT) unit within NAS COP³⁶. PMTCT's priorities relating to STIs are the triple elimination of mother-to-child transmission of HIV, viral hepatitis, and syphilis. These activities are funded through the Bill & Melinda Gates Foundation, and are initially targeting surveillance strengthening and communities, and demand creation of STI services³⁷. While syphilis and hepatitis B are the priority STIs of the unit,

other STIs may benefit from the current activities. The present PMTCT Program Manager, expressed a desire to build out programming for other STIs in the future. Echoing this sentiment, the department head indicated that the ideal scenario for STI management within NAS COP would be to have an STI officer/manager, yet lack of funding remains a constraint.

Kenya's STI response is primarily driven by the response to HIV and KP programming, with HIV routinely overshadowing other programmes. The MOH acknowledges the role STIs play in the spread of HIV and have repeatedly emphasized the link between the two. "STIs have public health importance because of their magnitude, potential complications, and their interaction with HIV/AIDS. STIs are viewed as a proxy indicator of behaviours placing people at a higher risk of acquiring and transmitting HIV infection"³⁸. In an interview, NAS COP leadership confirmed that the biggest barrier in STI work is the lack of funding for non-HIV programmes, suggesting that the national HIV response is doing well because of the funding from external partners. While conversations have been had with the President's Emergency Plan for AIDS Relief (PEPFAR) and other funders to incorporate STI programmes into existing HIV programmes, confirmed only The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) has incorporated STIs and viral hepatitis into the current funding proposal, but at a small scale.

In the absence of a strategic framework, the *2018 Kenya National Guidelines for Prevention, Management, and Control of Sexually Transmitted Infections*³⁹ is the guiding document for the national STI response. These guidelines include key programmatic considerations not included in previous guidelines, such as symptom and risk screening for STIs among KPs, health worker attitudes, integration of STI management in routine services, STI medication supply and chain management, STI treatment algorithms, and implementation of STI prevention and treatment programming³⁹.

In February 2020, a meeting to develop the first National Strategic Framework for STIs was held with the goal of completing an initial draft by March 2020⁴⁰. The framework is set to build upon the *2018*

Kenya National Guidelines and its objectives include implementing a surveillance system, conducting an AMR assessment, and integrating STI treatment and care into general service delivery⁴¹. A driving factor for completing this strategic framework is the funding from the Bill & Melinda Gates Foundation for the elimination of HIV, syphilis and viral hepatitis. The draft framework was not available for review at the time of writing this report, and it reportedly focuses only on syphilis and hepatitis. Funding for the activities laid forth in the framework has not been determined. Costing of the activities would be the next step following the finalization of the framework.

National antimicrobial resistance response

The burden of AMR within Kenya is largely unknown as no systematic surveillance has been undertaken. Barriers to completing such surveillance include laboratory capabilities, reporting systems, and laboratory personnel capacity. While most labs at level 4 and above have the resources and expertise to perform bacterial culture and sensitivity tests for common bacterial pathogens, these are not routinely conducted⁴². In the absence of established surveillance systems, the MOH has consistently followed global recommendations for combating AMR resistance and regional AMR patterns. The 2018 STI guidelines revised the first-line recommendation for the treatment of NG from quinolones to cephalosporins based on global resistance patterns, although no in-country resistance has been shown or susceptibility testing has been completed. Despite the recommendation and the government's stated commitment, NG AMR, unlike TB and HIV AMR, is not a major priority for NASCOP due to the lack of surveillance and available information within the country.

Currently, the National Microbiology Reference Laboratory (NMRL), which is a division of the NPHL system, has the resources needed to complete AMR surveillance but cites inefficient and non-compliant specimen referral systems from the country laboratories, along with lack of skilled staff, as the reasons for limited completion of such tests⁴³. From

2015 to 2016, the NMRL completed 1,725 tests, of which the majority were water samples (n=1,022; 59.2%) followed by samples for confirmation of cholera (n=297; 17.2%), while only 2.9% (n=48) of samples were used to determine the efficacy of (non-specified) treatment⁴⁴. There are plans to build this capacity both through external partner support (CDC) and within the NPHL strategic plan^{45,46}.

Several studies have indicated that antibiotic resistance within Kenya is widespread⁴⁷. The reasons for Kenya's high AMR rates include the high burden of infectious diseases, healthcare environment and behaviour, and antibiotic use in livestock. An analysis of studies by Kenya's Global Antibiotic Resistance Partnership found that within the healthcare system, a substantial fear of negative outcomes has led to widespread prescription of broad-spectrum antibiotics, as well as some self-medication. In Nairobi, over one third of residents stated that they use retail pharmacies as the first stop for outpatient care. A cross-sectional study by Mukokinya et al. evaluated the extent of self-medication of antibiotics and dispensing practices in three selected pharmacies in Nairobi between January and March 2017, focusing on antibiotics sold both with and without a prescription. Their conclusion showed that there were low levels of self-medication of antibiotics and high adherence to quality standards for dispensing⁴⁸.

The Government of Kenya has made public commitments to strengthening the national AMR response, calling AMR an international and domestic health priority. Following the adoption of the WHO *2015 Global Action Plan on AMR* (GAP), Kenya developed the National Action Plan on Prevention and Containment of Antimicrobial Resistance, 2017–2022⁴⁹ (NAP). Outlined within the NAP is a multi-sector One Health approach to AMR led by the MOH and the ministries, departments and agencies responsible for agriculture (crop, livestock, and fisheries).

In 2017, Kenya also established a National Antimicrobial Stewardship Interagency Committee responsible for policy direction, resource

mobilization, budget and work plan approval⁵⁰. Subsequent guideline documents for the AMR response, such as a Communication Strategy for

the Prevention and Containment of Antimicrobial Resistance, have also been developed (2018). The NAP has five strategic objectives (Figure 2):

Figure 2: National Action Plan strategic objectives

Strategic issue	Strategic objective			
1. Public awareness and education	Improve public awareness and understanding, and promote education and training of professionals			
2. Surveillance and monitoring	Continuously monitor antimicrobial resistance and use of antimicrobials, and appropriately understand the trends and spread of AMR			
3. Infection prevention and control	Prevent the spread of antimicrobial-resistant organisms by implementing appropriate infection prevention and control measures			
4. Appropriate use of antimicrobials	Promote appropriate use of antimicrobials in the fields of healthcare, livestock production, agriculture, and aquaculture			
5. Research and development	Promote research on AMR and foster R&D to secure the means to prevent, diagnose and treat antimicrobial-resistant infections			

Strategic intervention	Activity	Deliverables	Timeframe	Implementing organization(s)
2.1 Standardize methods of laboratory testing and strengthen testing functions of AMR at public and private laboratories	2.2.1 Assess the AMR capacity in the existing NPHL, and other relevant public and private labs	Report on AMR capacity in existing labs published	2017	MOH/MALF NPHLS NMRA
	2.2.2 Expand and strengthen the national and county infrastructure for public health surveillance	Infrastructure for public health surveillance improved	2017–2022	MOH
	2.2.3 Develop or review relevant SOPs for AMR tests	Relevant SOPs for AMR tests in use	2017	MOH/MALF NPHLS NMRA
	2.2.4 Conduct international and local training of technical personnel on monitoring, surveillance, testing methods and laboratory operations, including compliance to accreditation standards	Technical personnel trained	2017–2022	MOH/MALF NPHLS NMRA Agencies

AMR, antimicrobial resistance; MALF, Ministry of Agriculture, Land, and Forestry; MOH, ministry of health; NMRA, National Medicines Regulatory Authority; NPHL, National Public Health Laboratory; R&D, research and development; SOP, standard operating procedure

Objective 4, “Appropriate use of antimicrobials”, includes the following strategic interventions, with the MOH as the main implementing partner:

- 4.1. Develop and review guidelines and strategies to optimize and regulate use of antimicrobials
- 4.2. Implement antimicrobial stewardship programs (ASP) guidelines
- 4.3. Improve the registration, marketing authorization and post-marketing surveillance of antimicrobials
- 4.4. Foster an enabling environment for the rational use of medicines
- 4.5. Deployment of technical staff to support prudent use of antimicrobials

4.6. Ensure access to essential antimicrobial agents

4.7. Strengthen quality control capacity

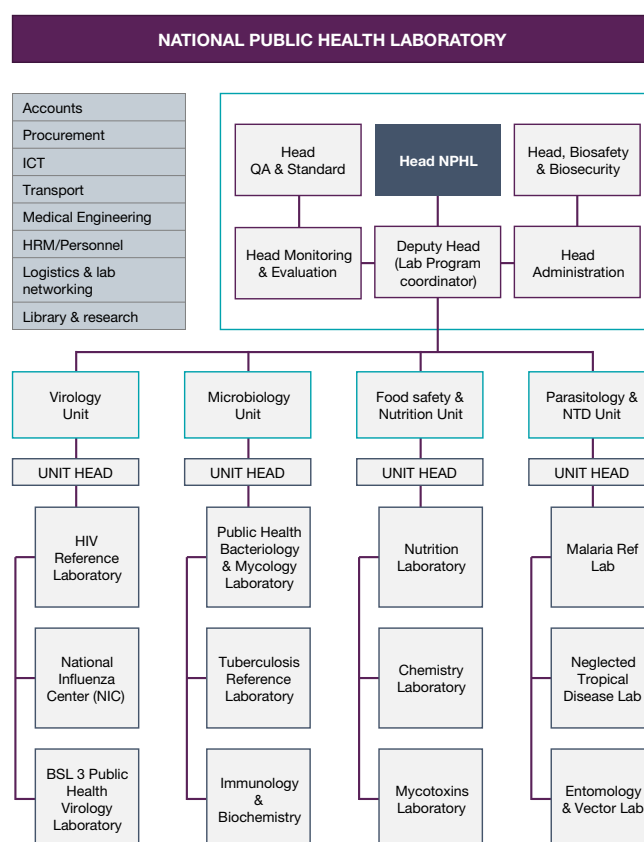
Most of the strategic interventions have a 2022 timeline for completion. The healthcare worker interviewed was not trained on AMR (intervention 4.4), and at the time of this report the ASP guidelines (Intervention 4.2) had not been developed. Despite the lack of training, a healthcare worker interviewed indicated that AMR is of major concern (an 8 on the Likert scale). As a recent graduate, the healthcare worker’s knowledge of the topic largely came from her education, not from any government training.

National Health Laboratory Services

At its highest level, the National Public Health Laboratory (NPHL) is housed within the Department of Preventive and Promotive Health in the MOH. Released in 2016, the NPHL Strategic Plan guides the operations of the lab networks. The mandate of the NPHL is to “perform specialized testing for priority infectious and non-communicable diseases, laboratory-based disease surveillance, and to provide quality assurance for the public health laboratory network”. The NPHL comprises four reference laboratory units that provide referral services linking national, international, and county laboratories (Figure 3).

At the lower levels, Kenya’s NPHL system follows the health facilities rating (levels 1–6), with level 1 clinics having very limited diagnostic capacity, and level 6 laboratories being able to provide specialized healthcare testing and research capabilities. There are two level 6 laboratories within Kenya, 10 level 5 regional referral hospitals/laboratories, and 47 level 4 county referral hospitals/laboratories. There are a large number of level 2 and 3 laboratories, and over 900 public health laboratories within the country^{51,52}. In 2019, Kenya had 189 GeneXpert machines in the public sector at level 3 or level 4 facilities, with the greatest number in Nairobi County, Kisumu and Mombasa⁵³. The private sector has an additional

Figure 3: Structure of the Kenya National Public Health Laboratory system (Strategic Plan 2016–2020)



NPHL, National Public Health Laboratory; NTD, neglected tropical disease; QA, quality assurance

37 such platforms. Currently, GeneXpert is used primarily for the diagnosis of TB, and, in a limited capacity, for early infant diagnosis of HIV.

The majority of laboratories (70%) are owned by the government⁵¹. Funding restraints aside, the Principal Secretary of Health has stated that the government is committed to ensuring that all health facilities have laboratories. There is no timeline for completing this as funding remains short. These labs are to conduct a minimum level of testing, such as blood grouping and glucose levels, urine analysis, stool culture, and diagnosis of syphilis, HIV, TB, and malaria. As proclaimed by the *Medical Laboratory Technicians and Technologists Act 1999*, all laboratory tests must be conducted by a laboratory technician, meaning “a person holding a certificate in medical laboratory technology issued by the Kenya Medical Training College or other similar institution”⁵⁴. The Act includes all point-of-care tests and lateral flow assays. In addition to the laboratory inputs, compliance with this Act would require that every health facility has a lab staffed with at least one lab technologist (minimum 3 years of training) and/or a lab technician (2 years of training).

In 2017, the MOH issued the *Task Sharing Policy 2017–2030* and the *Task Sharing Policy Guidelines*. These guidelines specify that laboratory tests should be conducted by laboratory personnel; however, this document doesn’t differentiate between complicated and uncomplicated tests (i.e. HIV testing versus malaria rapid tests). Often in lower-level facilities, nurses do the uncomplicated tests. With respect to HIV, laboratory staff are not able to counsel patients, so nurses will continue to offer POC HIV tests. The MOH is currently discussing revisions with the Laboratory Union and Laboratory Board with respect to tests.

While Kenyan laboratory facilities have the capacity to detect the most prevalent infectious diseases (i.e. typhoid, diarrhea-related infectious diseases, hepatitis, HIV, TB, and malaria), the 2016–2020 Strategic Plan identifies several challenges for the NPHL system, including:

- ▶ limited resources to address AMR, proliferation of noncommunicable diseases, health threats from emerging and re-emerging diseases;
- ▶ neglected development of laboratory systems targeting noncommunicable diseases;
- ▶ inability to meet targets set by international bodies (e.g. International Health Regulations, global UNAIDS 90:90:90 targets for HIV);
- ▶ staff turnover; and
- ▶ the fact that technological turnover is sometimes faster than the ability of staff to keep abreast of new developments.

The NMRL performs specialized tests such as typing and characterization of common microorganisms and AMR surveillance. However, county laboratories lack a proper and efficient specimen referral system. The NMRL has recently been refurbished and received ISO 15189 certification. Current staff adequately handle the laboratory’s workload, but specialized skills are still needed, especially in the area of molecular techniques. The laboratory sometimes lacks specialized media to culture all applicable priority disease-causing organisms as well as some reagents for key referral tests.

CURRENT SEXUALLY TRANSMITTED INFECTION MANAGEMENT

Sexually transmitted infection care-seeking and access to care

Publicly available information on care-seeking and access to care in Kenya is limited. From the 2014 DHS⁵⁵, among those surveyed with symptoms for any STI, 75% of women and 85% of men sought treatment at a clinic, hospital, private or other healthcare provider. These high rates of care-seeking behaviour for STIs were confirmed by KSIs, and studies show similarly high rates of care-seeking behaviours among key populations ^{56,57}.

Public vs. private care-seeking: where patients seek care (private versus public sector) primarily depends on what the patient can afford. Although public facilities are less expensive, the costs of many small, informal private sector clinics are not significantly higher and often have key advantages, such as shorter waiting times, greater perceived privacy, and less stigma. For this reason, many patients who are able to pay attend the private sector for their first STI-related health encounter⁵⁸. Care-seeking is also driven by location and how the health facility is perceived. For example, in a rural setting, patients may go to the district hospital due to mistrust of lower-level facilities. In urban settings, patients attend smaller facilities because they know they are sufficiently staffed and stocked with needed commodities⁵⁹. There are mixed opinions among KSIs on whether patients seek care at pharmacies; some KSIs indicated that patients only use pharmacies for STI care if they have previously been diagnosed and successfully treated for the same condition. The 2014 DHS found that 2% of women and 5% of men with a suspected STI sought the advice of a pharmacist.

The public health sector has a cost-sharing model which varies based on the level of the health facility. For example, in most level 2 facilities the patient

and government pay KSh 20 each through cost sharing, and treatment is free, while most level 4 facilities charge KSh 100 for a consultation and KSh 100 for treatment as part of cost sharing. If medication is not in stock at a public facility, the prescription for suspected NG infection is KSh 600 and the medicine has to be procured by the patient from a private facility. Private sector costs for suspected NG infection vary greatly depending on the facility level. Consultations cost between KSh 200 and 1,500, and treatment costs between KSh 500 and 7,000.

Men vs. women: care-seeking behaviour varies between men and women. Men tend to seek care earlier (depending on the nature and intensity of their symptoms) and attend private facilities where there is a perception of greater privacy and shorter wait times^{60,61}. Women, on the other hand, tend to wait longer to seek care, and are more likely to attend public facilities. This resonated with KSI interpretation of care-seeking, who reported that women become more familiar with the public sector through antenatal care, and tend to build a rapport with nurses, while men are more likely to hide their STI symptoms and may present one set of symptoms (e.g. throat infection) in an attempt to self-treat their urethral discharge. If a man establishes an affinity with the clinician, he may reveal the real reason for his visit at the end of the appointment (e.g. “By the way, I have this other thing...”⁶²).

Key populations: KPs have high levels of care-seeking behaviour, as they are aware of the risks associated with their sexual and or drug use practices. In addition, they have peer educators who inform them about the risks on a regular basis⁶³. In Mombasa, KPs attend drop-in centres – partner-supported clinics focused on treatment for KPs – every 3 months for syndromic STI screening that involves questions about symptoms, but not a

physical examination. It is rare for KPs to seek care at a public facility (other than at specialist STI clinics); if they do attend a public facility, they usually do not identify themselves as a KP. Some drop-in centres have integrated general health services because KPs do not feel comfortable seeking care at public facilities. KPs are also notified through outreach services by healthcare workers (HCWs) from the STI clinics and drop-in centres that offer services to KPs, for example, those who work in brothels.

Case example:

Special Treatment Centre, Starehe Constituency, Nairobi City County

The Special Treatment Centre (STC) is a former STI clinic that began offering general health services to help avoid the stigma associated with STIs. The STC sees approximately 20 STI patients a day. There is an equal proportion of men and women and the vast majority of patients are >18 years of age, with most patients between the ages of 25–40 years.

Of the 20 STI patients seen daily, approximately 20% are from key populations (60% FSW, 40% MSM), as the STC is well known for stigma-free STI service delivery. Only a few AGYW present at the STC. The Centre states that individuals from KPs visit approximately 3–4 times a year, as they are aware of prevention issues and are careful about the clients they choose. Interestingly, MSM with only one partner generally do not return for re-testing and they also generally do not take PrEP.

The STC has started to see two different kinds of behaviours for KPs with the introduction of PrEP:

- ▶ MSM sex workers who are on PrEP and come for testing every 3 months: generally they are not using the dual protection of PrEP and condoms, and therefore come in only to screen for other STIs as they feel protected against HIV, which they consider to be the most important risk factor. These MSM are willing to have sex without a condom in exchange for more money, and then will use the money for STI treatment.
- ▶ MSM sex workers who are on PrEP and do not come back every 3 months: they are using

dual protection, and they do not come back for retesting as they feel they are protected against STIs and HIV. The STC has seen a drop in testing among these individuals.

Sexually transmitted infection guidelines and management practices

Since 1990, Kenya has been using a syndromic algorithm for STI management, citing costs and limited laboratory access as the biggest barriers to etiological management. Kenya used an STI management algorithm introduced in 1995 and applied until 2015, when a new algorithm for HIV, called Rapid Advice, was implemented throughout the country. The Rapid Advice algorithm remains largely in use today, with the exception of treatment changes made in 2018. In 2018, Kenya released updated STI guidelines³⁹ in line with the WHO Global Health Sector Strategy on Sexually Transmitted Infections (2016–2021) (Figures 6–8).

Within the 2018 guidelines, there remains a clear preference for syndromic management; eight advantages of the practice are listed and only one disadvantage, namely, that many patients may receive more drugs than they need, which leads to overtreatment.

Even with the 2018 guidelines, healthcare practices continue to show a preference for syndromic management, since a lack of resources in LMICs has made the etiological approach to STI management inaccessible, e.g. not enough funds for equipment and personnel. In addition, where etiological diagnosis exists, many patients fail to return for their laboratory results and therefore do not receive treatment. Etiologic testing requires good laboratory infrastructure and well-trained personnel, which are not yet widely accessible in Kenya.

The guidelines stipulate that only in extreme cases of treatment failure should patients have their STIs managed etilogically. In these instances, the guidelines state that laboratory analysis should be used to confirm etiological diagnosis, although no KSI could recall a time when this was routinely done. The clinical officer interviewed said they would

continue to try several rounds of treatment before doing etiological testing; if patients fail treatment several times, it is common for patients to leave the public sector and seek treatment in the private

sector before agreeing to etiological testing. Should a laboratory analysis be completed, the guidance offered (Figure 4) is based on CDC's Sexually Transmitted Diseases Treatment Guidelines (2006).

Figure 4: 2018 Guidelines for laboratory analysis

Genital condition	Diagnostic test	Site(s) & sampling device/specimen needed	Specimen transport/laboratory requirement
Gonorrhoea	Culture/PCR Gram-negative intracellular diplococci within PMNL on microscopy	Endocervical, urethral swabs and first catch urine specimen	<p>Swab specimen for culture: charcoal transport media or direct plate onto selective culture media, and transport in CO₂ rich atmosphere. Do not refrigerate.</p> <p>Swab specimen for PCR: add 0,2ml of transport medium to specimen.</p> <p>Urine specimen for PCR: aliquot specimen in 2ml screw capped vials.</p> <p>Storage conditions for PCR specimens: store samples at 2–8°C for no longer than 24 hours, or freeze at -20–80°C packed with charged ice packs, and transport before they thaw. Frozen in liquid nitrogen or dry shipper</p>
Chlamydia	PCR or LCR (Nucleic acid amplification tests)	First catch urine or endocervical swab Urethral swab for men, rectal and pharyngeal swabs	<p>Swab specimen: add 0,2ml of transport medium</p> <p>Urine specimen for PCR: aliquot specimen in 2ml screw capped vials.</p> <p>Storage conditions for PCR specimens: store samples at 2–8°C for no longer than 24 hours, or freeze at -20–80°C packed with charged ice packs, and transport before they thaw. Frozen in liquid nitrogen or dry shipper</p>

LCR, ligase chain reaction; PCR, polymerase chain reaction; PMNL, polymorphonuclear leukocytes

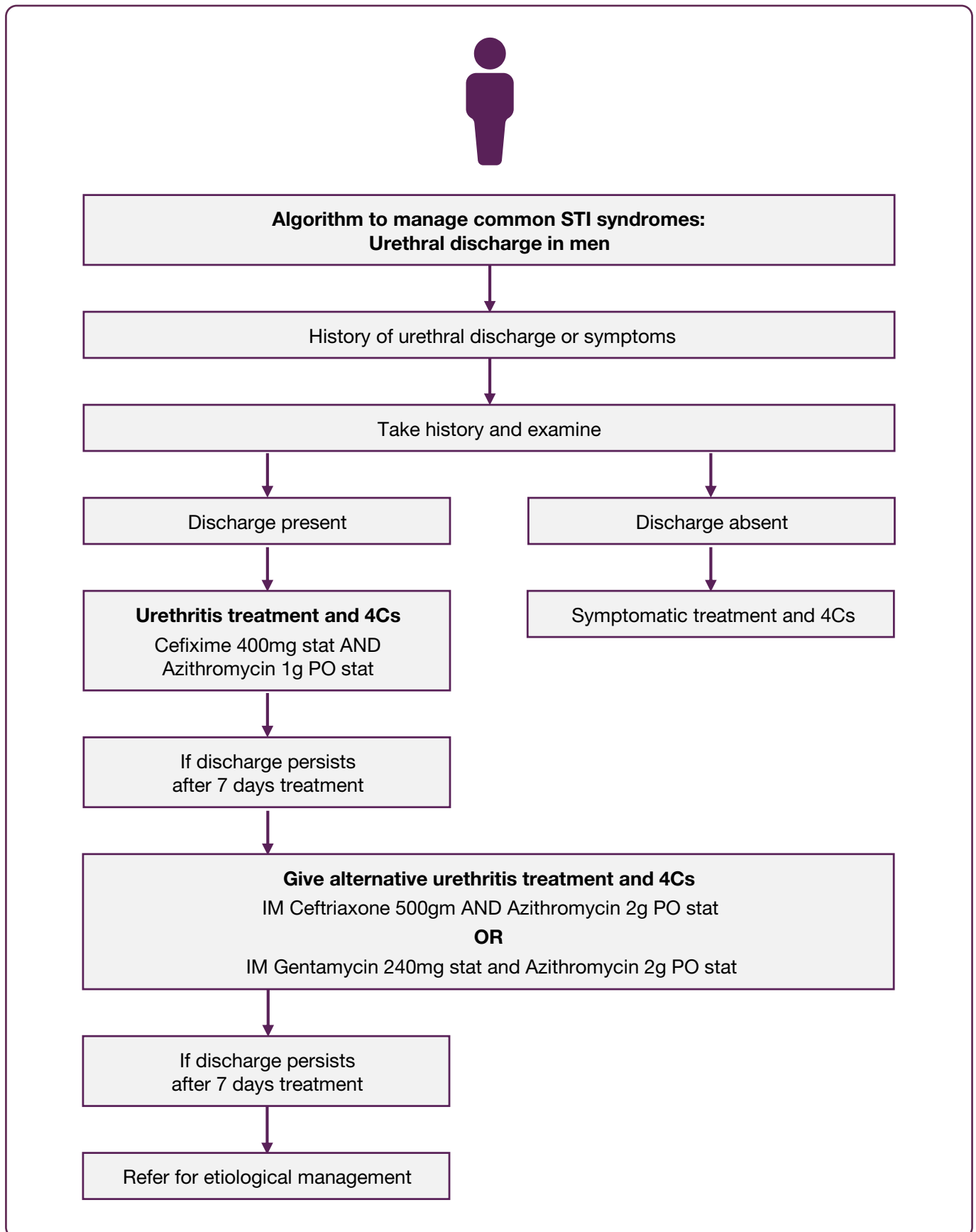
The 2018 guidelines have not been widely disseminated, nor have most HCWs been trained on the changes in disease management⁶⁴. The guidelines were disseminated at a national level, and lower levels of dissemination have depended on partner support. Accompanying materials, such as job aids, updated algorithms, and reporting tools have also not been developed. Dr Catherine Ngugi of NASCOP indicated that there were gaps in the 2018 guidelines in terms of treatment and testing, with the guidelines still leaning toward KPs. There are still minor reviews to be done before the guidelines will be signed and widely disseminated. There is no timeline for this, however, nor is it clear if there will be a refresher training and job aids accompanying the dissemination.

The major STI treatment and management change in the 2018 guidelines is the revision of the first-line treatment for NG to cefixime and second-line treatment to ceftriaxone, replacing quinolones (norfloxacin, ciprofloxacin). These changes were based on WHO guidance and global NG antimicrobial

susceptibility trends, and not based on in-country susceptibility testing. Other additions to the 2018 guidelines, compared with the 2015 guidelines, include applying WHO-recommended frameworks for STI surveillance (e.g. case reporting, AMR monitoring, and quality assurance and control, although these recommendations have not been implemented fully. Per the guidelines, AMR surveillance is to be completed annually at sentinel sites but this has not occurred thus far. Similarly, monthly summary forms are to be uploaded onto District Health Information Software 2 (DHIS2), as per the National Health Information System guidelines, but this has not yet been implemented⁶⁵.

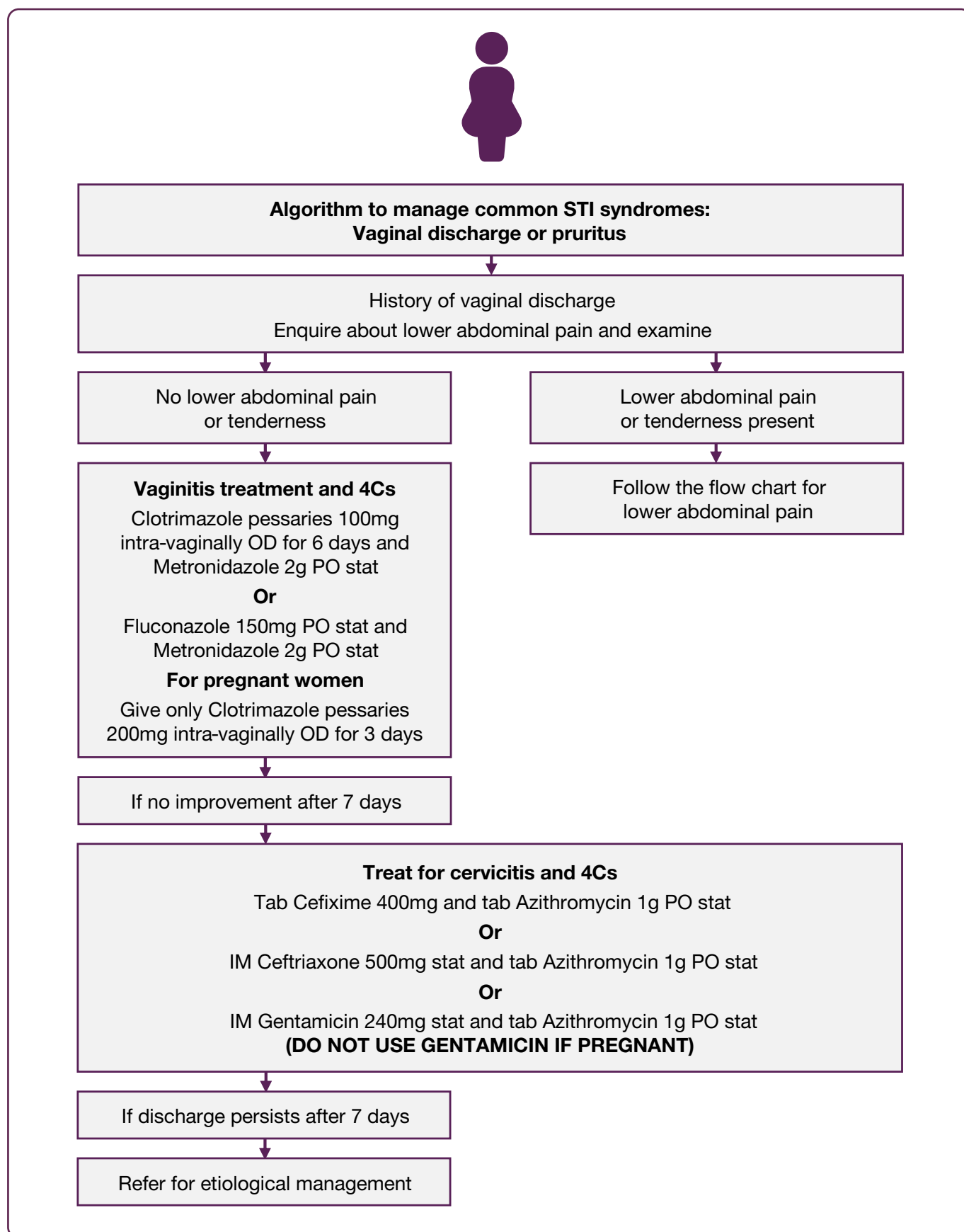
The guidelines provide specific management practices for urethral and vaginal discharge and specify treatment protocols for women with lower abdominal pain; otherwise both sexes follow the same protocol. An examination of the symptoms for all syndromes is included within the algorithm, and some, such as vaginal discharge, recommend a speculum examination.

Figure 5: Flowchart for managing urethral discharge in men (Kenya STI Guidelines 2018)



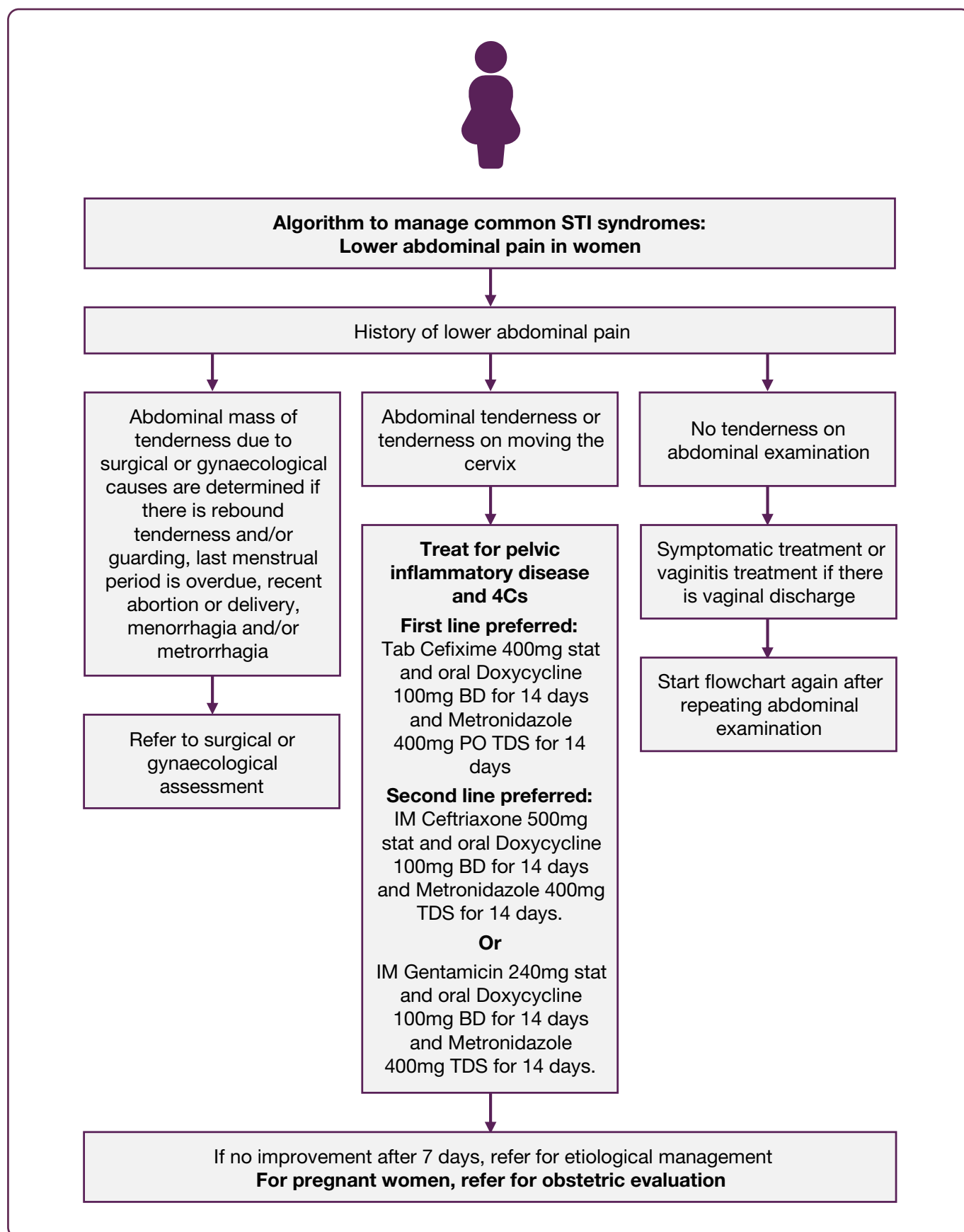
PO; orally; stat; in one dose; STI, sexually transmitted infection

Figure 6: Flowchart for managing vaginal discharge (Kenya STI Guidelines 2018)



OD; once daily; PO; orally; stat; in one dose; STI, sexually transmitted infection

Figure 7: Flowchart for managing lower abdominal pain in women (Kenya STI Guidelines 2018)



The recommendations state that women presenting with vaginal discharge or pruritus should first receive treatment for vaginitis with clotrimazole or fluconazole; if no improvement is seen in seven days, then treatment with cefixime and azithromycin should be given for cervicitis (suspected NG/CT). In practice, the treatment is highly dependent on what drugs are available in the facilities as stock outs are common, particularly for cefixime due to its use for pneumonia. A 2014 assessment of public health clinic facilities, for instance, found that only 48% and 27% of surveyed health centres and dispensaries, respectively, had 16 essential tracer drugs in stock at the time of the survey⁶⁶. At times, HCWs are forced to use amoxicillin and procaine penicillin for the treatment of STIs if no other treatment options are available⁶¹. Treatment for STIs is free, regardless of National Health Insurance Fund (NHIF) status, as long as the drugs are in stock. If they are not in stock, the patient must procure them at their own cost from a private pharmacy at approximately KSh 600 per treatment. Because it is cost-prohibitive, patients do not often pursue this option, and instead continue returning to the clinic until the drugs are in stock.

It is also common for treatment for both vaginitis and cervicitis to be prescribed at the first intake. At the Special Treatment Center in Nairobi, the most common STI-associated syndromes seen within facilities are vaginal candidiasis (yeast infection) and pelvic inflammatory disease (PID). A clinic officer interviewed as part of this study states she would treat PID using three drugs (one antimicrobial, one antibiotic, and one antifungal), to address all the possible causes of the PID. The prescription of an antifungal for PID is not part of the guidelines. This pattern of treating with broad-spectrum antibiotics to cover multiple potential diagnoses and causes is consistent with AMR reviews completed in Kenya.

Interviewees expressed that the guidelines' lack of specificity makes them difficult to follow and implement. The 2018 STI Guidelines³⁹ state "All pregnant women aged <25 years and older women at increased risk for infection should be routinely screened for other STIs". However, it is unclear how frequently routine screening is done, what qualifies a woman to be at increased risk, which STIs to screen for, and what screening protocol

(questionnaire about symptoms) to use. Without this additional information, county and district health systems cannot plan and budget for supplies and staff effectively, and therefore routine screening is unlikely to occur.

Clinic operations and diagnostic testing

Sexually transmitted infections within facility operations

Within Kenya's health facilities, STIs are a priority but the clinical workload is difficult to determine due to the lack of reporting. In a 2012 study of providers' perspectives on STI treatment, 87 providers across 21 facilities (from level 3 through level 6) on average ranked STIs as a 5 on the Likert scale, with a maximum score of 10 as highest prioritization when asked how much they prioritized STIs within their work. Reasons for this included the prevalence of STIs, the link between STIs and HIV, STIs as an entry point for other services, and increasing AMR to some STI therapies⁶⁷. Healthcare workers who viewed STIs as a low priority cited the limited importance of STIs to higher levels of management, and not their personal views, as the reason for the lower ranking. The influence of facility management on the prioritization of STIs was also evaluated through the KSIs; at the STC in Nairobi cited above, a provider interviewed in March 2020 ranked STIs to have an importance of 9 out of 10.

The number of patients seen daily depends on location and facility level. A 2017 study of 42 public, faith-based, and private level 2 and level 3 facilities⁶⁸ found that public facilities evaluated an average of 113 patients daily with an average staff size of four, while private facilities report an average of 22 patients per day with an average staff size of 2.6. Similarly, the number of STIs seen by a provider per day varies between facilities. At the high end, one provider at a level 4 facility reported that STIs may be up to half of their workload⁶⁹. A clinical officer at a special treatment centre in Nairobi estimates that STI visits take about 15 minutes of provider time. This is significantly higher compared with other common alignments, with TB reported to take 7 minutes per visit, asthma 10 minutes, and diarrheal diseases 4–5 minutes, as reported in a 2017 Ministry of Health study in Nairobi, Kenya⁷⁰.

Syndromic screening practices

For symptomatic patients, actual STI symptom and risk screening practices vary among providers, facility levels, and patient populations. The 2017 report by Chesang et al. found that there was no standard screening procedure for STI symptoms in the country. While many HCWs inquired about genital symptoms, if none were reported, no confirmation test was done. Healthcare workers also admitted they did not ask about symptoms and risk screening when the workload was high. Patients may not voluntarily disclose symptoms due to stigma so when omitted by the HCW, these symptoms are never raised. While there is less stigma for STIs than for HIV, STIs still carry stigmatic cultural beliefs (e.g. STIs are a punishment for having sex with an underage person)⁶¹. This can lead patients to not disclose symptoms even when directly asked.

Some key populations, such as FSWs and MSM, have higher adherence to the symptom screening guidance⁷¹ if they self-identify as such. A history-taking guide is provided for KPs (FWS, MSM, and transgender sex workers), which includes a risk assessment. The 2018 guidelines recommend syndromic STI screening for KPs every three months. A representative from the International Centre for Reproductive Health, implementing a key population programme for over 10,000 KPs in the coastal region of Kenya, reported high coverage of STI symptoms and risk screening for self-identified KPs. However, if KPs do not disclose themselves, they are treated as a member of the general population and are therefore not screened at the recommended frequency.

Physical examinations rarely occur to confirm reported symptoms, with HCWs citing a lack of resources, time, and cultural beliefs as barriers. People who are more likely to receive a physical examination upon reporting symptoms include first-time patients, survivors of rape, pregnant women, women seeking family planning services, self-identified FSWs, and patients returning with persistent symptoms. A 2012 clinic review found that most clinics lacked the necessary equipment to perform examinations included within the guidelines, such as speculums, appropriate lighting sources, and equipment for sterilization. If an examination was required, patients would be referred to a higher-level facility that had

the necessary equipment. Cultural beliefs and stigma may also prevent physical examination, particularly for the perianal area. All 87 HCWs within Chesang's study reported never conducting anal examinations. Chesang et al. found a dearth of information on and discomfort about anal STIs among HCWs, leading to neglect and perhaps mismanagement of patients with anal STIs and reluctance to discuss anal sex practices with patients. Training is another barrier to completing the physical examinations, with HCWs noting lack of confidence in diagnosing STIs. In Dr Ngugi's opinion, there is a huge need for retraining and capacity building of HCWs in terms of STI management; however, funding remains the biggest constraint to retraining.

Etiological screening practices

Etiological testing only occurs once a patient does not respond to the second course of treatment prescribed during syndromic management. As per the STI guidelines³⁹, patients are first to be prescribed four different treatments and must have symptoms for 14 days before they are referred for diagnostic testing. In practice, however, there is limited evidence that these guidelines are being followed. When surveyed in 2017, HCWs listed the following benefits of syndromic versus etiologic STI management: (1) availing treatment quickly, (2) upholding confidentiality and reducing stigma, (3) not losing patients through referral to the laboratory, and (4) avoiding laboratory costs. This is consistent with the barriers to etiologic diagnosis noted by interviewees:

- 1. Test turnaround time.** If the facility (levels 4–6) has diagnostic capabilities, a HCW would collect the sample and take the sample to the lab for analysis. Within study settings, culture results took an average of three days to be returned to county hospitals and many HCWs worry about losing patients due to the turnaround time.
- 2. Weak referral networks.** Facilities without laboratory capabilities (levels 1–3) refer patients to higher level facilities. There is no referral tracking system to confirm if the patient sought treatment at a higher-level facility. If they did, they would be syndromically screened again and it would be up to the clinical officer at the higher level facility to

determine if a diagnostic test is indicated. The referrals are only for a consultation, not for testing, as nurses cannot perform such a test. More commonly in this situation, the clinician would prescribe another course of treatment before recommending a diagnostic test.

- 3. Perceptions of NPHL.** Resources at the NPHL were a concern among interviewees. While at the time of this report, reagents were currently in stock, historically repeated stock outs within the country caused clinicians to stop ordering the tests. Additionally, the capacity of laboratory staff to complete the required tests was questioned by representatives from NASCOP, the NPHL, and researchers.

In spite of all these challenges, a few HCWs prefer etiologic diagnosis because it is more specific, better at helping manage recurring infection, eliminates the over-prescription of treatments, and can help monitor drug resistance.⁷²

Surveillance and programme updates

Current sexually transmitted infection surveillance

While the 2018 guidelines indicate where STI information should be documented for reporting (e.g. clinical sheets, registers and tally sheets), STI surveillance in Kenya remains limited and a major weakness of the health programme. There has never been a national STI survey or surveillance, programme and reporting on clinical screenings is essentially nonexistent.

A review of Kenya's DHIS in 2015 found that the quality of data "is limited by constraints such as inadequate financial and human resources, limited quality assurance, and minimal supervisory support"⁷³. As only 10% of public hospitals have electronic medical records, outpatient department registers are to be aggregated at the end of the month and added to DHIS2. However, reporting is not enforced or standardized; STI indicators used, and when they get reported, are at the discretion of the clinical officer. Review of the DHIS2 confirmed that STI indicators are not reported, with the only significant reporting having occurred in February

2019, most likely due to an STI campaign. More specifically, nine of the 12 STI indicators reviewed were not reported in the 12 months prior to the review⁷⁴. Most private sector hospitals have electronic systems for patient records and medication supply, but this is not included in the public sector reporting.

Specifically for STI indicators, most HCWs interviewed in 2017 were unaware of a specific STI reporting tool. The interviews confirmed that HCWs have not been sensitized or trained on record keeping based on syndromic diagnosis. There is an urgent need for reporting tools to be made available in the health system and to strengthen HCW capacity to diagnose and record information in an effective manner.

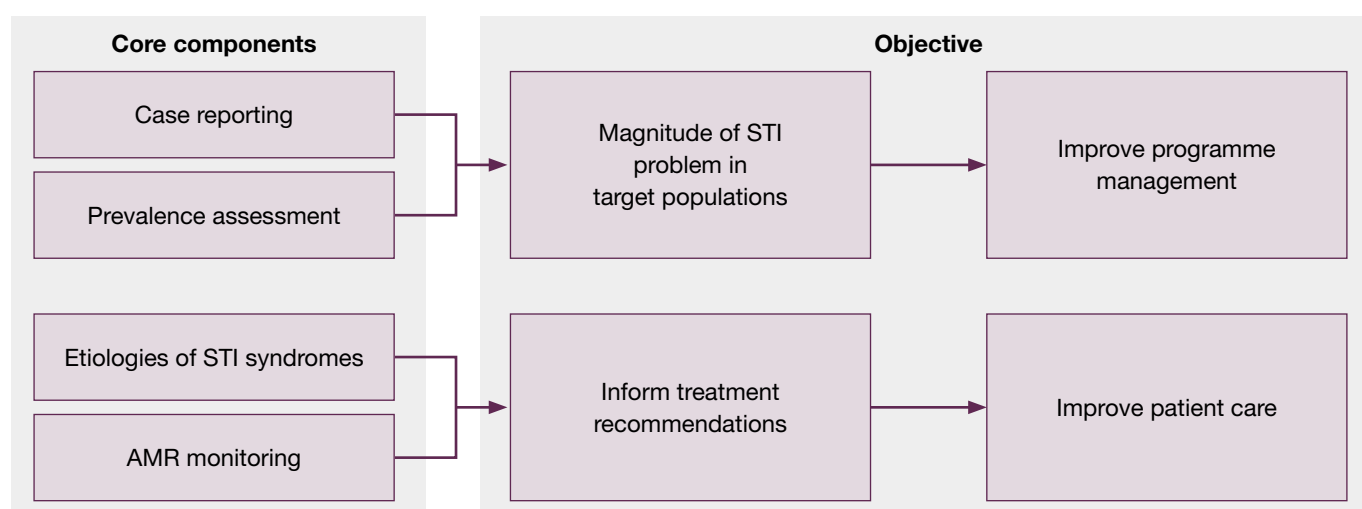
In the absence of national surveillance, research studies remain the most robust source of information on STIs in the country, although they are often region- and population-specific. As a result, the reported STI prevalence varies significantly from 1% to over 15%⁷⁵. The studies that confirmed NG/CT commonly used GeneXpert but noted that using this test for routine screening is not recommended before a cost effectiveness study is completed⁷⁶. NASCOP also confirmed there are no resources to support adoption of this method. At KSh 2,300 for a combined test⁷⁷, funding from an external partner would be required for routine use of GeneXpert. The most robust study on STI prevalence is currently ongoing in 10 facilities (levels 2–5) throughout Kenya, with publication expected in 2020⁷⁸.

Surveillance updates

A national strategy for HIV and STI surveillance was expected to be launched by April 2020 to align with WHO's second generation surveillance guidelines, and will include AMR surveillance. The structure

is expected to follow the objectives set forth in the guidelines and will be based on the WHO *Strategies and laboratory methods for strengthening surveillance of sexually transmitted infections (2012)* (Figure 9).

Figure 8: Core components and objectives of STI surveillance



STI, sexually transmitted infection

One interviewee reported that the surveillance strategy would include routine etiological surveillance to establish prevalence⁷⁹, but this has not been confirmed with NASCOP, nor were details available about which test platform would be used for the surveillance. The Global Fund is funding the development of the strategy, and ownership for the surveillance and reporting will be with the NPHL, not NASCOP. Funding for the implementation of the surveillance strategy has not yet been secured.

The ongoing East African Community (EAC) Boresha Huduma STI study that focuses on non-HIV STIs could fill many of the information and surveillance gaps on STIs in Kenya. The study is funded by Sweden (Sida) for Tanzania and Zanzibar, Burundi, Rwanda, Uganda, Kenya, and South Sudan⁸⁰. Phase 1 of the study, documenting strategies and guidelines in STI management within the EAC partner states and documenting STI management practices within the EAC partner states, is now completed. It pointed out that no countries are conducting etiological testing because of the high cost of the GeneXpert test kits. Phase 2, which has yet to be funded, aims

to document STI prevalence by syndrome and/or causative agents within the EAC partner states; conduct antimicrobial susceptibility testing to establish sensitivity patterns for select STIs within the EAC partner states; determine the phenotypic and molecular characteristics of common STI isolates within the EAC region; and identify key areas of harmonization within the EAC partner states.

Sexually transmitted infection programmatic updates

An STI framework is currently in development, but only syphilis and hepatitis B are included due to the current priorities of the PMTCT programme and available funding. A draft was not available for review, but similar frameworks have laid forth the government's commitments, targets and key activities towards producing needed guidelines. Treatment guidelines are reviewed every three years, with the next guideline review occurring in 2021. Kenya, and NASCOP specifically, has a history of rapidly adopting WHO guidelines and the next guidelines are expected to align with any revisions made by WHO.

KEY USE SCENARIOS FOR A *NEISSERIA GONORRHOEA* AND *CHLAMYDIA TRACHOMATIS* POINT-OF-CARE TEST

The KSIs laid out a wide variety of use cases for both TPP1 Minimal and TPP1 Optimal. Below we summarize the findings and provide more context to the use cases most widely agreed upon and most clinically and programmatically relevant.

The test descriptions used in the interviews are as follows: TPP1 Minimal is a lateral flow test with >80% sensitivity and >95% specificity and costs

between 1–3 US dollars. This test is sensitive enough for screening of symptomatic patients but may not be sensitive enough for screening asymptomatic patients. TPP1 Optimal is a disposable molecular diagnostic test with >95% sensitivity and >98% specificity and costs approximately 8 US dollars. This test is sensitive enough to screen asymptomatic patients, with approximately 10–30 minutes for time to results⁸¹.

Use of TPP1 Minimal – symptomatic populations

Table 2 below shows the suggested use cases for TPP1 Minimal. From the 13 key stakeholder interviews conducted, 10 different use cases were identified, and four emerged as the most useful.

All would be used at level 1 and 2 facilities, with a focus on (i) pregnant women with symptoms, (ii) everyone presenting with possible NG symptoms, and (iii) symptomatic AGYW.

Table 2: TPP1 Minimal use cases

Use case	Facility	Symptomatic population	No. KSIs independently identifying the use case
1	Level 2 (and up)	Pregnant women with symptoms	7
2	Level 2 (and up)	Everyone with symptoms	5
3	Level 2 (and up)	AGYW with symptoms	4
4	Private facility, pharmacy self-test kits	General population attending private clinic	3
5	Level 4, 5, 6 only	Key populations with symptoms	2
6	Level 4, 5, 6 only	Pregnant women with symptoms	2
7	Research setting	Study population with symptoms	2
8	Level 4, 5, 6 only	AGYW with symptoms	1
9	Level 2	General population with symptoms	1
10	Level 2 (and up)	PrEP users with symptoms	1
11	Level 4, 5, 6	AGYW + ABYM with symptoms	1⁸²

ABYM, adolescent boys and young men; AGYW, adolescent girls and young women

The four most discussed use cases are outlined below in Figure 10 and in Annex 4.

TPP1 Minimal Use Case 1: level 2 facility (and up), pregnant women presenting with symptoms. The majority of KSIs recommended pregnant women as a target population.

Rationale:

- ▶ risk of neonatal morbidity from STIs
- ▶ higher risk of STI during pregnancy (e.g. no condom is used);
- ▶ risk of mother to child transmission during delivery
- ▶ need to confirm vaginal discharge (many pregnant women are treated for candidiasis while NG/CT is missed); and
- ▶ test may be covered under the NHIF Linda Mama Antenatal Care scheme^{83,84}

Concerns:

- ▶ may be lower yield than higher-risk key populations depending on underlying prevalence; and
- ▶ funding may be an issue if testing all pregnant women

Total potential demand: ~197,000 tests/year (range: 124,000–294,000)

TPP1 Minimal Use Case 2: level 2 facility (and higher) – anyone presenting with symptoms

Rationale:

- ▶ identify the specific STI that a patient has and treat appropriately, rather than treating with broad-spectrum antibiotics in the hope of curing what the patient has

Concerns:

- ▶ funding
- ▶ reporting systems to ensure appropriate diagnosis and treatment

Total potential demand: ~1,700,000 tests/year (range: 1 million–2.6 million)

TPP1 Minimal Use Case 3: level 2 facility (and up), AGYW⁸⁶ presenting with symptoms

Rationale:

- ▶ high-risk population – risk-taking behaviours with a low perception of risk

Concerns:

- ▶ difficult to determine the entry point (facilities with youth-friendly services could be starting point); and
- ▶ funding (for example, a pilot would need to be donor-funded)

Total potential demand: ~545,000 tests/year (range: 344,000–812,000)

TPP1 Minimal Use Case 4: KPs (MSM, FSW, PrEP users, PLHIV) with symptoms.

Although KPs were not one of the most mentioned priority populations for KSIs, they may be identified as a priority by the WHO. Three KSIs identified the use case and rationale below.

Rationale:

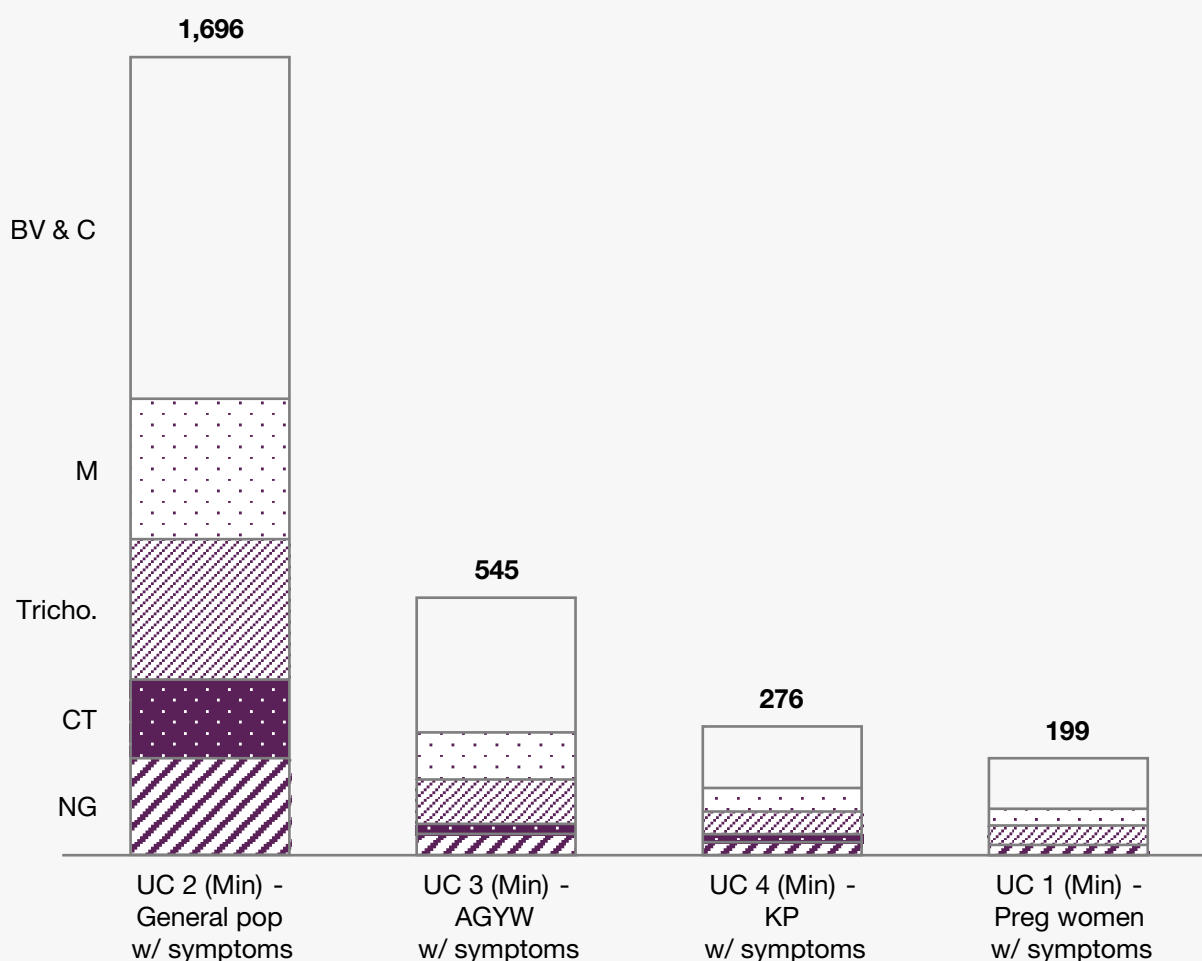
- ▶ high-risk population
- ▶ population already engaged in syndromic screening
- ▶ AMR concerns around over prescribing
- ▶ STI symptom and risk screening questions are already normalized

Concerns:

- ▶ funding

Total potential demand: ~ 276,000 tests/year (range: 145,000–543,000)

Figure 9: Total number of tests (midpoint estimate) by use case and type of underlying sexually transmitted infection (causing vaginal or urethral discharge), in thousands - TPP1 Minimal (Use cases 1, 2, 3 and 4)



BV & C, bacterial vaginosis & candidiasis; CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoea*; M, mycoplasma; Tricho, trichomonas; AGYW, adolescent girls and young women; Source: Market sizing model

TPP1 Minimal test considerations

Cost: the cost of TPP1 Minimal (KSh 100–300 per test) was a concern for 50% of the KSIs. Facilities would need to budget to provide free testing to patients. Given the current budget constraints, the facility budget would need to be increased at the county level. If patients had to pay for the test, testing uptake would be low as treatment is free at facilities, while lab testing is not⁸⁸. “I can’t imagine someone at a dispensary or health centre spending KSh 200 for a test when they can spend KSh 0 for syndromic management”⁸⁹. Several KSIs indicated that syndromic management is working, so questioned the need to replace this with etiological testing⁹⁰. For

reference, a dual test for HIV/syphilis costs US\$ 1.25, and the MOH believed this was too high. Key donors, like PEPFAR, are unlikely to pay US\$ 3/test⁹¹. A price of KSh 100 at public facilities was considered feasible; the interviewees believed the private sector may pay KSh 300 for such a test⁹². One KSI thought that even KSh 10 would be too much for many patients⁹³. The test would either have to be funded by a programme or a patient would have to pay out of pocket. Another KSI pointed out that the government would not pay for this test, as KSh 300 is too high a cost⁹⁴. The head of NASCOP indicated that KSh 100–150 would be acceptable for such a test⁹⁵.

Sample collection: several KSIs agreed that for this test to be widely adopted, the preferred sample type should be urine. There were serious concerns about a HCW collecting a vaginal swab (e.g. lack of privacy, lack of speculums, or refusal for cultural reasons). The general consensus was that self-collection of a vaginal swab would not be possible because clients, particularly within the rural communities, wouldn't know how to collect the sample and women might not be receptive to doing so⁹⁶.

POC vs. closer-to-care: KSI response with respect to who would conduct the POC NG/CT test once the sample was collected. A NASCOP interviewee indicated laboratory personnel would conduct the test. Half the KSIs⁹⁷ suggested that the test could be done by the HCW, especially in a level 2 facility where there is no lab available.

However, for facilities with a lab, all laboratory tests (except HIV tests) are to be conducted by a laboratory technician. HIV tests are conducted by an HIV Testing Services (HTS) Counselor, so there is still a referral from the clinical officer to HTS for testing, and back to the clinical officer for treatment. The same flow was suggested by several KSIs for the POC NG test, where the clinical officer would request the test, the patient would go to the lab, provide a urine sample and wait for the results which they would then take back to the clinical officer, who would provide treatment if results were positive.

Sensitivity consideration: there was concern from one KSI regarding the 80% sensitivity of the TPP1 Minimal test being too low, and that higher sensitivity would be required to replace current syndromic management⁹⁸.

Use of TPP1 Optimal – asymptomatic populations

Table 3 below shows the suggested use cases for TPP1 Optimal. From the 13 interviews conducted with key stakeholders, eight different use cases were identified, and two emerged independently as the most useful: (1) wealthier pregnant women, with or without symptoms, who could afford a screening test provided by the private sector even though they

attend ANC clinics; and (2) high-risk populations with or without symptoms, through programmes targeting these populations. However, given the cost of the test, all KSIs indicated that it would be difficult to introduce into the public sector without additional information showing that asymptomatic NG is a serious health concern.

Table 3: TPP1 Optimal use cases

Use case	Facility	Population	No. KSIs independently identifying the use case
1	Private, research	Pregnant women	5
2	Private, research	Key populations	3
3	Private, research	AGYW	3
4	Level 6	Key populations	2
5	Level 6	Pregnant women	2
6	Level 6	AGYW	2
7	HIV clinics	Key Pops	2
8	Private	General population - who can afford private	1
9	Donor funded project setting, level 1–2 mostly 2	Key populations, pregnant women	1

AGYW, adolescent girls and young women

TPP1 Optimal Use Case 1: Private sector – pregnant women, at the patient’s cost.

Rationale:

- ▶ if people can pay for screening, it is a useful test to diagnose asymptomatic NG infections that may be missed through symptom screening

Concerns:

- ▶ low test volumes for such a small population
- ▶ potentially low yields in pregnant women⁹⁹

Total potential demand: ~380,000 tests/year¹⁰⁰

TPP1 Optimal Use Case 2: High-risk populations (MSM, FSW, AGYW, sexually active women, pregnant women at high risk, all PLHIV, especially if young and having multiple sex partners) identified using a screening algorithm through implementation research

Rationale:

- ▶ this would decrease testing volume (and thus costs)
- ▶ could increase positivity yields
- ▶ could decrease transmission among high-risk groups

Note: this more targeted approach may be more palatable for funders than broad implementation and could be a good way to pilot implementation and gather data concurrently to inform future utility and cost-effectiveness.

Concerns:

- ▶ if some KPs are tested, this may generate testing demand among lower-risk individuals
- ▶ within the general KP programmes funded by development partners, the test is still considered too costly
- ▶ given that many KPs are testing every 3 months, testing costs would cripple the entire programme¹⁰¹

Total potential demand: ~1.9 million tests/year. Note that this figure comprises MSM, FSW, PrEP, PLHIV, and AGYW¹⁰². While it might be desirable financially, it is unlikely that all of these populations could be targeted.

TPP1 Optimal test considerations

Cost: although many KSIs recognized the need for a screening test to identify asymptomatic cases and to decrease onward transmission, the cost of KSh 800 for TPP1 Optimal was deemed too prohibitive for use in public facilities. Without data to support the probability that asymptomatic cases are a health problem, Dr Ngugi confirmed that the cost for TPP1 Optimal was too high.

Prioritization of use target product profiles

KSIs were very interested in the two tests. From a prioritization standpoint, the majority of KSIs¹⁰³ (12 respondents through six interviews) said they would

prioritize TPP1 Minimal for Kenya. This decision was mainly from a cost feasibility standpoint. Two KSI researchers prioritized TPP1 Optimal, as it “solves a current problem,” i.e. it can identify asymptomatic cases, while TPP1 Minimal “would only be able to do what symptomatic management is already doing”. However, both KSIs indicated that the current cost for TPP1 Optimal was prohibitive. Three KSIs indicated that they would not prioritize any test right now, indicating that there are many disadvantages to replacing the syndromic approach – cost being one of the biggest factors for both for TPP1 Minimal and TPP1 Optimal. In the end, the Head of Surveillance within the NPHL and the Head of Clinical Diagnostics stated that the MOH would conduct a cost-effectiveness evaluation before accepting either test.

CONSIDERATIONS FOR INTRODUCING A POINT-OF-CARE TEST FOR *NEISSERIA GONORRHOEA* AND *CHLAMYDIA TRACHOMATIS*

Who will conduct the test?

There was debate over whether laboratories or HCWs should conduct the tests. The laboratory unit indicated that any lab test should be conducted by a laboratory technologist, and healthcare professionals indicated that labs are reversing all the gains that have been achieved. For the last few years, labs have been trying to enforce the conduct of tests by laboratory technologists rather than by nurses in low-resource settings¹⁰⁴. In level 2 facilities, which lack laboratories, this could result in the test not being implemented; however, there is an ongoing discussion on the introduction of essential lab services at all public health facilities, including level 2, in the near future. For level 3 facilities and above, where labs are present, it was generally agreed that the lab would conduct the tests after sample collection.

Additional workload/time

At level 2 facilities, from the perspective of HCWs, the barrier to nurses conducting the test instead of lab technicians was the turnaround time. If the time to conduct the test is greater than five minutes, it will be met with resistance from HCWs. Additionally, the task of recording the test result may also be met with resistance. One KSI even voiced concern that nurses and midwives may not be appropriately trained to conduct diagnostic tests, resulting in the need for intensive training programmes (even if the test is relatively straightforward). However, it was generally accepted that if a test is included in the diagnostic algorithm, the healthcare provider would conduct the test. One suggestion was to have the HTS counsellor, who is trained on pre- and post-test

counselling, conduct the test prescribed by the nurse to improve patient flow.

At level 3 and higher facilities, there was little concern from the provider perspective, since all other laboratory tests (except for HIV tests) are conducted at the lab, and this test would not be any different than other lab tests being ordered. Healthcare providers would be happy to get test results, and to be able to correctly treat their patients, rather than needing to refer patients up to a level 4 facility following treatment failure.

Training

A potential barrier/concern regarding a new POC test being introduced is training¹⁰⁵. From a provider perspective, the *why* of a new test is important for uptake within facilities, along with regular training. The current 2018 STI guidelines³⁹ have not been broadly disseminated due to lack of resources. The main considerations to training and dissemination have to do with who is being trained (i.e. lab technologists at level 3+, nurses at level 2, which would mean 2 different training curriculums), and who is paying for the training.

Demand generation

When HIV POC tests and PrEP were introduced in Kenya, the communities did a thorough job of engaging with advocacy/civil society groups, which helped in demand creation. Communities are key stakeholders that are needed to create demand.

Budget/cost

The MOH cannot prioritize NG since the true burden for the general population cannot be quantified due to syndromic management and lack of surveillance data. A cost-benefit analysis is necessary, even if a donor provides the tests. Additional costs may be incurred due to the need for partner testing.

Sustainability of supplies

Ensuring a proper supply chain and source of supplies is necessary when implementing a new test. Many KSIs indicated that other etiological testing used to be conducted, but as reagents stocked out HCWs stopped ordering tests, and laboratory technologists forgot how to conduct the tests.

Sample collection

There was a broad consensus that urine was the preferred sample type.

Test sensitivity

One KSI expressed concern that the TPP1 Minimal test has low sensitivity, suggesting that 80% sensitivity would not be sufficient nor cost-effective compared with syndromic management. The current gold standard for NG diagnosis is nucleic acid amplification testing (e.g. GeneXpert), which has a >90% sensitivity¹⁰⁶ although at the moment it is only used in research settings in Kenya.

Patient acceptance

Symptomatic patients. The main patient acceptance factor cited by KSIs was the sample collection process (urine vs. vaginal swab done by HCWs). It was reported that women from rural Kenya would not feel comfortable self-collecting a vaginal swab, and there were mixed reviews from KSIs on whether women would accept a HCW collecting a vaginal swab (given cultural issues, privacy, availability of supplies, etc.). Otherwise, KSIs suggested that patients are open to being tested when they are symptomatic.

Asymptomatic patients. There were also considerations for TPP1 Optimal. Certain populations would be open to testing even if asymptomatic (e.g. pregnant women who want to protect their baby, key populations who acknowledge their risk), but others would resist (e.g. *“why are you testing me? Do you think I have an STI? I don’t have symptoms”*). However, if a patient trusts their physician, they may be willing to follow what the physician prescribes.

DISCUSSION: SYNDROMIC VERSUS ETIOLOGICAL MANAGEMENT OF SEXUALLY TRANSMITTED INFECTIONS AND ASYMPTOMATIC INFECTIONS

Without a cost-effective alternative, syndromic management is viewed as good enough

While interviewees and programmatic documents acknowledged the limitations of syndromic management, there was also the sentiment that, given the current available resources in Kenya, syndromic management is sufficient for treating suspected NG. When discussing the different profiles of the POC test, the value added from the diagnostic was not initially evident to interviewees. Most interviewees felt that although broad-spectrum antibiotics were prescribed, and sometimes repeat visits were necessary, STIs could be treated effectively with syndromic management.

Taking into consideration the scale of the population that presents with STI symptoms, as well as the current status of the health system, the STI guidelines³⁹ state, “Syndromic approaches will remain the mainstay of STI treatment in Kenya because of the need for prompt treatment of large populations in settings without laboratory services.” Interviewees were quick to extrapolate the cost implications of rolling out a POC test for critical populations (estimated cost: KSh 300–800 per test) and what this would mean when integrated into the broader health system. One KSI who oversees a KP programme in the coastal region remarked that including TPP1 Minimal, the lower-priced test, within the current every three-month STI screening practices of KPs would account for over half of their annual operating budget. To continue providing routine health services to all, syndromic management is seen as the only cost-effective management practice.

Without any clear data that syndromic management is not working effectively, the push to invest in more costly management practices is not one which is imaginable for the current Kenyan health system. Prior to beginning the procurement process, a cost-effectiveness study would need to be conducted before the government could move to tender for the diagnostic.

While AMR is a concern due to the use of broad-spectrum antibiotics, it is not an area the MOH is currently prioritizing through investing in training, guidelines, or diagnostics to change this practice within the health facilities. Furthermore, AMR in STIs is not currently seen as a cost burden to the health system, and the guidelines cite syndromic management as “reducing chances of treatment failure and expediting effective treatment which reduces the risk of transmission and development of serious complications.”

Given the low costs associated with syndromic management and its longtime practice, it is likely such management will continue even if a POC rapid test is introduced. Etiological testing would occur only after treatment failure from syndromic management. This mixed approach discussed by four KSIs would include etiological testing in the algorithm at an earlier stage than is currently practiced. Based on the reported laboratory data and KSI input, etiological testing does not currently appear to be used at any stage of the STI management algorithm. However, there was agreement that a POC test would promote compliance with the diagnostic algorithm as it would reduce reliance on laboratory

capacity to do the tests, and the potential loss to follow-up due to the turnaround time of tests.

Asymptomatic infections are not a concern given the burden of other diseases

While all the key stakeholders interviewed for this assessment recognized the clinical need to identify asymptomatic NG cases to prevent the continued spread of the infection, the notion that it would be a “hard sell” was repeated often. Within the Kenyan health system, the perceived burden of disease prevalence and the implications of the disease drive both the funding available for each condition and, consequently, the priorities of the MOH. Due to funding from the Bill & Melinda Gates Foundation, HIV, TB and comorbidities have dominated health research and funding for most sub-Saharan countries, with the exception of syphilis. Advocating for the adoption of a test that can identify asymptomatic cases faces two uphill battles – prioritization of STIs within an already overburdened, under-resourced health system, and finding enough funding.

Beyond specific research studies, the Kenya MOH does not have data for the burden of asymptomatic STI cases, and the STI guidelines³⁹, along with trainings for HCWs, have only focused on identifying symptomatic cases. During the interview with the Clinton Health Access Initiative, they reiterated the difficulties of prioritizing STIs, and even more so asymptomatic screening, stating “in developing countries, you prioritize what is the highest priority – right now, that’s hepatitis B, syphilis, and HIV. Without a system for documenting the prevalence, there is no way for this to become a priority”. Even during the interviews with KSIs about the POC NG/CT test, one group continued to mention HIV, asking if there was a way to incorporate an HIV test into the diagnostic. Therefore, until national level surveillance has been conducted for STIs, the focus will remain on diseases that can be quantified.

Data as a driver for change

Evidence-based decision-making has been the driver for the MOH and NASCOP to meet the needs of the country, despite limited resources. Two NASCOP guideline changes highlight how Kenya has adjusted to emerging domestic and global evidence with policy shifts. Kenya’s early adoption of PrEP, in 2016, was driven by evidence generated through demonstration projects and pilots within the country. As the second country in sub-Saharan Africa to issue full regulatory approval of PrEP, robust availability of information facilitated this uptake¹⁰⁷. Several KSIs requested that a similar approach using demonstration projects and pilots be used for a POC NG/CT diagnostic as an initial step for test introduction into the Kenyan market. Current data sources in the country are limited, as there is no national clinical reporting for STIs or STI syndromes and available prevalence rates come from studies that target specific populations and regions (Table 1). A pilot study would be able to generate more data regarding the prevalence of NG/CT, show the need for such a diagnostic, and estimate the feasibility of introducing the test into the health system. Suggested pilot areas would be Kisumu¹⁰⁸, refugee settlements¹⁰⁹, and Nairobi’s KP clinics¹¹⁰.

In the absence of in-country data, Kenya has also generally moved to align with global and regional trends, such as positioning their revision of first-line gonorrhoea treatment with WHO guidelines and global resistance patterns. This change came without any in-country data regarding treatment failure. The global and regional research, which prompted WHO to change their guidelines, subsequently led NASCOP to do so as well. In the absence of in-country surveillance or monitoring, regional and global evidence, if validated by WHO, should be sufficient for NASCOP to follow suit in their next STI guideline revisions (2021). One KSI indicated that the regional STI study being conducted across Eastern Africa would provide a true picture of STI prevalence in Kenya.

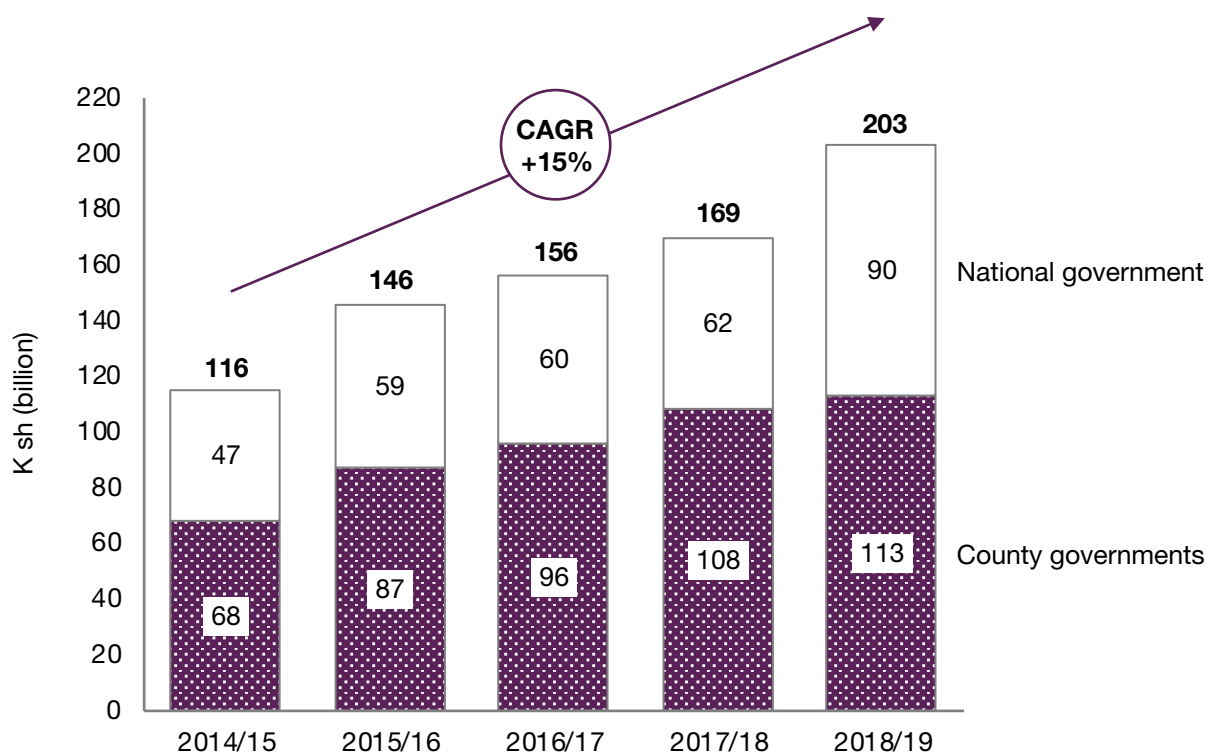
FINANCING AND ADOPTION CONSIDERATIONS

Public financing

In absolute value (US\$ 1 ~ KSh 100), the total government allocation for health has increased at an average rate of 15% per year between 2014–15

and 2018–19 (Figure 10), i.e. it exceeded inflation, which hovered between 5 and 8 percent¹¹¹ during the same period.

Figure 10: Health sector budget allocations in Kenya, 2014/15 to 2018/19



CAGR, compound annual growth rate

Source: Programme-based budget, and reports by the Controller of Budget on county governments' allocation.

As a proportion of the total government budget¹¹², the amounts allocated for health increased to 6.7% in the 2015/16 fiscal year, but are still well below the 15% recommended by the Abuja declaration¹¹³. The still low public investments in health and the low uptake of health insurance schemes mean that many Kenyans are forced to make frequent out-of-pocket payments to cover their health expenses. According to the latest National Health Accounts, out-of-pocket payments represent 26% of the total health expenditures for the 2015/16 fiscal year.¹¹³

To limit out-of-pocket payments, Kenya introduced a reduced and uniform user fee policy in 2004¹¹⁴ providing fee exemptions to many groups seeking care in public health facilities. Full fee exemptions are supposed to apply to specific services, including treatment for malaria, TB, STIs, all care for under 5-year-olds, births, and ANC¹¹⁵.

However, in practice, adherence to the user fee policy is low and patients are still required to pay out-of-pocket costs. One study conducted in

2010 found that only 4% of public health facilities adhered to the user fee policy for an adult with gonorrhoea¹¹⁶. The median value of over-charge for an adult with gonorrhoea compared with the user fee policy was US\$ 0.66, which can include consultation fees, laboratory tests, and drug costs.

With the devolution of Kenya's government that effectively started in 2013, health has become one of the primary responsibilities of the county governments. Counties' health budgets represented between 55% and 64% of the total government health budget, depending on the year. Encouragingly, over two thirds of the 47 counties increased the percentage of their budgetary resources allocated to health between the 2015/16 and 2016/17 fiscal years¹¹⁷. Allocations for medical drugs, as a percentage of the total health recurrent budget, increased from 7.8% in the 2014/15 fiscal year to 9.6% in the 2016/17 fiscal year, which signals a higher prioritization of health commodities by county governments¹¹⁸.

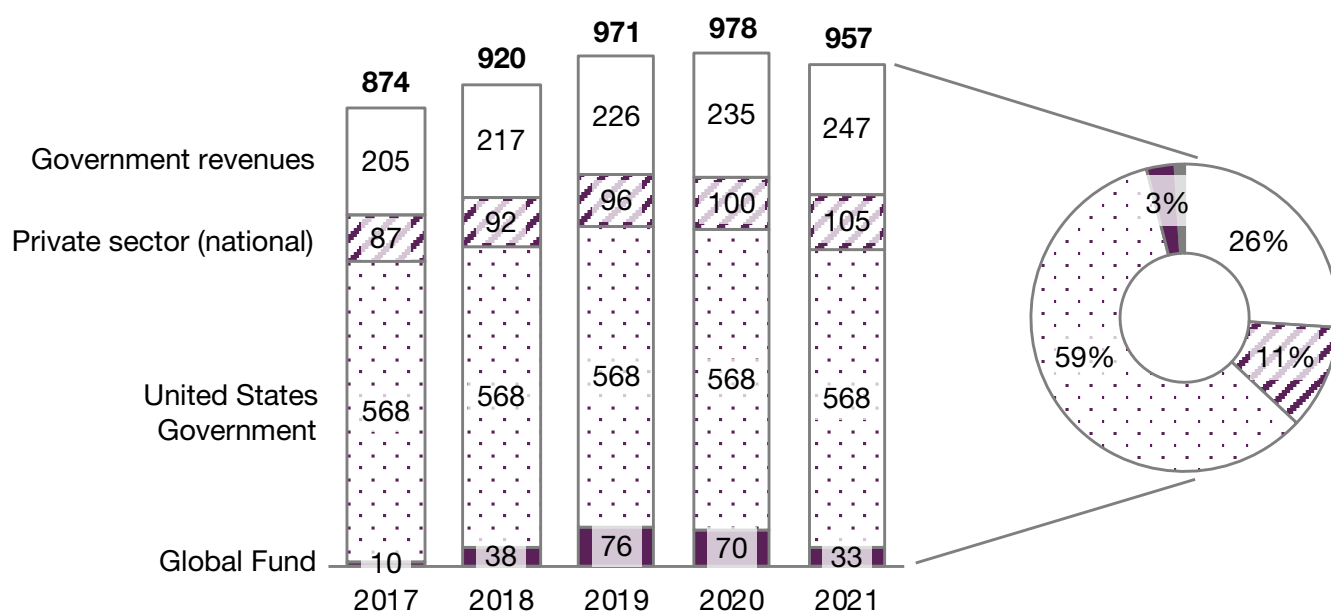
Domestic funding for an NG/CT POC test appears unlikely in the short-term¹¹⁹. NG is not currently prioritized in the national policies such as the NASCOP strategic plan, which is a crucial first step to unlocking domestic funding. The PMTCT Programme Manager indicated that hepatitis B and syphilis are the only STIs that will be included in the national STI framework (under development) as part of the triple elimination strategy¹²⁰. Revised WHO guidelines regarding STI management could, of course, elevate the NG priority level and influence the government to modify its national guidelines but this will not automatically guarantee domestic funding to cover the cost of a POC test.

Decreasing donor support means that the fiscal capacity to fund the HIV response – currently the main avenue for funding STI screening and treatment programmes – will decrease in the coming years as the government will have to step up its contribution to make up for the financing gap. Figure 11 shows that almost two thirds of the national HIV programme is currently funded by donors (mainly PEPFAR).

Figure 11: Financial contributions for the Kenyan national HIV programme (millions of US dollars)

A. Financial contributions for the national HIV programme (Million US\$)

B. 2021 breakdown of contributions by financing source (%)



Application Form - full review, HIV and TB, and RSSH.

Source: The Global Fund, 2018–2020 Funding Request.

In the context of scarce resources, the cost-effectiveness profile of an NG/CT POC test will be evaluated by the government. According to NASCOP, if public funds were to be allocated to purchase an NG/CT POC test, a cost-effectiveness study would first have to be conducted in a couple of health facilities. The data would then be used to model the cost of national scale-up and of additional cases the POC test would detect compared with the syndromic approach, and would assess the cost-effectiveness of the diagnostic test¹²¹. The importance of demonstrating cost-effectiveness was also stressed by the Head of Clinical Diagnostics at the MOH¹²².

In the absence of central government funding, some counties may decide to allocate a portion of their health budget to procure the NG/CT POC test and offer it for free to certain patients. While this scenario is in theory possible, it would make the practical introduction of the POC test complex since individual negotiations and advocacy with each of the 47 county authorities would have to take place. Besides, counties also face tough financial trade-offs. As a result, it seems unlikely that many will choose to fund a POC test unless they receive strong policy and clinical guidelines from MOH.

Health insurance

In the absence of government support, health insurance, whether private or government-sponsored, could be another option to cover the cost of an NG/CT POC test.

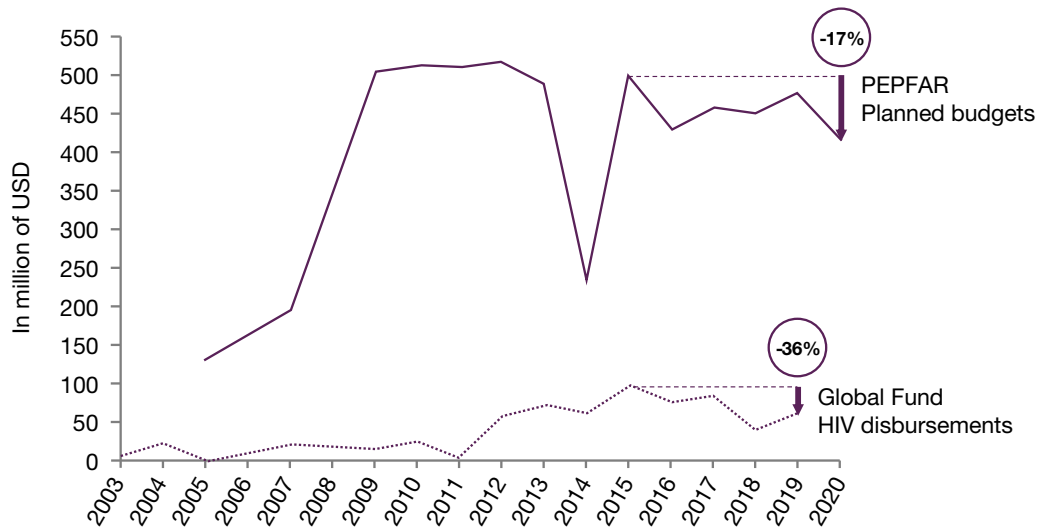
In Kenya, health insurance agencies typically cover members for STI screening and treatment. The NHIF¹²³ – one of the largest in Kenya – covers screening and treatment for STIs¹²⁴. And while health insurance coverage still remains limited, with only 22% of the population covered in 2016,¹²⁵ the uptake is rapid. NHIF member registration increased to 7.6 million principal members by mid-2018 from 4.7 million in mid-2014, i.e. an average growth rate of 10% per year over 5 years¹²⁶.

However, it seems also unlikely that a novel NG/CT POC test would be covered by NHIF. While in theory NHIF covers the costs of lab tests under its various schemes, an outpatient cap may apply and thus limit test uptake. Besides, and perhaps more importantly, MOH will ultimately determine what is included in the schedule of benefits based on an analysis of NHIF's long-term financial equilibrium. At the moment, the government of Kenya is prioritizing HIV/AIDS services and aims to finance parts of the HIV/AIDS services through the NHIF. According to government projections, the proposed inclusion of ART in the package offered by the NHIF would alone take 16–19% of the fund's revenue¹²⁷. Including the NG/CT POC within the WHO Essential Diagnostics List would help justify its coverage through NHIF.

External financing

Most of the external funding available for STIs is incorporated in HIV/AIDS programming. Like in many other sub-Saharan African countries, the Global Fund and PEPFAR are the largest funders of the HIV/AIDS response in Kenya yet both have significantly cut back on their financial contributions since 2015 (Figure 12).

Figure 12: HIV/AIDS funding by PEPFAR (planned) and the Global Fund (disbursed)

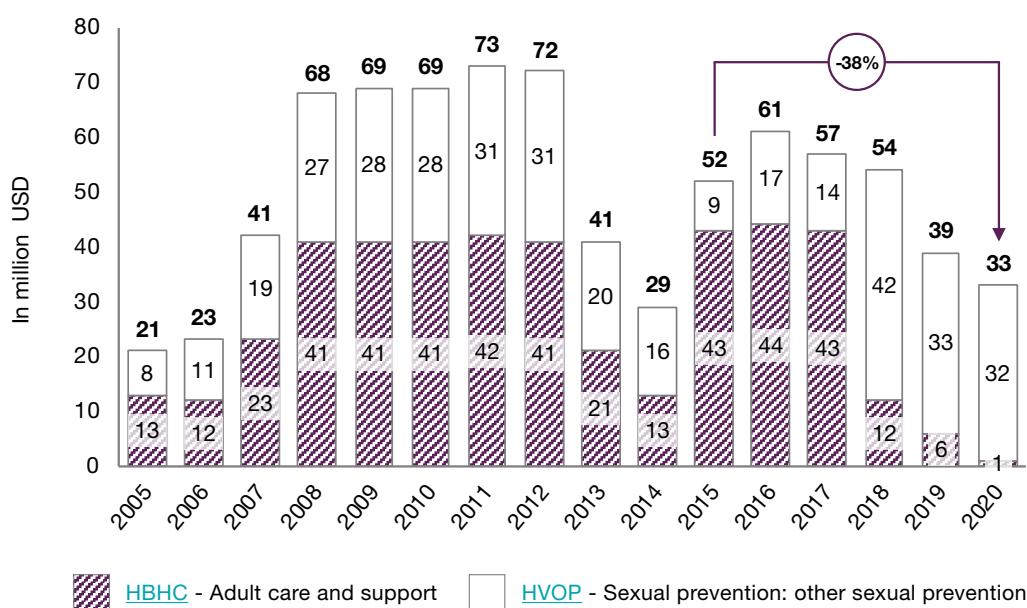


PEPFAR, President's Emergency Plan for AIDS Relief.

Source: The Global Fund (2020) and PEPFAR (2020).

For PEPFAR, the reduction in funding is even more significant for the two budget codes under which STI interventions are usually included, i.e. Sexual Prevention and Adult Care and Support¹²⁸ (Figure 14).

Figure 13: PEPFAR planned funding



PEPFAR, President's Emergency Plan for AIDS Relief.

Source: PEPFAR (2020), <https://copsdata.amfar.org/s/Kenya>

The current Global Fund grant includes STI screening and treatment interventions for the following key populations¹²⁹:

- ▶ comprehensive prevention programme for MSM (total: US\$ 2.7 million over four years), with a target coverage of 23,000 MSM by the end of the grant period;
- ▶ comprehensive prevention programme for sex workers and their clients (total: US\$5 million over four years) with a target coverage of 35,000 FSWs by the end of the grant period;
- ▶ HIV testing services (total: US\$ 8.2 million over four years)¹³⁰; and
- ▶ a prioritized allocation request to expand the prevention and management of coinfections and comorbidities for FSW (US\$ 9.4 million).

A back of the envelope calculation indicates that the annual amounts of external HIV funding that could be allocated for NG/CT testing would probably be less than \$1 million per year¹³¹. Assuming a total cost per test of between US\$ 5–12.5 for either TPP1 Minimal or Optimal (including procurement, distribution, and programme costs), this amount would allow the testing of 60,000–150,000 patients every year, i.e. close to what is needed to test the patient populations corresponding to use case #1 (TPP1 Minimal - pregnant women with symptoms) and use case #4 (TPP1 Minimal - key population with symptoms), but well below what would be required to implement other use cases at scale.



Source: FIND/Katie G. Nelson

REGULATORY ENVIRONMENT

Manufacturers must register new medical devices with the Pharmacy and Poison Board (PPB)¹³². The process is as follows:

- ▶ **Dossier submission:** applications must use the Common Submission Dossier Template and be submitted online on the PPB website. NG/CT POC diagnostic tests fall under class C¹³³. The registration fee is US\$ 1,000 for class C devices (non-refundable).
- ▶ **Review:** turnaround time range between 120–220 days depending on whether the application undergoes an expedited, abridged, or full review. Expedited and abridged reviews are only granted to devices that have been approved by three stringent regulatory agencies for a labeled use identical to that intended for marketing in Kenya.
- ▶ **Annual retention of medical devices:** each product is required to be listed on PPB's online register. Listings are done for the calendar year for US\$ 300 for class C medical devices.

It is advisable to also engage with the Kenya Medical Laboratory Technician Technologist Board (KMLTTB) during the registration process as this professional association is influential when it comes to diagnostic test selection in the country.



Source: FIND/John Rae

TEST SELECTION, PROCUREMENT, AND DISTRIBUTION

Test selection

Introducing a new diagnostic test is a long process that involves multiple stakeholders. For example, it took about 10 years for HIV self-testing to become an official policy in Kenya (in 2017) after the first pilots were conducted by the CDC in 2006.

The STI programme within NASCOP would be the main entity in charge of introducing the new test. A first step would be to conduct several field studies to assess the acceptability, feasibility, and cost-effectiveness of the POC test. As discussed earlier in this report, a POC test meeting the TPP1 Minimal will only get acceptance in Kenya if its cost-effectiveness profile is favorable.

Once the evidence base has been established, an updated STI strategy, STI clinical guidelines, and revised national medical supply list should be developed by NASCOP. In parallel, product registration can start. Once the PPB approves the technology, the designated distributor (often the local authorized representative listed in the registration dossier) pays a standard import permit to bring the POC test into Kenya before importing and distributing the test.

Figure 14 below summarizes the different steps, decision-makers and influencers that will be involved in the selection of the test.

Figure 14: Matrix of stakeholder involvement

		Decision makers	Influencers	Key activities
Activity		MOH-NASCOP	MOH-NASCOP	<ul style="list-style-type: none"> ▶ Coordinate pilot studies (e.g. cost-effectiveness) ▶ Revise STI guidelines ▶ Catalogue POC test in the Kenya Essential Medicines List
Production registration		PPB	WHO KMLTTB	<ul style="list-style-type: none"> ▶ Local agent of the manufacturer submits POC test registration dossier to PPB
Financing	National level	MOH-NASCOP, Ministry of Finance	WHO GF, PEPFAR	<ul style="list-style-type: none"> ▶ Prepare grant applications ▶ Prepare Government budget
	Counties	County Government	MOH, County assemblies, NGO	<ul style="list-style-type: none"> ▶ Prepare the country budget including health ▶ Seek approval from the County assembly
Procurement & distribution	National level	KEMSA/MEDS	MOH – Division of clinical Diagnosis	<ul style="list-style-type: none"> ▶ Float tender → select supplier ▶ Procure quantities → deliver to HF
	Counties	County Pharmacist	Health facilities, NGOs, patients associations	<ul style="list-style-type: none"> ▶ Pool orders from HF ▶ Place aggregated order to KEMSA
	Health facility (HF)	Pharmacist	MOH-NASCOP	<ul style="list-style-type: none"> ▶ Prepare order quantities based on historical cases, epidemiological profile of the county and budget available

HF, health facility; KMLTTB, Kenya Medical Laboratory Technician Technologist Board; PPB, Pharmacy and Poison Board; KEMSA, Kenya Medical Supplies Authority; MEDS, Mission for Essential Drugs and Supplies; MOH, Ministry of Health; NASCOP, National AIDS & STI Control Programme; NGO, non-governmental organization; STI, sexually transmitted infection; WHO, World Health Organization

Public sector

In the public sector, the Kenya Medical Supplies Authority (KEMSA) is responsible for the procurement of medical commodities. KEMSA uses a competitive procurement process. The MOH Division of Clinical Diagnostics will draft the test's technical specifications included in the tender notice¹³⁴.

KEMSA supplies commodities to about 4,000 health facilities, mainly public, based on orders received from counties. At the county level, the county pharmacist is responsible for pooling orders from individual health care facilities, aggregating these, and placing orders directly with KEMSA. The commodities and supplies are distributed to the facilities using a combination of in-house KEMSA vehicles and outsourced transporters. The agency also procures for some donor partners. Reports continue to indicate frequent stock-outs for key commodities and supplies at primary facilities.

With decentralization, KEMSA's role lost its prominence as county governments are no longer obliged to buy their supplies from KEMSA. Competitive pressure arising from decentralization forced KEMSA to adapt its business model and to enter into a service agreement with local governments for the purpose of providing procurement, warehousing and distribution services.

County health facilities will order and pay for their medical commodities on a demand-driven supply system. The funds acquired from these sales go towards replenishing KEMSA's stock. Counties now order as/when funds are available, which can be influenced by political dynamics outside of public health¹³⁵.

Private sector

Kenya has a vibrant and fast-growing pharmaceutical sector. One of the leading market players in the private sector is the Mission for Essential Drugs and Supplies (MEDS), a non-profit organization that procures and distributes medical items to about 1,800 faith-based, non-profit health facilities, and, since the decentralization in 2013, to some public health facilities as well.

Decentralization means that counties can now purchase from KEMSA in an ad-hoc manner, or from other suppliers such as MEDS¹³⁶. In August 2013, MEDS entered into partnerships with all the 47 county governments to strengthen the delivery of pharmaceutical and medical supplies under the decentralized governance structure.

The typical pricing structure in the country for medicines allows a 10% markup for the drug manufacturer over produced cost, a 15% margin for the distributor/wholesaler over the manufacturer's or importer's price, and a 33% margin for the retailer above the wholesale price¹³⁷. These margins can be reduced in competitive market segments.

ANNEX 1: INDIVIDUALS CONSULTED

	Organization	Interviewee	Date of interview
1	Kenya Red Cross Society	James Onsongo , Public Health Manager – Health and Social Services Dorothy Anjuri , Public Health Manager	12 Jan 2020
2	AMREF	Bernard Langat , Programme director: HIV, TB, Malaria and NCDs Julius Tome ; Head of Laboratory Program	27 Jan 2020
3	Kenya Medical Research Institute (KEMRI)	Dr Nelly Mugo , Chief Research Officer and Head, Sexual Reproductive and Adolescent Child Health Research Program	29 Jan 2020
4	Kenya Medical Research Institute (KEMRI)	Dr Simon Masha , Postdoctoral Researcher	29 Jan 2020
5	Clinton Health Access Initiative (CHAI)	Kennedy Mugambi , STI Program Manager Timothy Ngugi , Labs Associate	30 Jan 2020
6	International Centre for Reproductive Health Kenya (ICRHK)	Griffin Manguro , Acting Country Director and CEO	31 Jan 2020
7	STI Researcher	Vernon Mochache , Clinical Officer and Researcher	3 Feb 2020
8	United Nations Population Fund (UNFPA)	Dr Dan Okoro , SRH advisor	10 Feb 2020
9	National AIDS and STI Control Program (NASCOP)	Leonard King'Wara , Implementation, surveillance and Research Laboratory Lead	13 Feb 2020
10	Ministry of Health, Division of Clinical Diagnostics	Bernard Sande , Head of Clinical Diagnostics	20 Feb 2020
11	National AIDS and STI Control Program (NASCOP)	Dr Barbara Mambo , PMTCT Focal Person Janet Moma, STI Viral Hepatitis Focal Person	28 Feb 2020
12	Special Treatment Center - Nairobi	Dr Shilla Mwavua , Sub County HIV Programme Manager Dr Alina M , Clinical Officer	04 Mar 2020
13	National AIDS and STI Control Program (NASCOP)	Dr Catherine Ngugi , Head of NASCOP	20 Apr 2020

ANNEX 2: TEST PROFILES DESCRIBED TO KEY STAKEHOLDER INTERVIEWEES

During the key stakeholder interviews, all KSIs agreed that the characteristics for the two POC tests should be as follows. The test profiles shifted throughout the duration of the project, but to keep consistency, additional details were not provided to the interviewees.

	TPP1 Minimal	TPP1 Optimal
Key distinction	NG or NG/CT diagnosis in symptomatic patients	NG or NG/CT diagnosis in symptomatic patients and screening to detect asymptomatic infection
Cost	KSh 300	KSh 500–1,200
Sensitivity	Sensitivity: >80% Specificity: >95%	Sensitivity: >90% for LFA, 95% for molecular Specificity: >98%
Type of test	Uncertain at this time; either LFA or molecular	Uncertain at this time; either LFA or molecular
Time to result	Less than 30 minutes	Less than 30 minutes
Sample type	High vaginal or urethral swab	High vaginal or urethral swab; possibility urine

CT, *Chlamydia trachomatis*; KSh, Kenyan shilling; LFA, lateral flow assay; NG, *Neisseria gonorrhoea*

ANNEX 3: NEISSERIA GONORRHOEA POINT-OF-CARE TEST MARKET SIZING METHODOLOGY

Introduction

Our approach closely follows the methodology developed and improved over the years by WHO to quantify STI prevalence and incidence^{139,140}. WHO estimates are based upon literature reviews of prevalence data from 2005 through 2012, among general populations, for genitourinary infection with CT, NG, and trichomoniasis.

To generate the market sizes of the different use

case scenarios in Kenya, we used country-specific data, such as target population size and treatment-seeking rate by sex, whenever possible. We calculated the total available market in Kenya for two NG/CT POC tests (TPP1 Minimal and Optimal) under different use case scenarios.

Market sizes were calculated for the five following use cases (Table 4).

Table 4: Use cases considered for market sizing

Use case #	TPP1 Minimal	TPP
1	Key populations presenting with symptoms	Minimal
2	Pregnant women presenting with symptoms	Minimal
3	General population presenting with symptoms	Minimal
4	Pregnant women who can afford to pay for the test (private sector)	Optimal
5	Key populations	Optimal

Limitations of the market sizing

The estimates produced as part of the market sizing represent the potential demand based on estimates of incidence. Data are not available that would assist with any triangulation or validation of the estimated sizes.

The estimates also do not account for the following factors that would likely limit the potential demand for each use case. The market-size figures presented

in the report should, therefore, be interpreted as maximum rather than conservative estimates:

- ▶ For all use cases, it is likely that political and operational factors, funding and implementation capacity will constrain the scale of testing programmes. It is also likely that programmes will prioritize certain populations for pragmatic reasons (e.g.

the ability to leverage an existing service) as opposed to strict prioritization based on need, impact, or risk.

- ▶ At this time, there is no clear prioritization of any specific use case by the MOH, as stakeholders discussed multiple use cases and there were conflicting opinions about the populations to target and which level facility or public health agency should implement the test. The most frequent responses were considered, along with those of key decision-makers (i.e. head of NASCOP), but the ultimate direction the MOH will choose is unknown.
- ▶ Acceptability of the diagnostic by HCWs and laboratory personnel were not considered within the estimates. This includes their capacity and comfort level to complete such a test, and their perception of the additional workload etiological screening requires compared with syndromic management. These are highly dependent on information

that is not yet available, such as the sample type required for the test, the type of test, and the training needed. Within the estimates, workload, staffing, and human resources were not considered to determine the ceiling for the number of tests the health system could incorporate.

- ▶ Test acceptability by patients – including the sample collection method and associated costs of the diagnostic – was not accounted for within the potential demand estimates.

TPP1 Minimal – Market size calculation

The first test considered, “TPP1 Minimal”, is a basic POC test for NG/CT identification that could be used to diagnose patients who are symptomatic and seek care. For TPP1 Minimal, our estimates capture the total potential number of cases who present with urethral or vaginal symptoms and are seeking care. We did not model the effect of test adoption by government and HCWs over time or other drivers of demand.

Size of the target populations

Population sizes were obtained from the following sources:

Table 5: Source of population sizing

Population	TPP1 Minimal
Kenya total population by sex (15–49 years)	UN Population forecast for 2020 (https://population.un.org)
Number of pregnant women	[Crude birth rate x total population] – [# of multiple births] ¹⁴²
AGYW (15–24 years)	UN Population forecast for 2020 by age
MSM	UNAIDS Atlas of Key Population, 2018 data
FSW	UNAIDS Atlas of Key Population, 2018 data
PrEP users	PrEP Watch ¹⁴³ (https://www.prepwatch.org/country/kenya/)
PLHIV	PLHIV 15+ (https://aidsinfo.unaids.org/)

AGYW, adolescent girls and young women; MSM, men who have sex with men; FSW, female sex workers; PrEP, pre-exposure prophylaxis; PLHIV, people living with HIV

Incidence estimates

We used the incidence estimates for the Africa region as calculated by Newman (2015)¹⁴⁴. Briefly, pooled prevalence rates for chlamydia, gonorrhoea, and trichomoniasis were calculated from 79 studies¹⁴⁵ that met the inclusion criteria, i.e. sample size of at least 100 specimens collected from 2005 through 2012 in a population that could be considered representative of the general population. The study also used an internationally recognized diagnostic test with adequate performance characteristics on urine, urethral, or cervicovaginal specimens. Data were standardized for laboratory test type, geography, age, and high-risk populations, and combined using a Bayesian meta-analytic approach. Regional incidence estimates were generated from prevalence estimates by adjusting for the average duration of infection¹⁴⁶ using the equation: $\text{incidence} = \text{prevalence} / \text{average duration of infection}$ ¹⁴⁷.

We considered using the Spectrum STI Module¹⁴⁸ (Spectrum STI) with epidemiological studies conducted in Kenya to generate more context-specific incidence

estimates. Spectrum STI has 11 studies pre-populated in the Kenya file. The majority (6 out of 11) surveyed women at ANC clinics. Only one study surveyed men. No one tested positive for gonorrhoea in that study.

After reviewing Spectrum STI's output for Kenya, we decided not to proceed with this method for the following reasons:

1. Due to the limited number of country-specific studies, the 95% confidence intervals around the estimates were very wide (Figure 16 and Figure 17). Uncertainties in the national incidence estimates meant that the estimated number of cases would also be very uncertain.
2. Given that the only study that enrolled men did not identify anyone testing positive for gonorrhoea, the model was unable to generate an incidence estimate for gonorrhoea in Kenya (Figure 17).

Figure 15: Country-specific vs. Africa-wide NG and CT incidence rate (women aged 15–49 years)

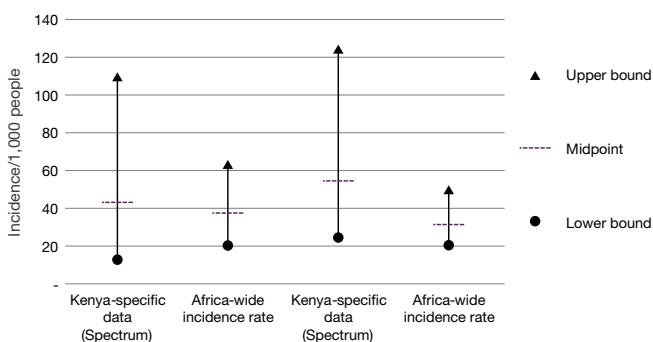
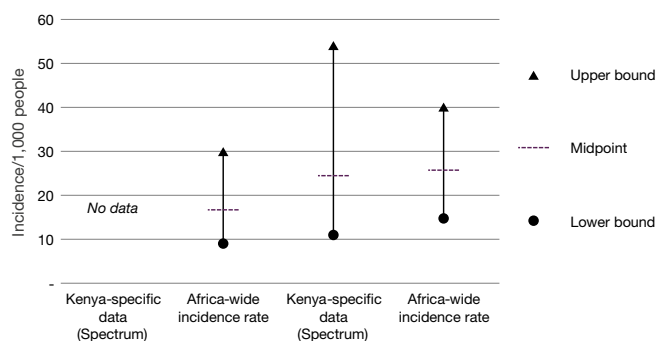


Figure 16: Country-specific vs. Africa-wide NG and CT incidence rate (men aged 15–49 years)



Due to the limitations of Spectrum STI, we decided to apply the incidence estimates for the Africa region provided in the Newman study to the Kenyan population. Those estimates have narrower confidence intervals and allowed us to generate more accurate quantification of the market sizes. Besides, as the midpoint estimates from the Newman study are generally close to midpoint estimates within Spectrum, using studies from a broader geographic area does not substantially over or

underestimate STI incidence in Kenya.

It should be noted that the above incidence estimates are valid for the general low-risk population. Since KPs, e.g. FSW and MSM, tend to have a higher risk of contracting STIs, these national or regional incidence rates should be adjusted. In our model, we used the adjustment factors prepopulated in Spectrum's STI module in our market sizing model (Table 6).

Table 6: Adjustment factors for high-risk populations (Spectrum's STI module)

STI	Prevalence ratio	Sex	Adjustment factor	Lower bound	Upper bound
Gonorrhoea	MSM to low-risk men	M	10	7.5	15
Gonorrhoea	FSW to low-risk women	F	10	7.5	15
Chlamydia	MSM to low-risk men	M	10	5	20
Chlamydia	FSW to low-risk women	F	5	3.75	7.5

MSM, men who have sex with men; FSW, female sex workers

Sources: Spectrum-STI estimations in Morocco (2016), Mongolia, Colombia and Georgia (2017) and South Africa (2018); Smolak A et al. The epidemiology of *Chlamydia trachomatis* in the Middle East and North Africa: Systematic review, meta-analyses, and meta-regressions. *Lancet Global Health*. 2019;7:e1197–225.

We cross-checked the above adjustment factors using Kenya-specific epidemiological studies of high-risk populations, i.e. FSW, MSM, and MSW. Table 7 shows the crude¹⁴⁹ ratio between prevalence rates among most-at-risk populations in Kenya and the pooled prevalence rates among low-risk populations in Africa. We found that MSM and MSW are 8–18 times more likely to be infected with gonorrhoea than low-risk males in Africa,

which is broadly in line with the adjustment factor used in Spectrum STI (midpoint = 10; range = 7.5–15). However, the STI prevalence rate among other high-risk groups in Kenya is not significantly higher than for low-risk populations in Africa. For instance, the prevalence of chlamydia among FSW in Kenya (Nairobi) was broadly similar to the one calculated across Africa among low-risk women.

Table 7: High-/low-risk population prevalence ratios

KP	STI	Prevalence among HRP (Kenya)*	# of data points (studies)	Pooled prevalence among LRP (Africa)**	Crude prevalence ratio (HRP/LRP)
FSW	Gonorrhoea	3.3%	2	1.7%	2.0
FSW	Chlamydia	4.2%	2	3.7%	1.1
FSW	Trichomoniasis	12.1%	2	11.5%	1.1
FSW	Bacterial vaginosis	15.1%	1	N/A	N/A
MSM	Gonorrhoea	4.2%	1	0.5%	8.4
MSM	Chlamydia	1.7%	1	2.5%	0.7
MSW	Gonorrhoea	8.8%	1	0.5%	17.6
MSW	Chlamydia	7.7%	1	2.5%	3.1

*When two or more studies among high-risk populations were found, a simple average was calculated; **Source: Newman 2015, op. cit.; HRP, high-risk population; LRP, low-risk population; FSW, female sex worker; MSM, men who have sex with men; MSW, male sex worker

Nevertheless, we think the adjustment factors populated in Spectrum STI are more robust than the ratios listed in Table 7. Indeed, very few recent STI prevalence studies exist for the most-at-risk populations in Kenya (two on FSW and one on MSM/MSW). All these studies were conducted in Nairobi. Their findings might not be applicable to the broader general population. By contrast, the adjustment factors used in Spectrum STI were informed by broader and richer data sources, i.e. one meta-analysis of chlamydia prevalence in the Middle East and North Africa drawing from 552 chlamydia prevalence measures from 20 countries, and insights from country modeling workshops in Morocco (2016), Mongolia, Colombia and Georgia (2017) and South Africa (2018).

Adjusting for coinfections

STI coinfections are common. If a significant proportion of the population is infected by several STIs at the same time, the number of incident infections could be much higher than the number of unique individuals. Since we aimed to estimate market sizes for a diagnostic test, we are interested in the number of unique individuals.

Korenromp (2017) uses a co-infection rate of 5–15% across the syndromes and STIs in her calculation¹⁵⁰. We used the midpoint of this range (10%) to adjust the number of incident infections downward and obtained the number of individuals infected.

Proportion of symptomatic patients

We used the proportion of symptomatic patients as provided in the Newman 2015 meta-analysis (Table 8). The values assigned to those parameters were reviewed in preparation for the WHO STI estimates and it was decided to use the same values as those used to generate the 2008 estimates, which were based on a literature review updated that year. We did not find sufficient Kenya-specific data to warrant changing those global estimates.

Table 8: Probability of men and women developing symptoms

Infection	Men	Women
Chlamydia	54%	17%
Gonorrhoea	64%	34%
Trichomoniasis	6.7%	34%

For PrEP users, as no disaggregation by sex was available, we used the median proportion of symptomatic cases between men and women to obtain the proportion of symptomatic cases.

Care seeking

Finally, we used access to care data among different population groups in Kenya to obtain the total number of symptomatic patients who seek or receive care and could therefore be tested for gonorrhoea. Treatment seeking and service coverage rates were obtained from the following sources (Table 9).

Table 9: Treatment seeking and coverage population group

Target group	Value	Source
Women seeking treatment for STIs	68%	Kenya DHS 2014, Figure 13.5
Men seeking treatment for STIs	70%	Kenya DHS 2014, Figure 13.5
Pregnant women (at least 1 ANC visit)	95%	Pregnant woman receiving at least 1 ANC consultation (Kenya DHS, 2014)
MSM (service coverage ¹⁵¹)	69%	Musyoki (2018) PLOS ONE. doi:10.1371/journal.pone.0203784
FSW (service coverage)	69%	Musyoki (2018). See above.
PLHIV (ART coverage)	68%	UNAIDS data (% on ART)

ANC, antenatal care; ART, antiretroviral therapy; DHS, Demographic Health Survey; FSW, female sex worker; MSM, men who have sex with men; PLHIV, people living with HIV; STIs, sexually transmitted infections

TPP1 Optimal – market size calculation

A test with higher sensitivity, “TPP1 Optimal”, would be used for screening asymptomatic patients, mainly high-risk and vulnerable populations. According to interviews, the populations that programmes would consider include FSW, MSM, HIV-positive patients, and people enrolled in PrEP.

Calculating the market size for this test requires a different approach. We started with the size of the KPs, applied the proportion who already have access to healthcare services (either because they are seeking healthcare at a public or private service point or are reached by NGO programmes), and multiplied these values by the frequency of testing.

Another use case proposed by several key interviewees would cover the needs of pregnant women who can afford to buy the test in the private sector. Here, we used the top wealth quintiles in the 2014 DHS as a proxy for the ability to pay for the test.

Size of the target populations

Population sizes were obtained from the following sources:

Table 10: Population sizes

Population	Source & methodology
Number of pregnant women	[Crude birth rate x total population] – [# of multiple births ¹⁵³]
MSM	UNAIDS Key Populations Atlas , 2018 data
FSW	UNAIDS Key Populations Atlas , 2018 data
PrEP users	PrEP Watch ¹⁵⁴ , https://www.prepwatch.org/country/kenya/
PLHIV	PLHIV 15+, https://aidsinfo.unaids.org/

FSW, female sex workers; MSM, men who have sex with men; PLHIV, people living with HIV; PrEP, pre-exposure prophylaxis

There are possible overlaps between members of high-risk and vulnerable populations. For instance, some PrEP users might also identify as MSM or FSW. However, the extent of overlap is not clear and we lack data to quantify this. The impact may be that a person is tested multiple times during a year; for example, a person might be screened during one of his/her routine ART medication refill visits and also through outreach to high-risk groups. In this case, the person would receive more than one test during the year.

Therefore, the figures presented in the market size section of the report should be considered a maximum, rather than conservative estimates.

Access to care

We define access to care either as the proportion of patients who spontaneously seek care in a public or private service point or individuals who are served by outreach services (e.g. NGO mobile clinics).

Table 11: Access to care by population group

Target group	Value	Source
Pregnant women (at least 1 ANC visit)	95%	Pregnant woman receiving at least 1 ANC consultation (Kenya DHS, 2014)
MSM (service coverage)	69%	Musyoki (2018) PLOS One. doi:10.1371/journal.pone.0203784
FSW (service coverage)	69%	Musyoki (2018). See above.
PLHIV (ART coverage)	68%	UNAIDS data (% on ART)

ANC, antenatal care; ART, antiretroviral therapy; FSW, female sex worker; MSM, men who have sex with men; PLHIV, people living with HIV

Frequency of testing

We assume that the most-at-risk populations, i.e., MSM, FSW, and PrEP users, are tested twice a year, while the other at-risk populations, i.e. PLHIV, AGYW, and pregnant women, are tested once a year¹⁵⁵.

ANNEX 4: KEY USE CASES FOR TPP1 MINIMUM AND OPTIMAL

TPP1 Minimum use case summary table

Use case	Populations presenting w/ symptoms	Potential demand	Health system entry point	Current initiatives that target those populations
1	Pregnant women	~197,000 tests/yr (Range: 124,000–294,000)	Level 2+, ANC units Routine access for ANC care	<i>7 out of 10 pregnant women in Kenya attend the four scheduled antenatal care¹⁵⁶.</i> Key partners: EGPAF, FHI360, m2m, CDC/PEPFAR
2	Anyone presenting with symptoms	~1,700,000 tests/yr (Range: 1M– 2.6M)	Level 2+	<i>No STI-specific programming. STIs are incorporated within HIV and SRH programs, and theoretically in routine primary care, however interviewees suggest training and knowledge are quite low among frontline health workers.</i>
3	AGYW	~545,000 tests/yr (Range: 344,000–812,000)	Level 2+ 7% of all facilities have youth friendly services at facilities (2010)	<i>Programming is focused within the urban centres of the country with substantial testing for HIV. 51% percent of AGYW in Nairobi reported that they had ever tested for HIV as a proxy for accessing care.</i> Key partners: PEPFAR (Dreams), FHI, GOAL-Kenya
4	KPs (MSM, FSW, PrEP users, PLHIV) with symptoms	~ 276,000 tests/yr (Range: 145,000–543,000)	Level 4,5,6	<i>Extensive partner and government support for KP programming.</i> Key partners: KEMRI, Kenya Key Populations Consortium ¹⁵⁸ , ICRHK

AGYW, adolescent girls and young women; FSW, female sex worker; KP, key populations; MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; w, with; Yr, year

TPP1 Optimal use case summary table

Use case	Population	Potential demand	Access the health system	Current initiatives that target those populations
1	Private sector – pregnant women	~380,000 tests/year	Private, research	<i>No nationwide programming known at this time.</i> Key partners: KEMRI, private hospitals
2	Highest high-risk populations identified using a screening algorithm for high-risk populations through implementation research	~1.9 million tests/year	Private/FBO/NGO, research	<i>KEMRI's Wellcome Trust Collaborative Research Program has initiated several research pilots including a recent (March 2020) Gonococcal Vaccine Study in Key Populations.</i> Key partners: KEMRI, CDC/PEPFAR

FBO, faith-based organization; KEMRI, Kenya Medical Research Institute; NGO, non-governmental organization

FOOTNOTES AND REFERENCES

1. Newman L et al. Global estimates of the prevalence and incidence of four curable sexually transmitted infections in 2012 based on systematic review and global reporting. PLOS ONE. 2015;10(12):e0143304. doi:10.1371/journal.pone.0143304.
2. World Health Organization. Global health sector strategy on sexually transmitted infections 2016–2021. 2016 (<https://www.who.int/publications/i/item/WHO-RHR-16.09>, accessed 17 July 2020).
3. While one KSI raised concerns about the representativeness of the DHS, it is the only publicly available data source for national STI reporting. Sentinel sites are not reporting, and other estimates available are from specific population or regionally based studies (Table 1).
4. Kenya National Bureau of Statistics; Ministry of Health, Kenya; National AIDS Control Council, Kenya; Kenya Medical Research Institute; and National Council for Population and Development, Kenya, 2015; Kenya Demographic and Health Survey 2014, Rockville, MD, USA.
5. The question asked within the 2014 Kenya DHS was “*During the last 12 months, have you had a disease which you got through sexual contact?*”
6. Griffin Manguro, International Centre for Reproductive Health Kenya (ICRHK), interviewed on 31 January 2020.
7. Maina AN et al. Prevalence and risk factors of three curable sexually transmitted infections among women in Nairobi, Kenya. BMC Res Notes. 2016;9:193. doi:10.1186/s13104-016-1990-x.
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13. Muraguri N et al. HIV and STI prevalence and risk factors among male sex workers and other men who have sex with men in Nairobi, Kenya. J Acquir Immune Defic Syndr. 2015;68(1):91–6. doi: 10.1097/QAI.0000000000000368.
14. Snowball sampling is a nonprobability sampling technique where existing study subjects recruit future subjects from among their acquaintances.
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17. National Aids Control Council. Kenya Aids Strategic Framework 2014/15–2018/19 (http://nacc.or.ke/wp-content/uploads/2015/09/KASF_Final.pdf, accessed 17 July 2020).
18. UNAIDS. Kenya/ 2019 (<https://www.unaids.org/en/regionscountries/countries/kenya>, accessed 17 July 2020).
19. PrEPWatch. Kenya. 2020 (<https://www.prepwatch.org/country/kenya/>, accessed 17 July 2020).
20. Ministry of Health. Kenya Health Sector Referral Strategy. 2014 (<https://www.measureevaluation.org/pima/referral-systems/referral-strategy>, accessed 17 July 2020).
21. The number of level 1 facilities is not defined, as most of these facilities are supported by an external partner or multiple partners and not the government.
22. The reach of a nurse’s ability to prescribe depends on the facility’s human resources. In lower-level facilities and those with limited resources, nurses can and do prescribe.
23. Interviews with Dr Vernon Mochache and Dr Griffins Manguro.
24. Kenya Master Health Facility List (<http://kmhfl.health.go.ke/> accessed April 21, 2020). Sources have indicated that although this is the official MOH facility mapping tool, it isn’t always 100% accurate in its facility type.
25. A clinical officer is a non-physician clinician who can diagnose and treat, but cannot perform surgery. The clinical officer role in Kenya is not clearly understood, which has given rise to some conflict (see Mbindyo P et al. Hum Resour Health. 2013;11:32. doi: 10.1186/1478-4491-11-32).
26. Kenya Master Health Facility List (<http://kmhfl.health.go.ke/> accessed April 21, 2020). Sources have indicated that although this is the official MOH facility mapping tool, it isn’t always 100% accurate in its facility type.
27. A medical officer is a physician who can diagnose, treat/prescribe, and perform surgery (see Mbindyo P et al. Hum Resour Health. 2013;11:32. doi: 10.1186/1478-4491-11-32).
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29. Netherlands Enterprise Agency. Kenyan Healthcare Sector: Opportunities for the Dutch Life and Science and Health Sector. 2016
30. Barnes J et al. Private health sector assessment in Kenya (English). World Bank working paper; no. 193. Washington, DC: World Bank. 2010 (<http://documents.worldbank.org/curated/en/434701468048274776/Private-health-sector-assessment-in-Kenya>, accessed 17 July 2020).
31. World Bank, 2013, op. cit.
32. Bernard Langat, African Medical and Research Foundation, interviewed on 27 January 2020.
33. Kenya National Bureau of Statistics, 2014, op. cit.
34. NACC is a semi-autonomous board that can attract separate funding, with the CEO decided by the board of directors, while NASCOP is part of the MOH, and members are appointed.
35. From interview with Drs Mochache and Manguro.
36. This placement was made by Dr Ngugi, as she wanted to anchor the STI work where she has easy access to it within NASCOP.
37. Clinton Health Access Initiative is the implementing partner of this funding and is the main partner supporting this work within the MOH.

38. Dr Okoro, United Nations Population Fund (UNFPA), interviewed on 10 February 2020.
39. NASCOP. Kenya National Guidelines for Prevention, Management and Control of Sexually Transmitted Infections. 2018 (<http://nak.or.ke/wp-content/uploads/2019/05/final-STI-guidelines-17th-October-2018.pdf>, accessed 17 July 2020).
40. Dr Masha, Kenya Medical Research Institute, interviewed on 29 January 2020, and Dr Mambo, NASCOP, interviewed on 28 February 2020.
41. Kennedy Mugambi, Clinton Health Access Initiative, interviewed on 30 January 2020, and Leonard King'Wara, NASCOP, interviewed on 13 February 2020.
42. Odhiambo, Fredrick et al. "Antimicrobial resistance: capacity and practices among clinical laboratories in Kenya, 2013." *The Pan African medical journal* vol. 19 332. 27 Nov. 2014, doi:10.11604/pamj.2014.19.332.5159. All labs (9) reviewed during Odhiambo, Fredrick et al., confirmed through KSIs
43. Ministry of Health. National Public Health Lab Strategic Plan 2016–2020 (<https://nphl.go.ke/wp-content/uploads/2018/10/NPHL-Strategic-Plan-2016-2020.pdf>, accessed 17 July 2020).
44. Division of National Public Health Laboratory Annual Report 2015–2016; the type of treatment was not available.
45. Stated by Leonard King'Wara, NASCOP, interviewed on 13 February 2020; and Bernard Langat; AMREF, interviewed on 27 January 2020.
46. In 2017, CDC and the National Public Health Laboratory Services piloted the AMR surveillance system and assessed infection prevention and control practices at two public hospitals in Thika and Kitale counties. Although basic laboratory equipment and laboratory information systems were in place, the assessment showed that testing and reporting capacities needed to be strengthened. There are plans to scale this pilot in the next 5 years. (see <https://www.cdc.gov/globalhealth/countries/kenya/blog/strengthening-antimicrobial-resistance-surveillance.html>, accessed 17 July 2020).
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48. Mukokinya MMA et al. Dispensing of antimicrobials in Kenya: a cross-sectional pilot study and its implications. *J Res Pharm Pract.* 2018 Apr-Jun; 7(2): 77–82.
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55. Kenya National Bureau of Statistics (2014), op. cit.
56. Morris CN, & Ferguson AG. Sexual and treatment-seeking behaviour for sexually transmitted infection in long-distance transport workers of East Africa. *Sex Transm Infect.* 2007;83(3):242–245. <https://doi.org/10.1136/sti.2006.024117>.
57. Lafort Y et al. Where do female sex workers seek HIV and reproductive health care and what motivates these choices? A survey in 4 cities in India, Kenya, Mozambique and South Africa. *PLOS ONE*2016;11(8):e0160730. doi:10.1371/journal.pone.0160730.
58. Morris et al. 2007, and interviews with Dr Manguro and Dr Mochache.
59. Griffin Manguro, International Centre for Reproductive Health Kenya (ICRHK), interviewed on 31 January 2020.
60. Moses et al, 1994, Morris et al 2007.
61. Chesang K et al. Healthcare provider perspectives on managing sexually transmitted infections in HIV care settings in Kenya: A qualitative thematic analysis. *PLOS Med.* 2017 Dec 27;14(12):e1002480. doi: 10.1371/journal.pmed.1002480.
62. Dr Dan Okoro, United Nations Population Fund (UNFPA), interviewed on 10 February 2020.
63. From interviews with Griffin Manguro, International Centre for Reproductive Health Kenya (ICRHK), interviewed on 31 January 2020 and with the Special Treatment Center – Nairobi, 04 March 2020.
64. The healthcare worker interviewed reported receiving the guidelines as a PDF on WhatsApp; this was her only access to them.
65. Only one month of data was available for 2019, and it was largely incomplete.
66. World Health Organization. Primary Health Care Systems (PRIMASYS): Case study from Kenya. 2017 (https://www.who.int/alliance-hpsr/projects/alliancehpsr_kenyaabridgedprimasys.pdf?ua=1, accessed 17 July 2020).
67. The study was conducted prior to a change of first-line treatment due to global resistance.
68. Level 2 facilities - 4 public, 10 private, 5 faith-based; level 3 facilities – 10 public, 8 private, 5 faith-based.
69. Reported by a clinical manager of a level 4 public facility who sees 80 patients a day, with half of them having an STI.
70. Daniels B et al. Use of standardised patients to assess quality of healthcare in Nairobi, Kenya: a pilot, cross-sectional study with international comparisons. *BMJ Glob Health.* 2017;2(2):e000333. doi: 10.1136/bmjgh-2017-000333.
71. The guidelines state that the healthcare provider should take a detailed history and carry out a careful oropharyngeal, pelvic and/or rectal examination to detect the presence of infection for all those who have a history of receptive anal intercourse. The 5 P's of sexual behaviours – partners, practices, prevention of pregnancy, protection from STDs, and past history of STDs – which are critical during STI screening can help the healthcare provider assess risk of STI in the patient.
72. Chesang. 2017. Op. cit.
73. Kihuba E et al. Assessing the ability of health information systems in hospitals to support evidence-informed decisions in Kenya. *Global Health Action.* 2014;7:24859. doi:10.3402/gha.v7.24859.
74. The three indicators that were reported on were urethral discharge re-attendance, urethral discharge referrals, urethral discharge initial visit, with the majority of reporting occurring in just one month (February 2019).
75. A list of consulted studies regarding the prevalence of NG is found in Table 1.

76. Masha et al. 2017. Op. cit.
77. The price of the GeneXpert test varied from KSh 1,000 to 2,300, possibly due to different terms of the pricing (reagent only, compared with reagent rental).
78. Study is being completed by King'wara as part of his PhD.
79. Leonard King'wara, NASCOP, interviewed on 13 February 2020.
80. EAC Regional Knowledge Management Portal For Health. EAC Boresha Huduma Sexually Transmitted Infections (STI) Study. 2020 (<https://health.eac.int/events/eac-boresha-huduma-sexually-transmitted-infections-sti-study>, accessed 17 July 2020).
81. See Annex 2 for descriptions of the tests used during the interviews.
82. Dr Catherine Ngugi strongly indicated a need to focus on AGYW and ABYM at level 4, 5 and 6 facilities. Her reasoning for the facility level was threefold: (1) these facilities all are supported by lab technologists who would conduct the test; (2) stigma and size of facility – level 2 facilities are in the village and the nurse knows everyone in the village, so patients worry about privacy. Therefore, they choose to go to more crowded, larger facilities where there are more people, and where there is a lesser likelihood of being seen/known; (3) there are more clinicians at level 4, 5, 6 facilities who can manage STIs.
83. A gram stain, the test that would be done to confirm NG costs KSh 200 to complete, yet it is not effective in women.
84. National Health Insurance Fund. Linda Mama (<http://www.nhif.or.ke/healthinsurance/lindamamaServices>, accessed April 2020).
85. Detailed calculations and assumptions are available in the Excel file "Kenya Gonorrhoea POC test market sizing".
86. Dr Ngugi indicated this use case would benefit from a pilot and there are existing systems within Kenya, specifically Kisumu, due to the high prevalence and robust donor support for programming in this region.
87. Dr Vernon Mochache, STI Researcher, interviewed on 3 February 2020.
88. Dr Barbara Mambo, NASCOP, interviewed on 28 February 2020.
89. Dr Griffin Manguro, International Centre for Reproductive Health Kenya (ICRHK), interviewed on 31 January 2020.
90. From interviews with Dr. Simon, Bernard Langat, Dr. Griffins.
91. Kennedy Mugambi, Clinton Health Access Initiative, interviewed on 30 January 2020.
92. UNFPA
93. Dr Vernon Mochache, STI researcher, interviewed on 3 February 2020
94. Bernard Langat; op. cit.
95. As a point of reference, there is a precedent during government transition to procure previously donor funded diagnostics. HIV test kits were fully funded through donor funding when rapid tests were first introduced, while now the MOH buys 70% of the test kits. In the next two years, the country will be transitioning to purchasing all the test kits.
96. From interviews with Dr Alina M, Dr Barbara Mambo, and Bernard Sande.
97. Dr Alina M, Special Treatment Center – Nairobi, 04 March 2020.
98. Dr Barbara Mambo, NASCOP, interviewed on 28 February 2020.
99. Masha et al. (2017), op. cit.
100. Detailed calculations and assumptions are available in the Excel file "Kenya Gonorrhoea POC test market sizing". Assumes pregnant women accessing private sector care belong to the highest economic quintiles.
101. Dr Griffin Manguro, International Centre for Reproductive Health Kenya (ICRHK), interviewed on 31 January 2020.
102. Estimates take into account the percentages of the population reached through both formal healthcare and NGO programmes. Specialty KP clinics are mostly FBO/NGO owned. While accessing care within the public sector, KPs often do not self-identify due to stigma. Detailed calculations and assumptions are available in the document "Kenya Gonorrhoea POC test market sizing".
103. All KSIs who were interviewed as a group concurred with one another on key opinions, therefore we count them as one interview.
104. While the Lab Technologist Act is several years old, one KSI indicated that this practice has increased in recent years due to an issue with false positive HIV tests in 2018.
105. Dr Simon Masha, Kenya Medical Research Institute (KEMRI), interviewed on 29 January 2020.
106. Cepheid. Xpert CT/NG: Fast and accurate diagnosis of Chlamydia and Gonorrhoea. 2019 (<https://p.widencdn.net/njgmun/Cepheid-Xpert-CT-NG-Brochure-CE-IVD-0379-English>, accessed 17 July 2020).
107. Avert. HIV and AIDS in Kenya. (<https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/kenya>, accessed April 2020).
108. Interviews with Dr Catherine Ngugi and Kenya Red Cross Society.
109. James Osongo, Kenya Red Cross Society, interviewed on 12 January 2020.
110. Dr Nelly Mugo, Kenya Medical Research Institute (KEMRI), interviewed on 29 January 2020.
111. Except during a brief spike in August 2017, during the elections, when the inflation rate shot up to 12%.
112. In other words, the national budget and the sum of the 47 counties' budget.
113. Ministry of Health. Kenya National Health Accounts 2015/2016. Nairobi, Kenya. 2019.
114. Under the so-called '10/20 policy' patients are required to pay a flat fee of ~US\$ 0.10 in dispensaries and ~US\$ 0.20 in health centres.
115. Ministry of Health. Kenya Health Policy 2014–2030, Nairobi, July 2014.
116. Opwora A et al. Implementation of patient charges at primary care facilities in Kenya: implications of low adherence to user fee policy for users and facility revenue. *Health Policy and Planning*. 2015;30(4):508–517. doi: 10.1093/heapol/czu026.
117. Ministry of Health. National and County Health Budget Analysis FY 2016/2017. Nairobi, Kenya. 2017.
118. Counties also increased recurrent budget allocation to non-pharmaceuticals (which could include medical devices and diagnostic tools), reaching 5% in the 2016/17 fiscal year from the 1.6% allocated in the 2014/15 fiscal year.
119. Opinion expressed by several respondents, notably Mr. Bernard Sande, Head of Clinical Diagnostics at the MOH, and Dr Barbara Mambo, NASCOP's PMTCT focal person.
120. Interview with Dr Barbara Mambo, NASCOP's PMTCT focal person, February 2020.
121. Interview with Leonard King'wara, NASCOP's implementation, surveillance and research lead, February 2020.
122. Interview with Mr. Bernard Sande, Head of Clinical Diagnostics at MOH, 20 February 2020.
123. The NHIF is available to workers in all sectors, both public, private, formal and informal. Enrollees pay monthly premiums. For those in the informal sector, the premium comes to about ~US\$ 5 per month.
124. National Health Insurance Fund, 2019, op. cit.

125. PharmAccess. A closer look at the healthcare system in Kenya. 2016 (<https://www.pharmaccess.org/wp-content/uploads/2018/01/The-healthcare-system-in-Kenya.pdf>, accessed 17 July 2020).
126. National Hospital Insurance Fund. Performance Report 2018. NHIF is a social health insurance fund, financed primarily from employee contributions paid for by formal sector workers who also constitute the main beneficiary population. Basic care, including drugs from the essential medicines and diagnostics list are covered under the fund.
127. Ministry of Health. Kenya Aids Strategic Framework 2014/2015 - 2018/2019, Nairobi, Kenya. 2014.
128. "Sexual Prevention" (HVOP budget code) includes STI management for PLHIV outside of care settings. STI treatment for PLHIV within care settings are coded under "adult care and support" (HBHC).
129. The Global Fund to Fight AIDS, Tuberculosis and Malaria. Funding Request Application Form (Full Review) - Period 2018–2020, Geneva. 2016.
130. While STI screening is not a major focus of this funding component, the proposal narrative mentions that in addition to HTS, "the grant will strengthen linkages from HTS to HIV treatment and care services, STI screening, diagnosis and treatment; and adolescent-friendly SRH services".
131. Assuming current funding for PEPFAR and the Global Fund Fight AIDS, Tuberculosis and Malaria is maintained at 2019/2020 levels, it is estimated that 2% of the relevant budget lines will be earmarked for NG/CT testing.
132. Ministry of Health – Pharmacy and Poisons Board. Guidelines on submission of documentation for registration of medical devices including in-vitro-diagnostics (IVD's), Nairobi, Kenya. 2018.
133. *ibid.*, p. 68
134. Interview with Mr. Bernard Sande, Head of Clinical Diagnostics at the MOH, 20 February 2020.
135. Tsofa B et al. Devolution and its effects on health workforce and commodities management – early implementation experiences in Kilifi County, Kenya. *Int J Equity Health*. 2017;16(1):169. doi: 10.1186/s12939-017-0663-2.
136. Yadav, Prashant. 2012. Kenya Medical Supplies Authority (KEMSA) : A case study of the ongoing transition from an ungainly bureaucracy to a competitive and customer focused medical logistics organization (English). Washington, D.C. : World Bank Group.
137. These markups are averages taken from a UNIDO report. UNIDO (UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION), Pharmaceutical Sector Profile: Kenya Global - UNIDO Project: Strengthening the local production of essential generic drugs in the least developed and developing countries, 2010.
138. Commonly referenced foreign exchange rate between the US dollar and Kenyan shilling is 100 Kenyan shillings to 1 US dollar. While the exchange rate fluctuates, for the purpose of the interviews this price point referenced an amount that was represented by the price of US\$ 5 to US\$ 12.
139. Newman L et al. Global estimates of the prevalence and incidence of four curable sexually transmitted infections in 2012 based on systematic review and global reporting. *PLOS ONE*. 2015;10(12):e0143304. doi: 10.1371/journal.pone.0143304.
140. Korenromp EL et al. Costing of national STI program implementation for the global STI control strategy for the health sector, 2016–2021. *PLOS ONE* 2017;12(1):e0170773. doi: 10.1371/journal.pone.0170773.
141. Source: UN Population data. We use the 2020–2025 crude birth rate projections, and the 2020 total population projections.
142. Gebremedhin S. Multiple births in sub-Saharan Africa: epidemiology, postnatal survival, and growth pattern. *twin research and human genetics*. *Twin Res Hum Genet*. 2015;18(1):100–107. doi:10.1017/thg.2014.82.
143. We use the midpoint of the range provided on the website. No disaggregation by sex was available.
144. Newman L et al. 2015. *Op. cit.*
145. 70 data points for chlamydia in women and 22 in men, 51 for gonorrhoea in women and 13 in men, and 45 for trichomoniasis in women and two in men.
146. Incidence is based on both prevalence and duration of illness. High prevalence of a disease within a population might reflect high incidence or prolonged survival without cure, or both. Conversely, low prevalence might indicate low incidence, a rapidly fatal process, or rapid recovery. This adjustment allows for determination of the infection rate from infectious people from the prevalence. If the average duration of infection is three days, then, on average, one third of the currently infected population recovers each day.
147. Boston University School of Public Health. Relationship among prevalence, incidence rate, and average duration of disease. 2016 (http://sphweb.bumc.bu.edu/otlt/MPH-Modules/EP/EP713_DiseaseFrequency/EP713_DiseaseFrequency7.html, accessed 17 July 2020).
148. The Spectrum STI module is a computer program developed to generate country estimates of prevalence levels and time trends for active syphilis, gonorrhoea and chlamydia. The STI module has been developed by Avenir Health with financial support from WHO.
149. Unadjusted for age structure, test type and other study characteristics. The prevalence ratios are therefore not entirely comparable and should be used as a rough sense check.
150. Korenromp EL et al. 2017. *Op. cit.*
151. Access to care for MSM and FSW were estimated using NASCOP's annual polling booth surveys in 2014 and 2015, which measure outcomes from the national HIV prevention programme for KPs. We use the proportion of MSM and FSW who reported receiving services from a project clinic or a drop-in centre.
152. Source: UN Population data. We use the 2020–2025 crude birth rate projections, and the 2020 total population projections.
153. Gebremedhin S. Multiple births in sub-Saharan Africa: epidemiology, postnatal survival, and growth pattern. *Twin Res Hum Genet*. 2015;18(1):100–107. doi:10.1017/thg.2014.82.
154. We use the midpoint of the range provided on the website. No disaggregation by sex was available.
155. While in the US, gonorrhoea screening of PrEP enrollees and KPs is recommended at least once a year, experts suggest this is not implemented due to the cost of current tests. Source: Foundation for Innovative New Diagnostics. High level assessment of market for point-of-care gonorrhoea tests (unpublished). 2019.
156. PEPFAR Annual Progress Report, Kenya, 2012.
157. Ziraba A et al. Understanding HIV risks among adolescent girls and young women in informal settlements of Nairobi, Kenya: Lessons for DREAMS. *PLOS ONE*. 2018;13(5):e0197479. doi: 10.1371/journal.pone.0197479.
158. The Kenya Key Populations Consortium is a network of organizations representing MSM, sex workers and people who use drugs — totaling over 90 KP-led organizations and allies.

