

RANDOX



The Global Economic Burden of STIs &
The Impact of the COVID-19 Pandemic
on Sexual Health



CONTENTS

OVERVIEW	1
URGENT NEED FOR A POSITIVE SEXUAL HEALTH STRATEGY	1
CURABLE & INCURABLE INFECTIONS	1
- Key Facts	1
- Asymptomatic STIs	3
- Antibiotic-Resistant Gonorrhoea	3
COVID-19 PANDEMIC	3
- Overview	3
- The Impact of COVID-19 Pandemic on Sexual Health Testing	4
RANDOX LABORATORIES	5
- CE Marked 10-plex STI Panel	5
- Test Menu	5
VIVALYTIC	6
- The Game Changing Molecular Diagnostics Platform	6
- Hi-plex Viavlytic Cartridges	6
- Vivalytic Workflow	6
CONCLUSION	7
REFERENCES	

AN OVERVIEW

Sexually Transmitted Infections (STIs) have a profound impact on sexual and reproductive health worldwide and can have serious consequences beyond the immediate impact of the infection itself. According to the World Health Organization (WHO, 2020) infections such as herpes and syphilis can increase the risk of HIV acquisition three-fold or more.¹ In England alone the number of new STI diagnoses in 2018 increased by 5% in comparison to 2017 (from 424,724 to 447,694) with Chlamydia remaining the most commonly diagnosed STI, accounting for almost half of new STI diagnoses in the year 2018.² More than 9 million women in the United States are diagnosed with an STI each year.³ Direct medical costs for eight major STIs such as human papillomavirus (HPV), herpes, syphilis, gonorrhoea and chlamydia have been estimated at US\$16.7 billion in the United States alone.⁴ Not only do STIs prove to be a great risk to health but they also impose major economic burdens on a global scale.

URGENT NEED FOR A POSITIVE SEXUAL HEALTH STRATEGY

The British Association for Sexual Health and HIV (BASHH), an organisation made up of medical practitioners, nurses, health advisers, scientists in the field of medicine and other healthcare workers have partnered up with the Terrence Higgins Trust, a British charity that campaigns on and provides services relating to HIV and sexual health launching a new State of The Nation Report on STIs 2020 in England. The report draws attention to the fact new STIs are diagnosed every 70 seconds in England, highlighting the urgent need for a positive and forward-looking national sexual health strategy to be put in place as soon as possible.¹³ Jonathan McShane, Chair of Terrence Higgins Trust says “this report shows that the nation’s sexual health is not in good shape and this must be a wake-up call to the Government to take action. Local government has played a key role in improving sexual health but has been held back by a combination of severe cuts to their public health budgets and the lack of a clear strategy. This has resulted in the rates of some STIs spiralling and services struggling to cope with demand. It is clear to see that sexual health has been neglected for too long and has not been a priority for successive governments. We urgently need comprehensive action that can help to halt the rising tide of STIs.”¹³ Dr Peter Salama, Executive Director for Universal Health Coverage and the Life-Course at the World Health Organisation (WHO) expressed his concern for the lack of progress in stopping the spread of sexually transmitted infections worldwide. “This is a wake-up call for a concerted effort to ensure everyone, everywhere can access the services they need to prevent and treat these debilitating diseases.”⁷

The dire need for the government to commit to a national sexual health strategy is evident in the lack of vision surrounding sexual health, the insufficient investment in public health funding and the soaring rate of STIs, especially in young people. The strategy must aim to reverse the increasing trends seen in the majority of STIs (syphilis, gonorrhoea, chlamydia and herpes), while continuing the progress made in others (genital warts and HPV). In addition to these, there must be a focus on the ever-worrying threat of drug resistance.¹⁴

CURABLE AND INCURABLE INFECTIONS

More than 30 different bacteria, viruses and parasites are known to be transmitted through sexual contact. STIs are predominantly spread by vaginal, anal and oral sexual contact however, some can also be spread through non-sexual relations such as blood or blood products. Eight of the 30 pathogens are linked to the greatest incidence of sexually transmitted disease, 4 are currently curable: syphilis, gonorrhoea, chlamydia and trichomoniasis. The other 4 are viral infections which are incurable: hepatitis B, which is one of the leading causes of liver cancer⁵, herpes simplex virus (HSV or herpes), HIV, and HPV. Symptoms or disease due to the incurable viral infections can be reduced, maintained or modified through correct treatment, reducing the risks of transference.¹

Key Facts:

- More than 1 million STIs are acquired every day worldwide.¹
- More than 500 million people are estimated to have a genital infection with herpes simplex virus (HSV).¹
- The majority of STIs have no symptoms or only mild symptoms that may not be recognised as an STI.¹
- STIs such as HSV type 2 and syphilis can increase the risk of HIV acquisition.¹
- STI diagnosis rates in 15-24 year olds are twice as high in men and seven times as high in women.⁶

Reports show chlamydia has remained the most commonly diagnosed STI in the UK, accounting for almost half of new STI diagnoses. The highest rates of chlamydia infection in both males and females are in the 20–24 years age group, accounting for 35% of male and 46% of female diagnoses. In 2018 there were 1,512 new episodes of chlamydia diagnosed in the UK, an increase of 2% since 2017 (Figure 1). Gonorrhoea is the second most common bacterial STI in the UK followed by syphilis, with gonorrhoea on the rise, showing an increase in diagnosis of 25% between 2017 and 2018.

		2014			2015			2016		
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
Chlamydia	<15	95	986	1,115	88	812	919	79	649	753
	15-19	16,843	48,738	66,192	15,457	43,593	59,633	14,726	42,026	57,436
	20-24	38,338	56,031	95,057	35,917	52,406	88,943	36,338	53,065	90,325
	25-34	30,254	27,688	58,161	30,517	27,741	58,538	31,613	28,995	61,060
	35-44	8,220	5,019	13,276	8,637	5,114	13,793	8,672	5,498	14,278
	45-64	4,298	1,803	6,119	4,575	1,709	6,303	4,716	1,849	6,603
	65+	279	51	332	275	47	340	340	62	415
	Unknown	147	119	639	138	148	770	106	107	506
Total	98,474	140,435	240,891	95,604	131,570	229,239	96,590	132,251	231,376	
Gonorrhoea	<15	7	75	82	19	65	85	11	46	57
	15-19	2,033	3,302	5,337	2,169	2,894	5,063	1,961	2,775	4,740
	20-24	7,145	3,490	10,636	7,998	3,450	11,456	6,910	3,480	10,400
	25-34	12,185	2,454	14,644	14,312	2,661	16,984	12,117	2,877	14,999
	35-44	5,546	629	6,176	6,740	646	7,389	5,582	708	6,295
	45-64	3,125	285	3,410	3,705	342	4,049	3,344	402	3,747
	65+	180	10	190	194	17	211	184	7	191
	Unknown	79	21	100	98	9	107	61	7	70
Total	30,300	10,266	40,575	35,235	10,084	45,344	30,170	10,302	40,499	
Syphilis	<15	0	0	0	1	0	1	0	1	1
	15-19	76	49	125	90	39	129	114	44	158
	20-24	455	60	515	596	84	680	667	87	755
	25-34	1,452	121	1,573	1,835	120	1,959	1,999	115	2,116
	35-44	1,313	52	1,365	1,490	70	1,560	1,665	63	1,729
	45-64	1,039	41	1,080	1,268	39	1,307	1,542	56	1,599
	65+	50	4	54	83	5	88	104	1	105
	Unknown	71	4	75	75	11	86	40	2	42
Total	4,456	331	4,787	5,438	368	5,810	6,131	369	6,505	
		2017			2018			2017-2018 Change		
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
Chlamydia	<15	78	546	635	82	590	695	5%	8%	9%
	15-19	14,523	41,268	56,279	14,654	40,688	55,817	1%	-1%	-1%
	20-24	36,340	53,728	90,661	36,723	54,915	92,173	1%	2%	2%
	25-34	32,084	29,535	61,907	35,016	31,546	66,805	9%	14%	8%
	35-44	9,150	5,680	14,896	10,936	5,935	16,930	20%	4%	14%
	45-64	5,254	1,874	7,156	6,520	2,131	8,679	24%	14%	21%
	65+	360	89	451	468	71	558	30%	-20%	24%
	Unknown	131	120	746	128	152	729	-2%	27%	-2%
Total	97,920	132,840	232,731	104,527	136,028	242,386	7%	2%	4%	
Gonorrhoea	<15	16	68	85	11	81	92	-31%	19%	8%
	15-19	2,514	3,704	6,227	3,094	4,585	7,708	23%	24%	24%
	20-24	8,060	4,366	12,439	9,706	5,508	15,260	20%	26%	23%
	25-34	14,643	3,349	18,021	18,107	4,446	22,592	24%	33%	25%
	35-44	6,690	850	7,558	8,318	1,156	9,485	24%	36%	25%
	45-64	4,186	431	4,623	5,600	584	6,196	34%	35%	34%
	65+	237	21	258	340	22	364	43%	5%	41%
	Unknown	71	10	81	66	12	78	7%	20%	-4%
Total	36,417	12,799	49,292	45,242	16,394	61,775	24%	14%	25%	
Syphilis	<15	1	2	3	0	0	0	-	-	-100%
	15-19	135	50	185	168	72	241	24%	44%	30%
	20-24	767	105	874	840	130	976	10%	24%	12%
	25-34	2,395	207	2,610	2,634	218	2,863	10%	5%	10%
	35-44	1,978	62	2,040	1,911	121	2,035	-3%	95%	0%
	45-64	1,868	53	1,928	1,967	57	2,039	5%	8%	6%
	65+	123	2	125	132	3	137	7%	50%	10%
	Unknown	45	0	45	36	1	37	-20%	-	-18%
Total	7,312	481	7,810	7,688	602	8,328	5%	25%	7%	

Figure 1 (Public Health England, 2019)
Number of selected STI diagnoses in the UK by gender & age group, 2014 - 2018

Asymptomatic STIs

The danger with STIs is that many are asymptomatic; meaning the infection fails to show the noticeable symptoms with which it is usually associated. Chlamydia is a bacterial infection which is asymptomatic in at least 50% of men and 70% of women.⁸ Women often have more serious health issues from STIs than men, including infertility, passing the infection onto the new-born and infection in other parts of the body.³ According to WHO, syphilis alone caused an estimated 200,000 stillbirths and new-born deaths in 2016, making it one of the leading causes of baby loss globally.⁷ Chlamydia and gonorrhoea are major causes of pelvic inflammatory disease (PID) and infertility in women, and in its later stages syphilis can cause serious cardiovascular and neurological disease.⁷ In 2018 there were 882 new episodes of gonorrhoea diagnosed in Northern Ireland GUM clinics, an increase of 30% since 2017.¹⁰ Of those tested, only 1 in 12 who get tested find they are infected with an STI, as most do not have any symptoms.⁶

Although STIs are asymptomatic, signs can include unusual discharge from the vagina, penis or anus, pain when urinating, lumps or skin growth around the genitals, a rash, unusual bleeding, itchiness or blisters around the genitals.² These symptoms usually appear after 2 to 3 weeks from exposure, but could start earlier or much later.⁹ On average, approximately 1 in 25 people globally have at least one case of STIs. According to the latest figures by WHO, those who have at least one STI, experience multiple infections at the same time.⁷

Antibiotic-Resistant Gonorrhoea

Antibiotic-resistance is the ability of bacteria to resist the effects of the drugs used to treat them, therefore the bacteria are free to keep multiplying.¹⁰ Gonorrhoea, which has developed a reputation as 'super gonorrhoea', has developed antibiotic resistance to three of the most common medications used to treat bacterial infections.⁶ According to WHO, super gonorrhoea has a high-level of resistance to the current treatment of the infection which includes penicillin, sulphonamides, tetracycline, fluoroquinolones, macrolides. Centers for Disease Control and Prevention (CDC) state that they are currently down to one last recommended and effective class of antibiotics, cephalosporins, to treat this extremely common infection.¹⁰ Super gonorrhoea has been reported by several countries including France, Japan, Spain, Australia and the UK.¹¹ With gonorrhoea outsmarting the antibiotics used to treat it, it is important to continuously monitor antibiotic resistance and encourage the research and development of new drugs, as this could help prevent future antibiotic resistant STIs.

CDC reports that ciprofloxacin, a fluoroquinolone, and two cephalosporins (ceftriaxone and cefixime) were the recommended treatments for gonorrhoea. However, in the late 1990s and early 2000s, ciprofloxacin resistance was detected in Hawaii and the West Coast. By 2004, ciprofloxacin-resistant gonorrhoea had significantly increased among men who have sex with men (MSM) leading to the discontinuation of the drug in this population. By 2006, nearly 14% of gonorrhoea samples were resistant to ciprofloxacin. Ciprofloxacin resistance was present in all regions of the United States and in the heterosexual population. On April 13, 2007, CDC stopped recommending fluoroquinolones as empiric treatment for gonorrhoea altogether. The cephalosporins, either cefixime or ceftriaxone, were the only remaining recommended treatments. Similar to trends observed elsewhere in the world, CDC observed worrisome trends of decreasing cephalosporin susceptibility. To preserve cephalosporins for as long as possible, CDC has updated its Sexually Transmitted Disease Treatment Guidelines frequently since 2010. Currently, only one regimen is recommended as first-line treatment for gonorrhoea: the injectable cephalosporin, ceftriaxone, alongside oral azithromycin.¹⁰

In the UK, the prevalence of ciprofloxacin resistance is high (36.4% in 2017), therefore BASHH have recommended ciprofloxacin as only first-line treatment to the infection if the infection indicates susceptibility.¹²

COVID-19 PANDEMIC

Overview

An outbreak of pneumonia caused by a novel human virus was first detected and reported by WHO in Wuhan City, Hubei Province of China in late December 2019. The new virus was confirmed as coronavirus, a family of viruses that cause illness ranging from the common cold, to more severe diseases such as Severe Acute Respiratory Syndrome (SARS-CoV) and Middle-East Respiratory Syndrome (MERS-CoV).¹⁵ This new virus has been officially named SARS-CoV-2, which is responsible for the new disease COVID-19. Most people infected with the virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like diabetes and chronic respiratory disease are more likely to develop serious illness.

The Impact of the COVID-19 Pandemic on Sexual Health Testing

The coronavirus pandemic continues to challenge healthcare systems across the world and with governments taking steps to reduce transmission of SARS-CoV-2 through the introduction of social and physical distancing measures, such steps have led to a decline in clinical services providing care for STIs. Public Health England (PHE) has undertaken analyses to assess the impact of the pandemic response on STIs, HIV and viral hepatitis service provision and epidemiology. Between March and May 2020 there was a reduction in:¹⁶

- Consultations undertaken by sexual health services and specialised HIV service;
- Testing for viral hepatitis in drug services, prisons, general practice and sexual health services;
- Testing for HIV and STIs;
- Vaccination of gay, bisexual and other men who have sex with men (MSM) against Human Papillomavirus (HPV), hepatitis B (HBV) and hepatitis A (HAV);
- Diagnoses of viral hepatitis, HIV and STIs;
- Hepatitis C (HCV) treatment initiations

Numbers of consultations, vaccinations, tests, diagnoses, and treatment initiations in the summer of 2020 were considerably lower (13%) than in corresponding months in 2019,¹⁶ indicating that people have been influenced by the compliance of social distancing measures as well as the potential change in risk perception and behaviours.

Testing for chlamydia, gonorrhoea and syphilis had a 30% reduction in 2020 compared to 2019 (Figure 2). Similarly for HIV, there was a 35% reduction in tests at sexual health services and consultations. Between January and June in 2019 and 2020, the number of gonorrhoea diagnoses fell by 18%. The number of gonorrhoea diagnoses declined by 58% between January and May 2020 and despite a slight increase in June 2020, the number of diagnoses was 31% lower than in June 2019.¹⁶

Number of chlamydia tests in 15 to 24 year olds at sexual health services in England, January 2019 to June 2020

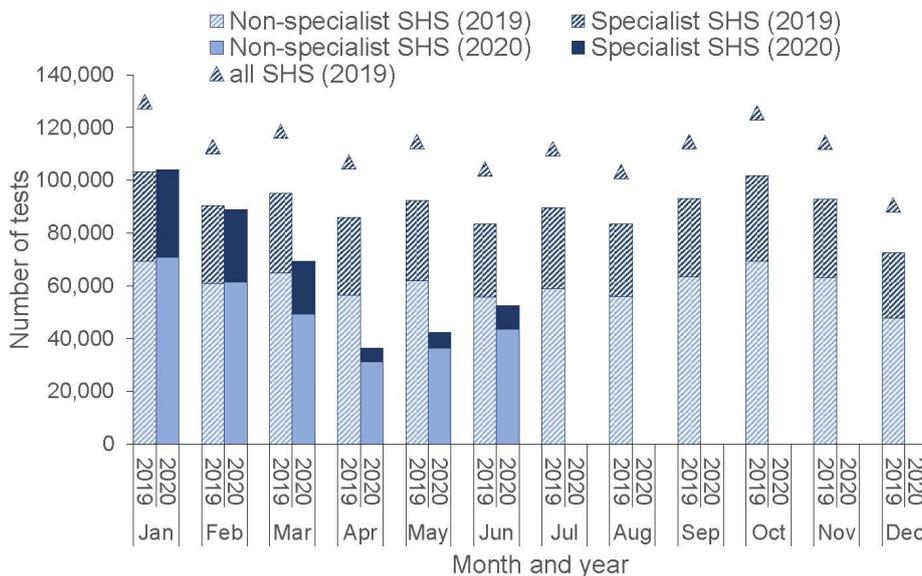


Figure 2
(Public Health England, 2020)

The number of bacterial STI tests declined by 71% between January and April 2020. Between January and February 2020, the proportion of bacterial STI tests (excluding blood tests) that were positive was similar to January and February 2019. Bacterial STI test positivity increased during March and April 2020; 17% of tests in April 2020 were positive compared to 13% in April 2019.

Test positivity in May and June 2020 was similar to corresponding months in 2019 (Figure 3). The increase in bacterial STI positivity in March and April 2020 is likely due to the prioritisation of services for those at higher risk, who are clinically vulnerable, or who have STI-related symptoms.

Bacterial STI test positivity at sexual health services in England, January 2019 to June 2020

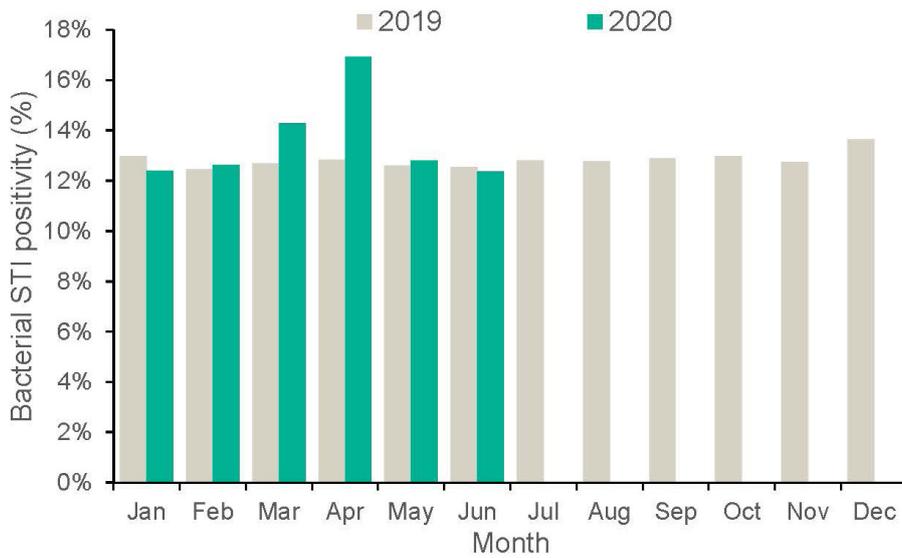


Figure 3
(Public Health England, 2020)

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CE marked 10-plex STI Panel

To support and encourage the reduced rate of STIs/STI testing, Randox offers a CE marked 10-plex array which is the broadest cartridge-based test on the market for point-of-care use. This test simultaneously detects 10 bacterial, viral and protozoan infections including asymptomatic and co-infections for a complete infection profile, using only a single swab or urine sample. The CE-marked STI Array provides excellent precision, specificity, sensitivity and accuracy for STI diagnosis, resulting in a reduced risk of false reporting and a reduced number of unnecessary confirmatory tests, saving healthcare providers both time and money. Simultaneous testing means smaller sample volumes are required which enables faster throughput and rapid patient diagnosis.

Test Menu

The STI panel targets bacterial species providing a wider scope for genitourinary infections, testing for both Mycoplasma hominis (MH) and Ureaplasma urealyticum (UU). These are not routinely tested for, as generally considered communal flora however, if left untreated, can be implicated in urethritis, cervicitis and infertility.

INFECTIONS	
Chlamydia Trachomatis (CT)	Herpes Simplex Virus 1 (HSV-1)
Neisseria Gonorrhoea (NG)	Herpes Simplex Virus 2 (HSV-2)
Trichomonas Vaginalis (TV)	Haemophilus Ducreyi (HD)
Mycoplasma Genitalium (MG)	Mycoplasma Hominis (MH)
Treponema Pallidum (Syphilis) (TP)	Ureaplasma Urealyticum (UU)

VIVALYTIC

The Game Changing Molecular Diagnostic Platform

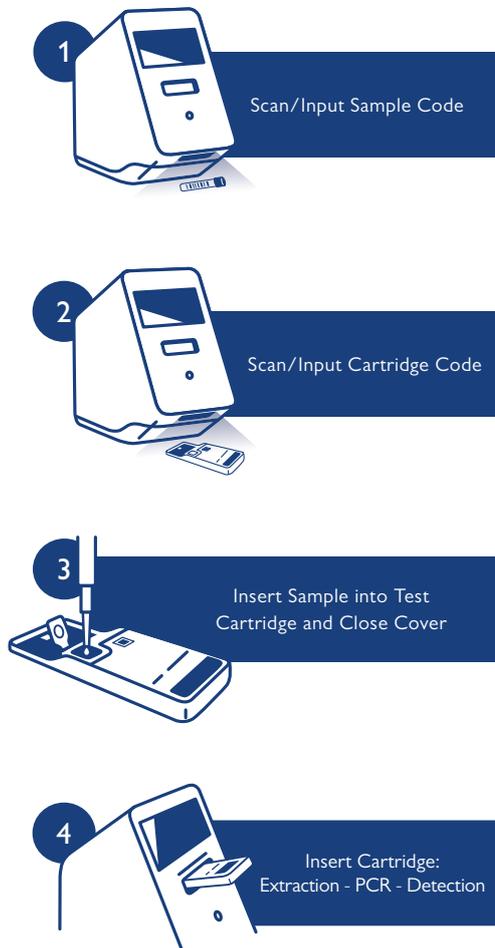
The 10-plex STI test is performed on the Vivalytic point-of-care molecular platform. Vivalytic enables sample to answer, cartridge-based molecular diagnostic testing and is capable of both Hi-Plex and Lo-Plex testing. Nucleic acid extraction, PCR amplification followed by a suite of detection methods are combined in a revolutionary, fully automated platform, made in partnership with Bosch in which manual preparation, cold chain reagents and the use of multiple devices are no longer required. No further components, such as laptops or barcode scanners are required, as the Vivalytic automatically generates a result report, making Vivalytic a unique space-saving, hygienic solution for molecular diagnostic testing.

Hi-Plex Vivalytic Cartridges: Powered by Randox Biochip Technology

Vivalytic cartridges are compact, utilising micro-fluidics to enable simple and accurate diagnostic testing. Hi-Plex tests utilise Randox patented Biochip Technology, enabling end-point qualitative PCR and providing multiple test results from each sample. Every biochip-powered cartridge produces multiple test results from each patient sample. The intelligent, chemically activated 9x9mm ceramic biochip acts as a solid phase reaction surface. The biochip detection system is based on a chemiluminescent signal, whereby each reaction is simultaneously detected and quantified using a Charge – Coupled Device (CCD) Camera.

Vivalytic Workflow

Intuitive engineering of Vivalytic ensures the analyser is user friendly. The process of patient sample to result comprises a very simple 4 step workflow. To begin the test, the user scans or enters sample information. The cartridge code is then scanned into the embedded Vivalytic software. The user then adds sample into the dedicated cartridge slot, closes the lid and inserts the cartridge into the Vivalytic. The touchscreen display will countdown the time remaining to test completion. Results will be displayed on the screen. Multiple Vivalytics can be wirelessly connected allowing the user to control multiple tests at one time, all reporting to a master Vivalytic platform.



CONCLUSION

STIs remain a persistent and endemic health threat worldwide. Timely and affordable testing and treatment is crucial for reducing the burden of STIs globally, alongside efforts to encourage people who are sexually active to get screened for STIs. There are a number of challenges we face including lack of public awareness, lack of training of health workers, and long-standing, widespread stigma around STIs acting as barriers to greater and more effective use of behavioural approaches.

People tend to shy away from this area of concern because the perception of this condition is seen as a consequence of low sanitation and hygiene. Reports show STIs are most common amongst the 16-24 year age group, but with lack of education around this topic, they may feel embarrassed to attend the likes of GUM clinics for better direction. In regards to the older generation, both the stigma and misconception that older people are not as sexually active means symptoms are not always picked up by health professionals. Older people may also perceive themselves as 'safe' because they are in stable relationships or are less likely to have multiple partners when in fact, many STIs are asymptomatic so it could be years until someone finds out they have a sexually transmitted infection. STIs are preventable through safe sexual practices, including correct and consistent use of protection methods and sexual health education. It is evident that the COVID-19 pandemic has caused implications for people gaining access to health clinics to receive testing and treatment for sexual health, however, because of social distancing measures put in place by governments to help stop the spread of SARS-CoV-2, STI testing is at an all-time low.

Implementing the Vivalytic platform along with the Randox 10-plex STI array would have a profound effect on sexual health, reducing economic costs and major health risks that can evolve through untreated STIs. The all-in-one molecular diagnostic platform utilises biochip technology, enabling simultaneous detection of 10 STI infections, producing time efficient results. The Biochip provides a unique platform for assessment in a rapid, accurate and easy to use format for point of care testing on Vivalytic, allowing physicians and medical staff to accurately achieve real-time, lab-quality diagnostic results within a matter of hours. Healthcare providers can make rapid triage and treatment decisions when diagnosing a patient's condition or monitoring a treatment response. By simplifying the testing process, clinicians can focus on what matters most – providing effective, quality patient care.

RANDOX LABORATORIES

Randox are committed to revolutionising healthcare through industry leading molecular and immunoassay diagnostic solutions; delivering diagnostic, prognostic and predictive assays to a variety of sectors including Clinical Laboratories, Biopharma, CROs and Academic Research Centres. Randox offers products that enable precise drug development and regulatory approval, with the potential to transform healthcare throughout the world. The award winning Randox Biochip Technology is at the core of our product offering, powering our multiplex diagnostic tests and platforms to provide precise reporting in a time and labour efficient manner.

WANT TO KNOW MORE VISIT:

World Health Organization,
[https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis))

National Centre for Biotechnology Information,
<https://www.ncbi.nlm.nih.gov/books/NBK525195/>

Public Health England,
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/806118/hpr1919_stis-ncsp_ann18.pdf

BBC News,
<https://www.bbc.co.uk/news/health-48509969>

Lets Get Checked,
<https://www.letsgetchecked.com/articles/highest-rate-of-stis-in-the-uk/>

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