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An HIV self-testing implementation action framework and tool-kit for cisgender gay, bisexual and other men who have sex with men, trans and gender diverse people in England and Wales

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Executive summary

Background

Strong evidence suggests that HIV self-testing is highly acceptable to cisgender gay, bisexual and other men who have sex with men (GBMSM), trans and gender diverse people in England and Wales, and that this novel technology can make a meaningful difference to HIV testing behaviours. HIV self-testing is feasible to deliver at large scale, can increase testing uptake and frequency without negatively impacting on linkage to care or testing for sexually transmitted infections (STIs). Question remain as to how best to deliver HIV self-testing in a way that responds to entrenched health inequalities. This Implementation action framework and tool-kit has been produced to facilitate and promote HIV self-testing service delivery in England and Wales with the key goal of improving health equity.

Methods

To produce this guidance, we synthesised key studies from England and Wales using the consolidated framework for implementation research as a structure. Evidence supporting innovative HIV self-testing implementation includes a large randomised controlled trial conducted in England and Wales (SELPHI) and extensive socaial science research conducted through the NIHR funded PANTHEON programme grant, PANTHEON 2 programme development grant, and the wider academic literature. Community and sexual health sectoral engagement shaped and refined our recommendations.

Implementation action framework and tool-kit

The implementation context in England and Wales is favourable for HIV self-testing. Those planning services, or seeking funding to do so, can harness this context by emphasising the need to continue to expand testing to meet the goal of HIV elimination by 2030. Concerns around linkage to care and surveillance can be addressed by highlighting the importance of respecting patient choice and autonomy.

This guidance establishes a standard level of support that should be provided with HIV self-testing interventions. This includes an optional result reporting system, clear information on linkage to care, inclusion of a helpline as well as clinical follow-up for those who report reactive HIV self-testing results but have not linked to care. Potential intervention adaptations which can address health inequalities between groups of GBMSM, trans and gender diverse people include innovative approaches to HIV self-testing kit delivery, additional tests (e.g. for bacterial STIs) that can be provided in interventions, demand generation activities and the provision of additional support for those requiring it, including the most marginalised.

Within organisations, HIV self-testing champions can highlight the importance of implementing this new technology and ensure buy-in of key organisational actors. When implementing, organisations should define the broad intervention and the components that will accompany it and engage with potential beneficiaries to optimise proposed approaches. Early, formative evaluation can help refined interventions, and summative evaluation can demonstrate outcomes to commissioners.

Examples of best practice include trial infrastructure developed during the SELPHI RCT of HIV self-testing, intervention approaches from SH:24 and the Terrence Higgins Trust and advertising used during the English National HIV testing week campaign.

Conclusion

This framework will be an invaluable resource for those seeking to plan and implement HIV self-testing among GBMSM, trans and gender diverse people in England and Wales. This guidance is not meant to be prescriptive, but rather provides an implementation roadmap detailing innovative approaches, and the evidence underpinning them, that can be used to improve health equity among the most marginalised.

Funding

This report presents independent research funded by the National Institute for Health Research (NIHR) under the Programme Development Grants programme PANTHEON 2 (towards an HIV self-testing implementation action framework and toolkit, NIHR203298). The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Suggested citation

Witzel, T. Charles; Weatherburn, Peter; Burns, Fiona M; Chu, Isaac YH; Samba, Phil; Rodger, Alison J. (2024). An HIV self-testing implementation action framework and tool-kit for cisgender gay, bisexual and other men who have sex with men, trans and gender diverse people in England and Wales. University College London.
https://doi.org/10.5522/04/26013646

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CHAPTER 1

BACKGROUND

Despite strong evidence that HIV self-testing is highly acceptable and can make a meaningful difference to HIV testing behaviours, so far service provision in the UK has been sporadic and patchy. This implementation action framework and tool-kit has been produced to facilitate and promote person-centred HIV self-testing service delivery in England and Wales. It is intended to be used by those thinking about or planning to implement HIV self-testing, including individuals from the voluntary sector, commissioners, policymakers and academics.

This work is the final outcome of an 9-year collaboration between researchers, HIV consultants and community members. This began with the NIHR-funded PANTHEON programme grant, which developed a substantial evidence base exploring how HIV self-testing can meet the needs of diverse groups of cisgender gay, bisexual and other men who have sex with men (GBMSM) and trans people. PANTHEON 2, a follow-on grant, was funded to further explore these issues in these key populations and develop this implementation framework, drawing on the expertise of community members and other key stakeholders in the UK HIV response.

Although this implementation framework is specifically focused on the rollout of HIV self-testing for GBMSM and trans people, many of the lessons in this guidance can shape service delivery for other key groups impacted by HIV in the UK, such as Black African heterosexual people and people who use drugs. However, further engagement with these communities would support effective service provision to these groups as there are substantial evidence gaps around how HIV self-testing is likely to be adopted by these populations, as well as their values and preferences for service delivery.

1.1 HIV in England and Wales

The HIV epidemic among GBMSM, trans and gender diverse people in England and Wales remains a significant public health challenge. Although there have been substantial reductions in HIV incidence since 2015, these are not equitably distributed. GBMSM from ethnic minority communities remain disproportionately impacted, with GBMSM from Asian and mixed or other ethnicity experiencing increasing HIV incidence in 2022 (1).

Reducing the time between HIV infection and diagnosis is a key goal with national guidelines recommending GBMSM test annually, or more frequently in the presence of additional risk factors, such as condomless anal intercourse (CAI), sexualised drug use or recent diagnosis of a sexually transmitted infection (STI) (2, 3). Trans women are also encouraged to test frequently, although recommendations are not provided for trans men and gender diverse people who may also be disproportionately impacted by HIV (4-6).

Rapid diagnosis of HIV has implications not just for individual health, with evidence indicating that suppressive antiretroviral therapy (ART) is beneficial at any CD4 count, but also for onward transmission of HIV (7-9) as successful ART means an individual cannot pass on HIV (10-12). The ‘Test and Treat’ approach has been enshrined in the UNAIDS global 95-95-95 targets which aim, by 2030, to achieve 95% of people with HIV being diagnosed, 95% of those diagnosed taking ART, and 95% of those on ART achieving virological suppression (1). The UK has been successful in this regard; in 2022 95% of people with HIV knew their status, 96% of those were linked to care and 98% of those receiving treatment had achieved virological suppression (1).

1.2 Evolution of HIV testing in England and Wales

HIV rapid diagnostic tests were developed in the late 1990s to facilitate faster return of results and to reduce testing costs (13, 14). Over time testing technology improved, and tests with higher sensitivity were developed by including assays which measured the presence of additional antibodies, and by 1999, antigens, with 4th generation tests significantly reducing window periods while improving performance (15, 16). Figure 1 presents different HIV testing generations and their associated window periods.

In the UK, from the mid-2000s, rapid diagnostic tests began to be used in community-based testing programmes, expanding testing first to community centres, and later to social settings including bars and nightclubs. This was done to increase access to those who might not consider themselves at risk, and to reduce testing barriers such as limited accessibility of clinics and concerns around stigma and homophobia (17, 18). HIV self-sampling, where an individual collects a blood sample themselves and returns it to a laboratory for processing, brought HIV testing into the home, beginning in 2012, in response to barriers around privacy. This new technology became critically important during the COVID-19 pandemic when self-sampling was the main way people tested for HIV and other sexually transmitted infections (STIs). Free HIV self-sampling is currently available in most local authorities in England and in all areas of Wales.

1.3 What is HIV self-testing?

A relatively new approach, HIV self-testing allows an individual to test themselves for HIV using a rapid diagnostic test. The individual

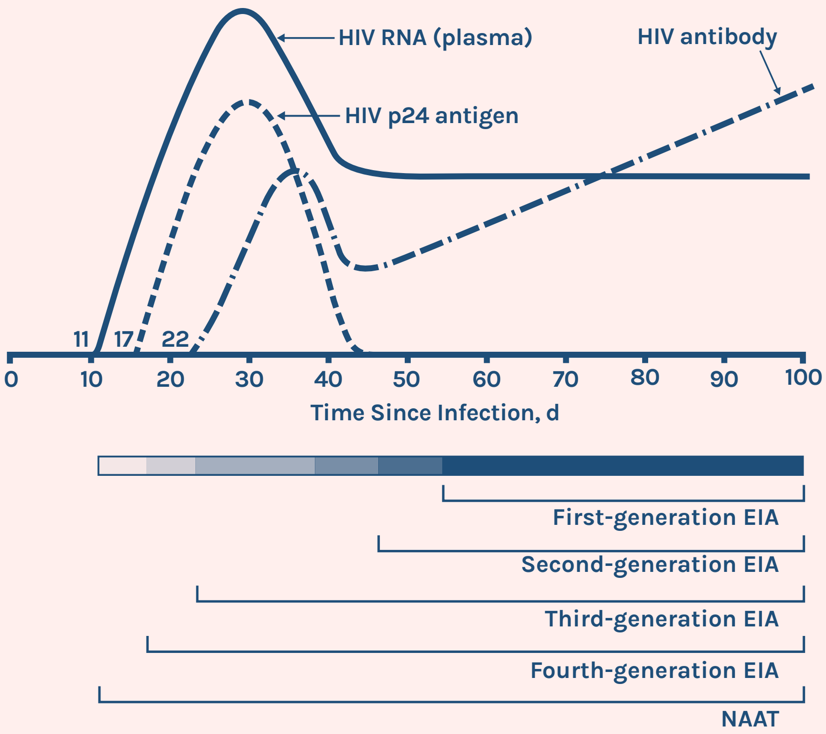


Figure 1: Window of detection for HIV, based on the test used. This material was accessed on the HIV clinical Resource website from www.hivguidelines.org EIA, enzyme immunoassay; NAAT, nucleic acid amplification testing

(either alone, or with support from partners, friends or family), takes their own sample (either blood or saliva), processes their test and reads their own result. This approach provides an empowering testing option which is especially useful for those who may face high barriers to conventional, clinic-based testing. These barriers include fear, stigma, privacy concerns and clinics which are inconvenient to access for reasons of geography or a lack of appointments (19-23). Historically, HIV self-testing implementation has been held back by concerns around potential self-harm in the absence of counselling, as well as unwanted pressure to test from others.

One critical benefit of HIV self-testing is the flexibility and adaptability of the intervention. Indeed, self-testing can be delivered in a variety of ways with a huge range of supportive options. This means that HIV self-testing can be tailored for specific populations through person-centred approaches, with the key goal of improving health equity.

HIV self-testing was first recommended by the World Health Organization as an additional approach for HIV testing in 2016 (24). Following the publication of further evidence, this recommendation was strengthened in 2019 (25). During this period, it has been implemented in several countries, mainly at cost to the user when purchased privately, but also through pilot and demonstration projects for free. HIV self-testing was recommended in UK national guidelines for the first time in 2020 (4), however as of 2024 progress implementing it has been limited.

1.4 History of HIV self-testing in England and Wales

HIV self-testing was banned in the UK in 1992 because of concerns about harm, especially in the absence of effective HIV treatment at this time. HIV self-testing was legalised in the UK in 2014 in response to the change in the meaning of an HIV diagnosis, with the first test coming to market shortly afterwards (26). Since then, HIV self-testing has been available at cost.

There have been a number of pilot and demonstration projects providing free HIV self-testing, including a large randomised controlled trial run as part of the PANTHEON programme grant and substantial linked social science work exploring how HIV self-testing can be implemented to improve health equity.

CHAPTER 2

EVIDENCE REVIEW

The HIV self-testing evidence base globally and in England and Wales has evolved rapidly over the last decade. Advances in understanding acceptability, values and preferences as well as implementation successes and challenges are critical for successful service delivery. This section presents the key evidence informing the recommendations in this framework. Where evidence exists, this is drawn from England and Wales, where there are gaps, evidence is drawn from other comparable settings. Table 1 provides an overview of the studies included, and table 2 presents an overview of the primary findings identified. This explores key themes in the evidence by: implementation context; intervention acceptability, feasibility, values and preferences and HIV self-testing outcomes.

Table 1: An overview of included studies

Reference	Year	Author	Study type	Data collection	Location	Study population	Aim
(23)	2015	Figueroa et al.	Literature review	Literature review (1995-2014)	Worldwide	Key populations	Focus on the acceptability, values and preferences on HIVST among key populations
(27)	2016	Gibson et al.	Demonstration project	Record analysis	UK	General population	Determine feasibility and acceptability of HIV home/self-testing
(19)	2016	Witzel et al.	Qualitative	Focus group discussion	UK	GBMSM	Explore the acceptability, preferences and concerns about HIVST
(28)	2016	Witzel et al.	Quantitative	Survey	UK	GBMSM (both cis and trans)	Identify which groups of MSM are less likely to have tested for HIV and their preferences for future tests
(22)	2017	Flowers et al.	Mixed methods	Survey Focus group discussion	UK	Cis-GBMSM	Explore preparedness for the HIVST among MSM and professionals in HIV care
(29)	2017	Brady et al.	Demonstration project	Record analysis	UK	HIVST users	Evaluate the feasibility and acceptability of HIV self-testing in a large-scale pilot
(30)	2017	Witzel et al.	Qualitative	Interview	UK	Service providers and commissioners	Understand the perspectives of key informants on the implementation of HIVST
(31)	2017	Witzel et al.	Qualitative	Focus group discussion	UK	GBMSM (both cis and trans)	Understand how HIVST compliments existing testing strategies considered or adopted by MSM
(32)	2018	Saunders et al.	Demonstration project	Record analysis	UK	Service users at a sexual health clinic in London	Determine whether self-testing-naïve individuals can correctly perform and interpret HIVST
(33)	2019	Baraitser et al.	Quantitative evaluation	Record analysis	UK	Users of a website offering free HIV tests	Measure the type of test chosen (HIVST or HIV self-sampling) and reasons for choices
(34)	2019	Vera et al.	Demonstration project	Survey and Record analysis	UK	Potential users of HIVST	Evaluate the acceptability and feasibility of using vending machine to distribute HIVST in communities
(35)	2019	Witzel et al.	Mixed methods	Interviews	UK	GBMSM and trans women	Assess the feasibility of recruiting SELPHI trial participants and kit receivers' acceptability of HIVST
(21)	2019	Witzel et al.	Qualitative	Interviews	UK	GBMSM	Explore how self-testers experience HIVST and the implications for intervention scale-up

Reference	Year	Author	Study type	Data collection	Location	Study population	Aim
(36)	2020	Rodger et al.	Trial	Trial surveys	UK	GBMSM (both cis and trans)	Report the frequency of previous HIV testing at baseline in MSM enrolling in a randomised controlled trial
(20)	2020	Witzel et al.	Systematic review	Literature review (2006-2019)	Worldwide	Key populations	Understand which service delivery models of HIVST are effective for key populations
(37)	2020	Witzel et al.	Qualitative	Interviews	UK	GBMSM	Explore how HIVST interventions were experienced and the mechanisms of action leading to impact
(38)	2021	McCabe et al.	Trial	National surveillance, trial surveys	UK	GBMSM (both cis and trans)	Investigate if the offer of free, regular HIVST kits led to a reduction in time taken to receive an HIV diagnosis
(39)	2021	Middleton et al.	Qualitative	Interviews and focus group discussions	UK	People with mild learning disabilities	Explore barriers and facilitators to correct use of self-sampling kits for blood-borne virus and bacterial STI
(5)	2021	Witzel et al.	Mixed methods	Interviews	UK	Trans people	Describe key HIVST outcomes and HIVST acceptability for trans people
(40)	2022	Nicholls et al.	Qualitative	Interviews	UK	Asian, Black and Latin American GBMSM	Explore participants' experiences in accessing the gay scene, HIV testing services and preferred adaptation of HIVST
(41)	2022	Rodger et al.	Randomised controlled trial	National surveillance, trial surveys	UK	GBMSM (both cis and trans)	Assess whether the offer of a single, free HIVST kit led to increased HIV diagnoses with linkage to care
(42)	2023	Howells et al.	Demonstration project	Record analysis	UK	HIVST users	Compare the uptake of HIVST to HIV self-sampling among users of online-ordered free tests
(43)	2023	Cambiano et al.	Quantitative	Modelling	UK	GBMSM	Understand the contribution of different interventions in reducing HIV incidence
(44)	2023	Nadarzynski et al.	Quantitative	Survey	UK	Men and gender diverse people who have sex with men	Identify the characteristics of respondents requiring sexual health promotion and clinical support
(45)	2023	Witzel et al.	Mixed methods	Trial surveys and interviews	UK	GBMSM (both cis and trans)	Understand the relationship between HIVST and harm in SELPHI, the largest randomised trial of HIVST in the UK

Reference	Year	Author	Study type	Data collection	Location	Study population	Aim
(46)	2024	Chu et al.	Qualitative	Interviews	UK	GBMSM and trans women	Develop a contextual understanding of individuals' social networks and HIV testing needs
(47)	2024	Chu et al. (forthcoming)	Qualitative	Interviews	UK	GBMSM and trans women	Explore the perspectives of multiply marginalised participants on whether HIVST might increase their uptake of HIV testing
(48)	2024	Gobin et al.	Demonstration project	Observations and survey	UK	HIVST users	Investigate the acceptability and uptake of publicly available machines dispensing STI and HIV testing kits
(49)	2024	Palich et al.	Qualitative	Interviews	UK	GBMSM and trans people	Explore how people reporting non-consensual sex accessed health care services and how this experience influenced subsequent HIV testing

GBMSM: Gay, bisexual and other men who have sex with men; HIVST: HIV Self-testing

The term 'Key populations' includes GBMSM, transgender people, sex workers, people who inject drugs and people in prison per WHO definition.

Table 2: HIV self-testing evidence review

HIV self-testing implementation context		
Area	**Finding**	**Sources**
Public health environment	'Zero' chance of reaching the 2030 HIV transmission target of fewer than 50 infections among GBMSM in England. A combined substantial increase in HIV testing (by 30%) and an increase in PrEP provision could avert 34% of new HIV infections. This would require a 16% reduction in the cost of delivery of testing to remain cost-effective. Self-testing has a key role in doing this while keeping costs low.	(43)
Organisational contexts	HIV self-testing broadly acceptable to stakeholders, including clinical and community-based organisation staff. However, some have concerns about support for individuals self-testing	(30)
Acceptability, feasibility and values and preferences		
Area	**Finding**	**Sources**
Acceptability	HIV self-testing is highly acceptable to a diverse range of GBMSM, trans and gender diverse people.	(5, 19, 28, 31, 35, 40)
	HIV self-testing may be a supplementary testing option for most GBMSM, unless they have psychosocial or geographic barriers to existing services.	(19, 31)
	For GBMSM from minority ethnic communities, HIV self-testing provides opportunity to avoid clinic waiting rooms and staff perceived to be potential sources of confidentiality breaches.	(40)
	HIV self-testing enables trans people to avoid testing in sexual health clinics which can be sites of discrimination and can increase dysphoria.	(5)
Feasibility	HIV self-testing is feasible to implement for GBMSM, trans and gender diverse people.	(5, 35)
	HIV self-testing is usable for GBMSM, trans and gender diverse people, including those who are marginalised based on ethnicity, education, sexual orientation, gender and migration status.	(21, 32, 35, 40, 47, 50)
Values and preferences	4th generation tests strongly preferred because of short window period. For many, HIVST will be supplementary until this is available	(19)
	GBMSM generally prefer blood-based samples because of accuracy concerns, a minority with aversion to blood draw will not test using a blood-based sample.	(19, 21, 23)
	GBMSM generally prefer postal delivered self-testing for convenience. Those living in shared accommodation and with domestic privacy concerns (including many from ethnic minority backgrounds) require alternative to postal delivery options.	(19)
	Both written and video instruction options are useful.	(19, 21)
	Individuals with mild learning difficulties may benefit from additional support when using HIVST.	(39)
HIV self-testing outcomes		
Area	**Finding**	**Sources**
Testing uptake/ frequency	HIV self-testing can lead to dramatic increases in testing uptake and frequency among GBMSM, trans and gender diverse people by reducing barriers related to privacy, fear, opportunity cost, stigma and discrimination.	(5, 20, 35, 36, 38, 40, 41)
Positivity	HIV self-testing can potentially lead to increases in numbers of diagnoses, especially in high prevalence populations.	(20)

HIV self-testing outcomes

Area	Finding	Sources
Linkage to prevention	HIV self-testing can reduce barriers to clinic attendance. For some SELPHI participants, re-engaging with clinics through HIV self-testing facilitated PrEP uptake.	(21, 37)
Linkage to care	Most people with positive results link to care quickly with support from kits and social networks.	(21, 38, 41)
	Linkage overall may be sub-optimal compared to clinic-based approaches.	(20, 38, 41)
STI testing	HIV self-testing does not lead to statistically significant decreases in STI testing overall.	(21, 38, 41)
	Individuals who have high psychosocial or geographic barriers to testing may use HIVST as a primary testing method and test for STIs less frequently if not offered together.	(21, 37, 47)
Harms	Harms from HIV self-testing are very rare.	(20, 45, 49)
	Except for those relating to the kit itself, harms do not usually reduce HIVST acceptability.	(45)
Support	Most individuals access support (following both positive and negative results) from their wider social networks.	(21, 46)
	Those who have lack social network support will require additional supportive options when using HIV self-testing.	(46)

2.1 HIV self-testing implementation context

Recently published modelling work from the Pantheon research programme demonstrated a zero chance in England of reaching the HIV transmission target of fewer than 50 new infections among GBMSM per year by 2030. However, a combined substantial increase in HIV testing (by 30%) and an increase in PrEP delivery could avert 34% of new infections. This however would require a 16% reduction in the cost of delivery of testing to remain cost-effective (43). The authors suggest that HIV self-testing has a key role in this as an inexpensive, low threshold testing option.

Qualitative research with stakeholders in the HIV response conducted in 2015 found that organisational contexts were generally supportive of HIV self-testing, but that stakeholders had some concerns about support accompanying self-tests (30).

2.2 HIV self-testing acceptability

It is critical to understand the acceptability of potential interventions among the population's services seek to engage.

HIV self-testing is highly acceptable to both cisgender GBMSM and trans people in England and Wales, although the context in which individuals might use self-tests vary.

Survey data from 2014 shows that HIV self-testing was the option most preferred by GBMSM least likely to have previously tested for HIV, including those who were younger, older, and not gay identified (28). GBMSM who had never tested preferred HIV self-testing and self-sampling compared to all other approaches (28).

Qualitative research from 2015 conducted with 46 GBMSM in England (most of whom had not used HIV self-testing) found that HIV self-testing was most likely to be used when testing because of a small amount of anxiety about a person's HIV status, or to meet social norms emphasising the importance of testing (31). HIV self-testing in response to risk was most useful for people who had high barriers to clinical services, including geographic isolation, fears of discrimination and other privacy concerns (31). A small minority felt that HIV self-testing was an unwelcome incursion of healthcare into the home (31).

Extensive evaluation research conducted as part of the SELPHI RCT provides helpful insights from individuals who had experience of self-testing. Across 4 studies including 94 qualitative interview participants, HIV self-testing acceptability was very high, however the reasons for this varied across groups.

This research confirmed findings from focus groups that for GBMSM and trans people with higher psychosocial or geographical barriers to traditional service access, HIV self-testing was likely to be a primary testing mechanism, but remained secondary for others (5, 37, 51).

Trans participants in SELPHI in particular felt that HIV self-testing was useful in avoiding sexual health clinics where they often faced barriers related to discrimination, services which were not designed with their needs in mind and tests which increased gender dysphoria (5). Asian, Black and Latin American GBMSM in SELPHI also used HIV self-testing to avoid clinical services, related mainly to concerns around privacy which were described as greater than in other groups, especially compared with White GBMSM (40).

Some men in SELPHI with previous difficulties accessing HIV testing described how HIV self-testing facilitated clinic attendance. It did this through normalising HIV testing and reducing fear as a testing barrier (37).

Generally, trust in results from HIV self-testing was high for those with negative results and variable for those with positive ones (51).

GBMSM, trans and gender diverse people with supportive social networks typically sought support from friends, family members and peers during and following self-testing. Those without such strong networks may require additional support to use HIV self-testing optimally.

Pilot research evaluating an HIV self-testing vending machine in Brighton found that testing delivered in this way was highly acceptable, with several participants recommending the intervention to others (34). Some reported concerns about receiving a reactive result without support (34). Further, several had used the HIV self-test as a risk assessment ahead of having condomless sex; these men did not have full understanding of the window period of these tests, highlighting the importance of clear supportive information (34). This has since been expanded to several sites in Brighton and Bristol, coupled with self-sampling for STIs, hepatitis C and HIV (48).

2.3 HIV self-testing preferences

Self-testing is often the preferred option over tests requiring self-sampling, especially when there are not concerns around support. When offered the choice between HIV self-testing and self-sampling in a pilot project in England, around two-thirds choose the self-testing option (33). This is likely driven in part by the difficulties in collecting a sample large enough for HIV self-sampling, which required substantially more blood than currently available blood-based HIV self-tests.

In focus group research, 4th generation HIV self-tests with short window periods were the most preferred tests, despite currently not being available. Overall, GBMSM tended to prefer blood-based kits (because of accuracy concerns) and postal delivery (for convenience) but a minority would not test if oral fluid testing was not available because of concerns about collecting a blood sample (19). A further minority, mostly GBMSM from ethnic minority communities and those living in shared accommodation, expressed the need for self-testing to be available through community-based organisations, pharmacies and click-and-collect services for very wide reach (19). Both written and video instructions were felt to be useful.

GBMSM, trans and gender diverse people experiencing multiple elements of marginalisation reported that HIV self-testing was straightforward to use, met their testing needs and was generally felt to be trustworthy (47).

2.4 Feasibility and usability

People can generally use HIV self-testing correctly. A study seeking to determine whether sexual health attendees could correctly determine HIVST results found that among 200 participants, 97.0% conducted the test correctly and 94.0% correctly interpreted the result (32). In SELPHI qualitative research, usability issues occurred most often with the lancet and test processing stage; these resolved with experience (51). Confidence in use may have also increased following widespread rapid testing during the COVID-19 pandemic.

SELPHI and a number of pilot and demonstration projects that have been implemented in England and Wales and show that HIV self-testing is feasible to deliver to end users successfully. The majority of these have used the BioSure^{TM} HIV self-test (now Chembio SureCheck) (29, 33, 34, 41), with only 1 having provided an oral fluid option (42). Nearly all services promoted HIV self-testing online and delivered kits through the post, with one further study successfully distributing self-tests through a vending machine in a sex on premise venue, an approach which has since been expanded to other locations (48).

HIV self-testing can be successful in engaging GBMSM who have not previously tested for HIV, or who test infrequently (29, 33, 34, 41). Self-testing also has higher test completion rates than self-sampling, with between 90-97% of individuals who completed results reporting surveys using the kit, compared to between 50-60% of those who returned self-samples for processing (33, 35, 41), although some studies had low rates of response to follow-up after HIV self-testing meaning that test completion and results are not always known to the providers (27, 34).

GBMSM, trans and gender diverse people in SELPHI experiencing multiple types of marginalisation did not describe substantial concerns about HIV self-test usability following HIVST testing (47).

2.5 Outcomes following HIV self-testing

Testing uptake

Systematic review evidence shows that HIV self-testing, compared to standard HIV testing approaches, increases testing uptake by 48% (Risk ratio (RR)=1.48; 95%CI 1.21, 1.81) (20). In online and mail distributed self-testing, uptake was increased by 61% (RR=1.61; 95%CI 1.33, 1.94) (20). Frequency of HIV testing was increased in GBMSM and trans people by a mean of 2.56 tests over follow-up (mean difference=2.56; 95%CI 1.24, 3.88) (20). These results are echoed by results from the SELPHI randomised controlled trial, which found that, compared to standard of care, HIV self-testing led to dramatic increases in HIV testing uptake and frequency in cisgender GBMSM and trans people (5, 36, 38). Qualitative research found that this greatly increased testing uptake was because of the reduction of testing barriers, related to privacy, fear, inconvenient clinics, stigma and discrimination (5, 21, 40).

Positive results

In systematic review evidence, identification of positive HIV results among GBMSM and trans people randomised to HIV self-testing was more than doubled (RR=2.12 95% CI 1.20, 4.08) (20). However, in England and Wales low HIV incidence in GBMSM made this difficult to assess. Indeed, in SELPHI, HIV self-testing did not lead to increases in diagnosis of existing or new HIV infections, this was likely because the trial became underpowered to assess differences because of the collapse in HIV incidence during the trial period (38, 41). New diagnoses of HIV in pilot and demonstration projects were generally rare, largely because of relatively small numbers of kits being made available, and related also to falling HIV incidence (36).

Linkage to prevention and testing

Data from implementation studies in the UK on linkage to HIV prevention interventions following HIV self-testing is very limited. However qualitative research among SELPHI participants found that HIV self-testing could reduce barriers to clinic attendance and in some cases this facilitated engagement with PrEP services (21, 37).

Linkage to care

Although linkage to care was not reduced by a statistically significant amount in GBMSM and trans people in systematic review evidence, when these populations were pooled with female sex workers, linkage to care was reduced by 17% (RR = 0.83; 95% CI 0.74, 0.92) (20). Encouragingly, SELPHI found no differences in linkage to care (38, 41). Qualitative research found that most SELPHI participants with a positive result linked to care promptly (within days), usually with support from others within their social networks (21, 40).

Condom use

Systematic review evidence found no adverse impacts on condom use among GBMSM and trans people who used HIV self-testing (20). SELPHI found similar levels of condomless sex in those randomised to receive free HIV self-tests and those who were not (41). A pilot project distributing HIV self-testing through vending machines found that some men used these to test before condomless sex, without understanding the window periods of the test highlighting the need for supportive information accompanying kits (34).

STI testing

In SELPHI and systematic review evidence, STI testing was not significantly reduced in those randomised to free HIV self-testing compared to those who received standard of care for HIV testing, although STI testing was very low among trans people generally (5, 20, 41). In qualitative research, people who use HIV self-testing as a primary testing mechanism felt that they were likely to test for bacterial STIs less frequently if such tests were not included in a self-testing intervention (21, 37).

Harms

Harms (defined as undesirable occurrences which may not have happened with clinic-based testing) were assessed in-depth both quantitively and qualitatively in SELPHI. This research found that harms were very rare, and experienced by less than 4% of people who participated (45). When these did occur, they were related to the technology itself, to the intervention more broadly or the social circumstances of individuals (45). Except for technological harms, these negative experiences generally did not reduce intervention acceptability. It should also be noted that most harms were felt to be minor in nature, with transient impacts. See figure 2.

Technological harms

- From how the technology itself performs
- False positives /negatives
- Reduced HIVST acceptability

Intervention harms

- From how the wider intervention functioned
- Psychosocial components impacting wellbeing
- HIVST acceptability not substantially reduced

Socially emergent harms

- Drawn from the social circumstance of individual
- Coercion to test, relationship discord
- No impact on HIVST acceptability

Figure 2: Typology of HIV self-testing harms

CHAPTER 3

HOW DID WE DESIGN THIS GUIDANCE?

3.1 Engagement groups

A Community and policy engagement group representing key stakeholders in the HIV response (see table 3 for membership), as well as a participant and public involvement group with 7 ethnically diverse cis-GBMSM, trans and gender diverse people have been central in the development of this guidance. Both groups have fed into our methods and reviewed our recommendations to ensure they reflect current best practice and their own experiences. They have also directly shaped many of our recommendations.

3.2 Evidence synthesis

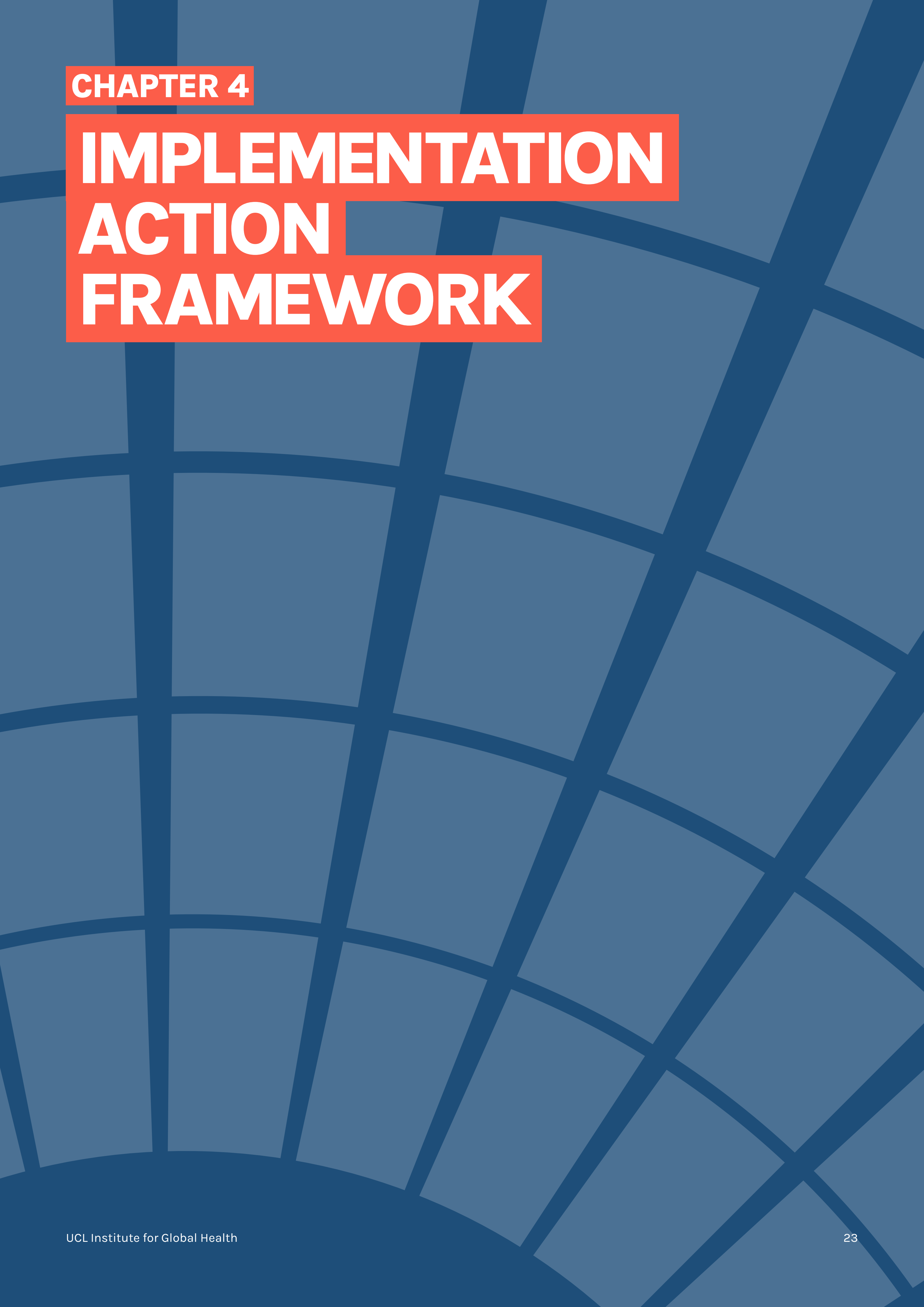
In order to develop this guidance, we have synthesised evidence from a range of sources. This has included systematic reviews, academic publications detailing HIV self-testing implementation and evaluation, conference abstracts and reports from community and voluntary sector organisations. Where necessary and possible, we have asked those working on self-testing and self-sampling projects in England and Wales to provide additional insights and data to make sure this evidence is comprehensive and up to date.

3.3 Consolidated framework for implementation research

We have used the Consolidated Framework for Implementation Research (CFIR) (52, 53), as a rough guide to structure our implementation action framework. CFIR described how successful implementation and translation of interventions to new contexts works best if attention is being paid to five key areas (52-55). Firstly, CFIR explores the role of context (inner and outer setting) in shaping intervention delivery, paying attention especially to the structural, political, economic and social contexts in which an intervention is being implemented (52). Perhaps the most important domain, the intervention, contains all characteristics of the intervention which is being implemented, acknowledging that many interventions need adaptations to work optimally (52). Following, CFIR explores how individuals involved shape implementation, recognising that individuals within and outside an organisation have agency to shape or to hinder delivery (52). The final domain refers to the process of implementation which is contingent on the organisation implementing the intervention (52). Using this framework helps us make sure this guidance is comprehensive and covers a range of different areas necessary for successful intervention implementation.

Table 3: Community and policy engagement group members

Name	Organisation
Deborah Gold (chair)	National AIDS Trust
Adrian Kelly	Sexual Health London
Camille Barker	English HIV and Sexual Health Commissioners Group
Claire Dewsnap	British Association for Sexual Health and HIV
David Gillespie	Cardiff University
Jane Nicholls	Cardiff Royal Infirmary
Justin Harbottle	SH:24
Kate Nambiar	Terrence Higgins Trust
Kevin Fenton	Office for Health Improvement and Disparities
Negar Mohammadian	SH:24
Phil Samba	LoveTank
Taku Mukiwa	Terrence Higgins Trust
Zoe Cousins	Public Health Wales



CHAPTER 4

IMPLEMENTATION ACTION FRAMEWORK

It is vital that new healthcare approaches are implemented in a way that is mindful of the needs of diverse individuals, especially those who experience marginalisation based on ethnicity, educational attainment, sexual orientation, gender and migration status. This implementation actions framework is meant to be used as a guide to make decision about how to implement HIV self-testing in a person-centred way that meets a range of needs. This guidance is envisaged to support programmes which provide HIV self-testing to service beneficiaries at no cost.

This implementation framework covers the following areas:

1. **Context of implementation**: exploring how the wider political environment surrounding HIV self-testing implementation can be harnessed.
2. **HIV self-testing intervention design**: defining the core of the intervention and exploring adaptations that can make a difference when engaging diverse sub-groups of BMSM, trans and gender diverse people.
3. **Individuals involved in implementation**: describing how can staff be engaged in implementation.
4. **Process of implementation**: outlining key considerations in the implementation process, including evaluation.

4.1 Context of implementation

Political and public health environment

Understanding and harnessing the political and economic environment is critical to intervention success, particularly when using a new technology such as HIV self-testing.

Currently, the wider public health drive towards HIV elimination is highly favourable for HIV self-testing implementation. This includes the Getting to Zero aim, which is frequently cited by public health bodies, the government as well as clinical and voluntary sector organisations (56).

A key component of Getting to Zero is the 95-95-95 initiative, whereby 95% of people living with HIV know their status, 95% of those are on antiretroviral treatment and 95% of those have an undetectable viral load. HIV testing is the first step on this pathway. As testing options have expanded over the years, the proportion GBMSM, trans and gender diverse people with undiagnosed HIV has decreased. These decreases are not shared equitably, and marginalised groups continue to face higher burdens of HIV (1). As well as increasing the volume of tests, person-centred HIV self-testing provision may also help to achieve health equity if targeted properly and has the benefit of being cheaper than many other testing options. Improving equity should be a central consideration in implementation and is a key mechanism through which to argue for funding from commissioners. However, this will require continued political support for the maintenance and expansion of HIV testing in an environment which is increasingly economically strained. Highlighting that HIV self-testing can contribute to the continued expansion of testing in a financial sustainable way may be effective.

A public health barrier to HIV self-testing implementation is the strong emphasis on linkage to care and public health surveillance systems capturing new diagnoses and tracking outcomes. Indeed, all beneficiaries should be provided the tools and support necessary to link to care promptly. However, HIV self-testing challenges service providers, commissioners and policy makers to think differently about autonomy following testing: although non-linkage is likely to be rare, some individuals who test positive may choose not to attend services, including for follow-up testing and treatment. The duty of those commissioning and providing self-testing is to provide all the necessary tools to encourage engagement in care, but must acknowledge that some people may take time to engage. Service providers must respect the rights of individuals to make their own decisions, and to self-determination. This should be highlighted early in HIV self-testing implementation where policy makers may be reluctant to endorse the approach.

Concerns about linkage to care/surveillance with commissioners may also be addressed by highlighting the relative performance of self-testing compared to self-sampling in terms of increasing testing uptake. Indeed, greater numbers of individuals test and report their results in self-testing services compared with those who return samples in self-sampling initiatives. This gives self-testing an advantage compared to self-sampling and highlights the role of this approach in improving testing rates in line with the getting to zero aim.

Actions:

- Use the slide deck in the appendix of this guidance to highlight the benefits of HIV self-testing.
- Highlight the role of HIV person-centred self-testing in reducing health disparities for the marginalised populations.
- Leverage existing priorities through communication around shared goals, especially surrounding HIV elimination.
- Emphasise the importance of HIV testing expansion (including provision of HIV self-testing) when communicating with the government, public health bodies and commissioners.

Commissioning

Following the 2012 NHS and Social Care Act, commissioning of HIV testing in England rests with local authorities (57). Because of that, developing and implementing a service covering all of England would require buy-in from all 317 local authorities, which may be unlikely. Innovative approaches, such as harnessing collaborations between local authorities who commission services together and/or providing HIV self-testing through the voluntary and third-party organisations should be considered.

Sexual health services in Wales are commissioned centrally and it would thus be more straightforward to commission such a service, but it will require concerted political will.

In both countries the relatively low cost of HIV self-testing, especially when commissioning occurs at scale and lower kit prices can be negotiated with manufacturers, is a significant benefit, compared to all other means of expanding HIV testing options. However, it is vital in all settings that HIV self-testing is implemented alongside other testing options, as maintaining service diversification is important in meeting the diverse range of needs within the population.

Actions:

- Develop strategic partnerships early in planning including with potentially supportive commissioners.

- Identify and support HIV self-testing commissioning champions to advocate for implementation.

Community norms and buy-in

Strong norms emphasising the importance of HIV testing among GBMSM, trans and gender diverse people are a key facilitator of HIV self-testing. These norms can be leveraged in planning and delivering services, including while communicating with those responsible for commissioning. These norms are perhaps the strongest asset for HIV self-testing implementation.

In order to advocate for HIV self-testing programmes to be commissioned, community voices highlighting the utility of the technology can be harnessed and brought to the forefront. It is especially important that the potential role of HIV self-testing in reducing health inequalities is emphasised whenever possible. Further, empowerment is an often described benefit of HIV self-testing. Highlighting how self-testing is empowering for marginalised groups who face high barriers to clinical services is a critical mechanism through which to gain buy-in.

Actions:

- Empower community members to advocate for HIV self-testing implementation by sharing their own stories.
- Emphasise community voices highlighting HIV self-testing in discussions with the media.
- Engage community members in person-centred intervention design to ensure it meets the needs of a variety of end-users, including the most marginalised.

4.2 HIV self-testing intervention design

A key benefit of HIV self-testing interventions is the flexibility given in their design. Indeed, HIV self-testing services can be designed in a multitude of ways depending on the population being targeted, their needs and the priorities of service providers and commissioners.

As a rule, HIV self-testing interventions are defined by how the offer is configured. This includes the following considerations:

1. HIV self-test kit
2. Support options
3. Delivery mode
4. Instructions
5. Test accompaniments
6. Demand generation

For the purposes of this guidance, we consider the first two (the self-test kit and standard support) to be the basis (core) of any intervention and outline these directly in the following. We then provide an overview of the potential person-centred intervention adaptations that can be made depending on the target population. This includes various options around delivery mode, instructions, test accompaniments and strategies to generate demand. We also provide an overview of the additional possible support options for priority groups of GBMSM, trans and gender diverse people.

HIV self-testing core components

Core components of an intervention are elements which must accompany service delivery. We conceptualise the core components of an HIV self-testing service as comprising of 1) the self-testing kit and 2) the standard level of support that is offered.

This section explores decision making around these elements, including defining a standard level of support which should be provided.

Which test to use

There are currently 4 HIV self-tests available in the UK. Three of these use a whole blood sample and one uses oral fluid. All currently available tests are 2nd or 3rd generation which means they rely on antibodies to detect HIV and are less useful in identifying very recent infection (less than 4 weeks).

There are fourth-generation rapid diagnostic tests available, however none of these have been developed into an HIV self-test as yet. Because these tests detect both HIV antibodies and antigen, they have a shorter window period and are more useful for identifying early HIV infection. Once they become available as self-tests, they are likely to become the gold standard because of strong preference for tests with a shorter window period. When these are available, barring any significant capability or quality concerns, services should rapidly pivot to providing these.

Table 4 provides an overview of currently available tests, their sensitivity, specificity and benefits.

Generally, the tests currently available in the UK are either very simple to use but with a longer window period, or more challenging to use but with a shorter window period. When planning an intervention, decisions around the test implemented should be based on the trade-off between higher performance (Insti™ and Mylan™) and ease of use (SureCheck™ and OraQuick™). It should be noted that all available HIV self-tests are easier to use than the currently available self-sampling approach using Tiny Vial™ as these tests require smaller blood samples, utilise capillary draw or use oral fluid (58).

For the majority of GBMSM, trans and gender diverse people, a third-generation test using a whole blood sample will be preferred and will likely be the backbone of any services. This is because they have a slightly shorter window period and higher sensitivity than other tests, especially compared to OraQuick™.

Services should always consider having a secondary HIVST option providing oral fluid tests for those who have concerns about collecting a blood sample and/or a phobia of needles. This will ensure wide acceptability of any intervention. Supportive information when individuals are accessing a service and making decisions about which test to

Table 4: HIV self-tests in the UK

	Sample type	Generation	Sensitivity	Specificity	Window period	Benefits
OraQuick HIV self-test	Oral Fluid	2nd	92%	99.98%	6 weeks (can take up to 12 weeks)	Simple to use
SureCheck HIV self-test Chembio	Whole blood	2nd	99.7%	99.9%	6 weeks (can take up to 12 weeks)	Simple to use
Insti Rapid Detection HIV Self-Test	Whole blood	3rd	100%	99.5%	4 weeks (can take up to 12 weeks)	Shorter window period
Mylan HIV self-test	Whole blood	3rd	99.6%	99.8%	4 weeks (can take up to 12 weeks)	Shorter window period

order should highlight that blood-based kits generally have higher sensitivity and specificity. This is especially important for people using PrEP for whom seroconversion can be blunted, a particular issue with oral fluid testing. Providing clear information during test selection will enable beneficiaries to make informed decisions about which test is right for them.

Standard level of support for HIV self-testing

How to support people when self-testing is key to improving outcomes and well-being among service beneficiaries. This is a particular issue with HIV self-testing where linkage to care may be sub-optimal compared to other approaches. In line with that, it is important that a basic standard of support is provided with HIV self-testing and is consistent across services nationally so that people know what to expect, irrespective of the test provided or how it is delivered.

This approach may also help individuals feel connected to sexual health services more broadly and provide a roadmap for how to access further support, including HIV prevention measures such as PrEP, if needed. For most programmes, all components can be provided online, and automated through the mechanisms through which individuals sign-up to services.

For services specifically designed to engage GBMSM, trans and gender diverse people with the highest privacy barriers (for example services delivering self-testing through peers, outreach, community based-organisations and pharmacies), linkage to care information can be provided in physical form. This will usually be with links on a card packaged within the kit. This eliminates the requirements for individuals to provide contact details.

Table 5 outlines what should be provided and the rationale. Following, these components are described in greater depth.

Table 5: Standard level of support

Component	Target group	Aim
Results reporting system	All intervention beneficiaries	• Ensure data are available on proportions who have positive and negative HIV self-test results • Identify issues with kit delivery or performance • Facilitate linkage to care for those with positive results
Linkage to prevention/ care pathways	All intervention beneficiaries	• Highlight other potential HIV prevention opportunities • Facilitate linkage to care for those with positive results • Facilitate linkage to PrEP for those testing negative
Helpline	All intervention beneficiaries	• Provide access of support for those without supportive social networks • Facilitate linkage to care for those with positive results
Clinical follow-up	Intervention beneficiaries with positive results and with safeguarding concerns	• Facilitate linkage to care for those with positive results • Respond to identified safeguarding concerns

Results reporting system

Key to HIV self-testing service delivery is having a mechanism for service users to report their results. This will help follow-up those accessing testing, identify potential issues with the test and provide a mechanism to provide replacement self-tests if needed. A standard level of support should have an active result reporting mechanism as a default where possible, meaning that the service should contact the beneficiary and ask them about their result, usually from 8-14 days after their test was dispatched or collected. This will usually be done through a survey delivered via SMS, email or instant messaging such as WhatsApp. Motivational language in the message should highlight the importance of reporting results to the service for monitoring purposes and to support engagement in care. Reminders can be used, but no more than 3 to ensure service beneficiaries do not get overwhelmed by communication.

It is also important, however, that individuals signing up to an HIV self-testing service are able to opt-out of automated results reporting systems. This will facilitate engagement from individuals with very high privacy barriers and ensure widespread intervention acceptability. Providing linkage and a passive result reporting system in physical form, potentially using a QR code delivered with the kit, will remain an important intervention component and help facilitate the uptake of support.

Further, some service designs will specifically target those with the greatest privacy concern for whom providing any contact details will reduce intervention acceptability substantially and present an unrealistic burden on those delivering the intervention. These services will likely distribute self-tests through outreach, peers or community-based organisations. For such interventions, passive results reporting can be used, potentially through a QR code on accompanying supportive information. This approach will almost certainly result in fewer individuals reporting their results and but will represent an important part of differentiated person-centred HIV self-testing service delivery attempting to reach those with the greatest privacy concerns.

Linkage to care pathways

Ensuring individuals can access care following self-testing is vital for connecting people with a positive self-test to confirmatory testing and treatment if required. These pathways can also be used by service beneficiaries with negative self-test results to access further interventions, such as STI testing and PrEP.

Care pathways should be highlighted in communication about self-testing following service at and following enrolment. This can include sending links to webpages with regular communication about self-testing, especially confirmation messages following ordering a kit. In addition, providing a card with the self-test which highlights other HIV/STI testing and prevention opportunities is important. This information can be locally specific for interventions which target a certain area, or providers can refer to the National aidsmap clinic finder tool (figure 3).

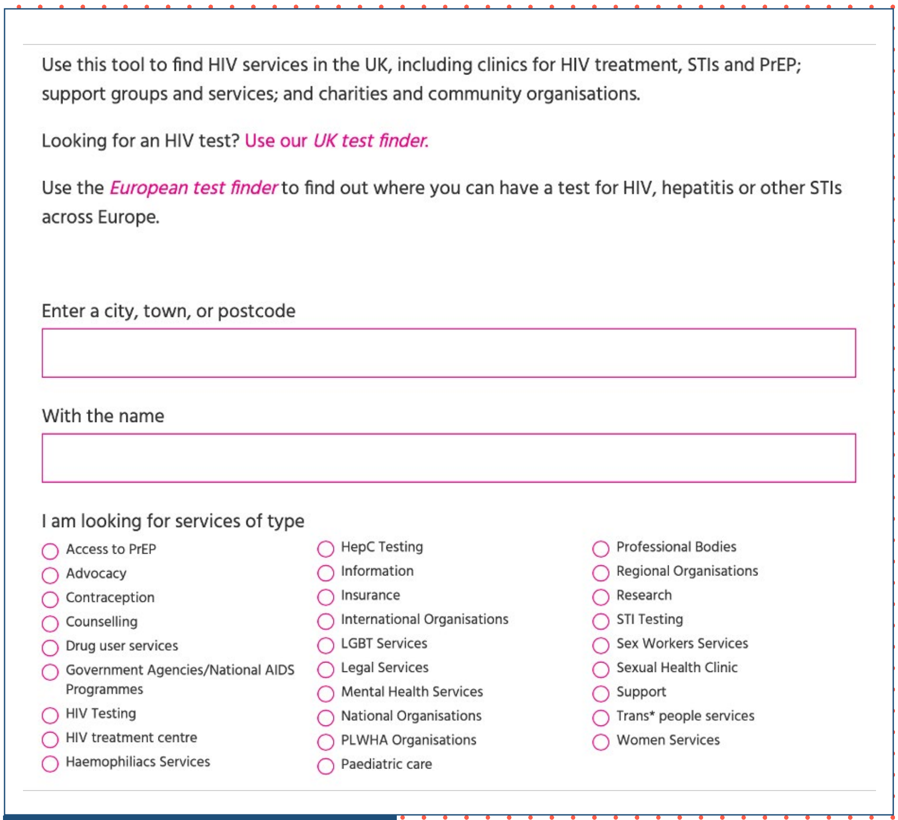
Helpline

Most people who use HIV self-testing seek support from their social networks. However, a helpline should be available for those using HIV self-testing and who require immediate or confidential support, including individuals who do not have supportive social networks. This can be bespoke and run by the implementing organisation or organisations can link to existing services such as the Terrence Higgins Trust Direct helpline or the LGBT Switchboard. The operating hours of the helpline should be clear.

This information should be included in regular communications following the beneficiary ordering an HIV self-test, and also be provided on a card with the kit itself. Hours of operation should be clearly presented as it may inform when people use the test, particularly if they have concerns about a positive result.

Clinical follow-up

Having a member of staff such as a clinician, nurse or health advisor follow-up individuals who report a positive result but not having a confirmatory test is important to facilitate linkage to care. Although evidence suggests this situation is likely to be uncommon, it is imperative that this is available to ensure those without supportive networks, including vulnerable and/or marginalised individuals, have the tools they need to access confirmatory testing and treatment should they wish to. This should be done over the phone if contact details are available, otherwise via email or instant messaging. The details provided by the beneficiary should be the only ones used for this, and services should not attempt to track individuals down through social media for example. For a basic level of support clinical follow-up is not required for those who test negative, unless a safeguarding concern such as intimate partner violence is identified through the service registration process, in the results reporting or through communication with the individual following registration.



Use this tool to find HIV services in the UK, including clinics for HIV treatment, STIs and PrEP; support groups and services; and charities and community organisations.

Looking for an HIV test? Use our *UK test finder.*

Use the *European test finder* to find out where you can have a test for HIV, hepatitis or other STIs across Europe.

Enter a city, town, or postcode

With the name

I am looking for services of type

○ Access to PrEP
○ Advocacy
○ Contraception
○ Counselling
○ Drug user services
○ Government Agencies/National AIDS Programmes
○ HIV Testing
○ HIV treatment centre
○ Haemophiliacs Services
○ HepC Testing
○ Information
○ Insurance
○ International Organisations
○ LGBT Services
○ Legal Services
○ Mental Health Services
○ National Organisations
○ PLWHA Organisations
○ Paediatric care
○ Professional Bodies
○ Regional Organisations
○ Research
○ STI Testing
○ Sex Workers Services
○ Sexual Health Clinic
○ Support
○ Trans* people services
○ Women Services

Figure 3: Aidsmap clinic finder tool

Potential intervention adaptations

A primary benefit of HIV self-testing is the flexibility afforded by the intervention. Indeed, this type of testing can be packaged and delivered in a huge variety of ways. Choosing how to implement HIV self-testing in a person-centred way will require identifying the target population, how best to reach them and what their support needs might be following self-testing. In this section we outline some of the intervention adaptations which can be made and which groups they support and how. This can be thought of as a menu of options available to service providers (see table 6).

Delivery mode

Delivery mode is possibly the most important element of a person-centred HIV self-testing service as it defines how scalable an intervention is and who is most likely to access it. Because self-testing is so flexible, delivery options are hugely varied. This guidance is not exhaustive but is intended to provide those seeking to implement self-testing with a range of options to consider based on the needs of the groups they are attempting to engage.

Online orders and postal delivered HIV self-testing will almost certainly remain the cornerstone of service delivery in England and Wales. As GBMSM, trans and gender diverse people in England and Wales are generally a highly digitally literate population (59, 60), this approach has the benefit of having a low barrier to access for beneficiaries and is straightforward for service providers to scale up. Delivery through the post also enhances the convenience of HIV self-testing while keeping costs low. Services which seek to reach large numbers of beneficiaries can use this approach as a primary option but acknowledge that it has potential limitations in reaching the most marginalised, including some from ethnic minority communities, individuals with domestic privacy concerns and people who have no fixed address.

Click-and-collect, whereby packages are sent to lockers and individuals type in a code to retrieve them, are especially useful in reaching individuals with domestic privacy concerns, and who are reluctant to visit a clinic to access testing or a community-based organisation to pick up a self-test. Providing click-and-collect options will therefore expand testing to groups not reached by sexual health services or, potentially, by online self-sampling.

Vending machine delivered HIV self-testing has been shown to be useful in reaching those with high privacy barriers and/or individuals at potentially increased risk in environments where they may socialise (34). Providing self-testing through vending machines in places such as sex-on-premises venues and neighbourhoods with a high concentration of LGBT venues may be an effective way of distributing kits to these groups, although numbers accessing will likely be small. Given the setting, additional information highlighting the limitations of the test window period is important. Additional materials such as condoms, lubricant and STI self-sampling kits could also be delivered from these machines. It should be noted that this is likely to be a very high-cost option and used only in limited circumstances where there are a very high proportion of GBMSM, trans and/or gender diverse people in one environment.

Community-based organisation and pharmacy distributed HIV self-testing (often

Table 6: HIV self-testing intervention adaptations

Component	Possible adaptations	Target audience	Evidence source
Delivery mode	**Postal**	**Most beneficiaries**	**(19-21, 27, 29, 33, 35, 51)**
	Click-and-collect from a post locker	Beneficiaries with domestic privacy concerns	(19, 29, 51)
	Community-based organisation, pharmacy	Beneficiaries with capability or support needs	(20)
	Peer/partner delivered	Beneficiaries at increased risk	(20)
	Outreach	Beneficiaries at increased risk Beneficiaries with capability concerns Beneficiaries from ethnic minority backgrounds	(20)
	Other (e.g. vending machine, SOPV pick-up)	Beneficiaries with high privacy barriers Beneficiaries at increased risk	(34)
Instructions	**Manufacturer's instructions**	**Most beneficiaries**	**(19-21, 27, 29, 32, 33, 35, 51)**
	Video	Most beneficiaries	(19, 21)
	Enhanced written instructions	Beneficiaries with minor capability needs	(19)
	Demonstration (in-person/ online)	Beneficiaries with pronounced capability needs, including mild learning disability	(39)
Accompaniments	**Linkage to testing and prevention**	**Beneficiaries from marginalised backgrounds** **Beneficiaries estranged from services**	**(21, 37)**
	Bacterial STI self-sampling	Beneficiaries who test at clinics infrequently	(21, 37)
	Syphilis self-testing	Beneficiaries who test at clinics infrequently and without prior syphilis diagnosis	(62, 63)
	HCV self-testing	Beneficiaries without previous HCV diagnosis Beneficiaries engaged in chemsex and group sex	(61)
Demand generation	**Marketing**	**All beneficiaries**	**(7, 21, 35-37)**
	Risk assessments	All beneficiaries	(21, 37)
	Testing reminders	Beneficiaries who don't have a testing routine	(21, 37)
Support	**Results reporting**	**All beneficiaries**	**(5, 19-21, 27, 29, 33, 35, 38, 41, 51)**
	Linkage to care pathways	**All beneficiaries**	**(5, 19-21, 27, 29, 33, 35, 38, 41, 51)**
	Help line	**All beneficiaries**	**(5, 19-21, 27, 29, 33, 35, 38, 41, 51)**
	Clinical follow-up	**Beneficiaries with positive results** **Beneficiaries with safeguarding issues**	**(33, 41)**
	Online counselling	Beneficiaries with highest needs, including learning disability	(46, 64, 65)

**Bold items are likely to be standard approaches in England and Wales.*

called facility-based distribution) may be an effective way of delivering a service to those who have specific support concerns, such as questions about test performance, or those with capability concerns and who require a small amount of guidance. Those implementing self-testing may consider having an option for service beneficiaries to self-test in these locations so that support is immediately accessible. This may be especially useful for those not confident in their ability to perform a test on their own including those who wish to have support immediately accessible in case of positive results. Distributing self-tests through these services will also help to reach the small minority who are not digitally literate. This approach may facilitate increased engagement with healthcare services. It should be noted that those with the highest psychosocial and geographic barriers to service access are unlikely to access self-testing delivered in this way.

Outreach workers can deliver HIV self-tests to their contacts while providing support in social and community venues. Like vending machine delivery, this may have the benefit of reaching beneficiaries at increased risk and with privacy concerns who might not otherwise access testing. If targeted properly, this approach can also facilitate engagement with beneficiaries from ethnic minority backgrounds in the environments they socialise in.

Peer/partner delivered HIV self-testing is when an index person is provided with a number of self-tests to distribute in their social networks. This approach has primarily been used in the USA, as well as for key populations in low- and middle-income countries. Applying this model in the UK may facilitate engagement from especially poorly served GBMSM, trans and gender diverse people who face high barriers to service access and experience intense marginalisation, including issues with digital literacy. This may facilitate engagement in future sexual health care by reducing fear and stigma as key testing barriers. Because this type of intervention is especially dislocated from clinical services, if using this method, those implementing should be mindful of ensuring accompanying supportive information is very comprehensive with clear links to follow-on care, including additional HIV/STI testing and prevention opportunities.

Instructions

All HIV self-tests available commercially in the UK have manufacturer provided written and video instructions. Evidence suggests that these will be sufficient for the majority of intervention beneficiaries to operate the tests successfully, especially with increasing experience. Further, research has found that manufacturer provided instructions were adequate for those experiencing multiple types of marginalisation including intersections between education, gender, sexual orientation and ethnicity. However, should a service seek to engage those with enhanced capability concerns, such as those with language barriers or specific learning difficulties, more detailed instructions can be developed, ideally with the input of community members. For individuals with the greatest capability issues, such as those with mild learning disabilities, in-person or online demonstrations can be provided to ensure the beneficiaries are confident in operating the test.

Accompaniments

To date, the majority of interventions in England and Wales have provided HIV self-testing without other tests accompanying it. While evidence shows that STI testing rates are not substantially impacted by HIV self-testing, it may be preferable, and more convenient for beneficiaries, to provide HIV self-tests packaged with other STI test kits.

Bacterial STI self-sampling is easy for most people to do. This can be sent out with HIV self-tests, with the samples returned to the lab with results coming later.

Syphilis self-testing is a relatively recent innovation. There is currently an approved syphilis antibody self-test in the UK which could be provided alongside HIV self-testing. However, because syphilis antibodies remain in the blood after treatment, these tests are only useful for those who have not previously had a syphilis diagnosis. Supporting information at service enrolment and accompanying the test must make this very clear.

Hepatitis C self-testing using oral fluid had been approved by the World Health Organization. While the is test is not currently approved in the UK it may well be in the future. Providing hepatitis C self-testing with HIV self-testing would benefit beneficiaries at increased hepatitis C risk, including those who engage in chemsex, group sex and inject drugs (61). These tests also only detect antibodies which stay in the blood following spontaneous clearance, treatment and recovery. Similar to syphilis self-testing, accompanying information must underline that a positive hepatitis C self-test does not necessarily indicate an active infection.

Demand generation

Engaging people in interventions is critically important for their success. In most cases HIV self-testing service delivery will be accompanied by advertisements and other marketing promoting the intervention. This marketing should be responsive to the populations the intervention is seeking to reach, and highlight intervention facilitators (e.g. convenience, ease of use, confidence) while reducing barriers (e.g. capability concerns, blood draw). Personal perspectives from diverse individuals who have accessed similar interventions can be used to promote self-testing to wide audiences. These initiatives should focus on reaching GBMSM, trans and gender diverse people in the online and physical spaces they socialise in.

Brief risk assessments incorporated into interventions (such as during the enrolment process) can provide an opportunity for individuals to consider their sexual behaviour, heightening the feeling of relevance of testing for HIV. Embedding risk assessments will help encourage service beneficiaries to access HIV self-testing again, as well as other clinical services including PrEP and STI testing.

Testing reminders are a powerful tool to continuously engage service beneficiaries in testing. With beneficiary opt-in and consent, these can be delivered to the contact details provided when individuals sign up for HIV testing. Service providers can also give beneficiaries the option for how frequently they would like to receive these reminders, based on their own testing routines, preferences and anticipated sexual behaviour. This is especially useful for those at increased risk and those who may have multiple competing personal pressures related to social and economic deprivation and find it difficult to prioritise testing.

Additional support options

For the majority of intervention beneficiaries, the basic level of support established in the previous section will be sufficient to use HIV self-testing safely and effectively, including for many people testing for the first time. However, some services, especially those reaching individuals with mild learning disability, or profound capability and support concerns, may wish to establish an option for real-time online counselling. This could draw on principles of pre- and post-test counselling used in HIV testing and also provide practical support on kit usage. Another option is to deliver self-testing in a location where healthcare workers are present (such as a community-based organisation) and can offer practical or emotional support as needed.

In addition, linkage to other prevention opportunities can be provided alongside HIV self-tests. This can include contact details to arrange follow-up testing or PrEP initiation. This could also take the form of a direct booking link to a clinic, or a link to outreach workers who can support referral. This may be especially useful for beneficiaries who face multiple forms of marginalisation based on ethnicity, educational attainment, sexual orientation, gender and migration status.

4.3 Individuals involved in implementation

As with all new interventions, in order to successfully implement HIV self-testing, organisations will need to have the buy-in of the staff responsible, as well as others involved in related service delivery. HIV self-testing may be especially challenging for staff to support as it requires a paradigm shift, with implementing organisations relinquishing control to the beneficiary, especially around decision making following self-testing. Difficulties accepting this paradigm may be compounded when some may feel at risk of displacement or redundancy, and may also be heightened by wider opposition to HIV self-testing within the sector. These issues may be especially challenging when working with organisations within the sector which have taken a different approach and have divergent values and preferences around intervention delivery.

Identifying and supporting implementation champions within organisations may support effective service delivery. These individuals typically effectively and enthusiastically promote implementation of an intervention within organisations, and with collaborators involved in service delivery (66). Using this approach may be an effective mechanism to gain buy-in from across organisations and counter reticence. Ensuring these champions are up to date on the evidence supporting HIV self-testing implementation is critical. They can also be centrally involved in discussion with collaborating organisations that have different values and influence more broadly across the sector.

Wherever possible, within organisations, the value of HIV self-testing programmes in facilitating positive outcomes for beneficiaries should be highlighted. Communication around this should draw on the evidence base, especially as it pertains to populations served by the organisations. Implementors can also highlight that self-testing can free up organisational capacity to focus on those who have the greatest needs, improving health equity and creating new organisational opportunities.

4.4 Process of implementation

Successful person-centred implementation requires considered stages, ensuring that various considerations are resolved at the appropriate time. This section provides guidance at four-steps of implementation for future HIV self-testing interventions and outlines what organisations may want to consider in during each phase. This is not meant to be prescriptive, but rather, provides an exploration of the various dimensions of implementation worth considering. These stages are as follows: 1) Planning, 2) Engaging, 3) Implementing and 4) Evaluating and reporting.

Stage 1: Planning

The first phase of HIV self-testing implementation is planning. It is critical in this phase that the target group for the intervention is identified, as are their priorities and needs. The intervention itself should be defined, ideally with members of the community the intervention seeks to reach. Various HIV self-testing adaptations can be chosen as this stage drawing upon the values and preferences of the intended beneficiaries and considering the existing evidence. This should take into account what is feasible for the organisation to deliver, acknowledging that each intervention adaptation introduces complexity and likely additional cost within the service budget.

Once the intervention has been defined, the organisation can consider what needs to be put in place to facilitate successful service delivery. For example, what infrastructure is needed for individuals to sign-up for the service? And will this be built in-house or will an external provider such as a survey software company provide this? A further consideration is who will distribute the kits. Will it be the implementing organisation, the kit manufacturer or someone else, such as a distribution centre?

It will also be important to consider how evaluation processes will work and ensure they are built into the service infrastructure so that value for money can be demonstrated. Finally, organisations must consider how follow-up will work and who will be responsible for clinical governance and contact with the end users, including if something goes wrong.

Stage 2: Engaging

Once the intervention has been roughly planned it is important to engage with broader opinion leaders in the community, health bodies and champions within the organisation. Each has a potential role in the success of the intervention. During this phase it is important to consider how HIV self-testing might further their own objectives, and ensure you are able to highlight that in communications. You may want to consider what kind of support you wish to gain from each group, as well as the optimal way to achieve that. Finally, if any of these actors are likely to be hostile to implementation, making a plan for managing that hostility before implementation is important.

Stage 3: Implementing

During this phase it is vital that it is clear who is responsible for which tasks and how they will be performed. In particular, understanding who has responsibility for each step or function in the intervention will ensure smooth service delivery with minimal errors. This includes more foundational points such as ensuring clear communication lines with organisations delivering the kits (if external), as well as ensuring that processes to identify service problems arising are in place and functional.

Stage 4: Evaluating and reporting

In order to capture outcomes, continuously improve services and demonstrate value for money, evaluation can be conducted at various points throughout implementation.

Formative evaluation

Early in implementation, especially when developing novel services or targeting new groups, formative evaluation can help refine interventions and ensure they are meeting a range of needs. In order to do this, implementing organisations can choose to embed structured questions at various points throughout the intervention, including during follow-up. For a more in-depth understanding of experiences and met/unmet need, organisations can also conduct a number of structured or semi-structured interviews exploring what works well and what works less well and make changes accordingly.

Summative evaluation

Summative evaluation exploring outcomes from services will be especially useful in ensuring HIV self-testing interventions are meeting their own aims. This includes understanding the individuals your intervention is reaching, and how well it is meeting their needs, including linking to HIV prevention services for those testing negative, uncovering undiagnosed HIV and linking to confirmatory testing/care. The utility of this information for organisations must be balanced against the extent to which gather this data is likely to reduce intervention acceptability for those undergoing self-testing. In particular it is important to ensure summative evaluation questions are not burdensome and do not reduce the ability for individuals to engage with the programme.

Harms

Harms from HIV self-testing are very rare (20, 45). Never-the-less, HIV self-testing services should have a mechanism through which individuals can report harms. This should specifically focus on technological harms (from the kit itself), intervention harms (from wider intervention components), and socially emergent harms (those emerging from the social circumstances of individuals). Enabling individuals to report these provides the opportunity to provide support and address particular concerns that may arise. Monitoring these will also enable services to adapt as evidence emerges.

CHAPTER 5

HIV SELF-TESTING TOOL-KIT

Implementing HIV self-testing sometimes involves new ways of working for organisations. This section provides a tool-kit with helpful examples of how the SELPHI trial, SH:24 and the Terrence Higgins Trust (THT) have implemented HIV self-testing in England and Wales. This is not meant to be prescriptive, but rather to provide a series of tools organisations can draw on when thinking about, designing and implementing new self-testing interventions. In particular, we provide examples in the following areas:

- Advertisement examples
- Service enrolment questions
- Results reporting questions
- Supportive resources
- Evaluation

In addition, in Appendix 1 we provide a slide deck presenting critical evidence on HIV self-testing for organisations to use in lobbying efforts. We also include an appendix (2) containing all survey questions presented in this section. Finally, we provide a series of short, sharable videos about HIV self-testing which are designed to stimulate demand (appendix 3).

5.1 Advertisement examples

HIV self-testing programmes will likely require some degree of advertising to engage individuals in services, especially when they are first implemented. Advertising will likely be primarily through organisational websites, social media and on geolocation social/ sexual networking apps but can also be provided in physical form especially during outreach to those potentially most at risk. Depending on the scope (and budget) of an intervention advertising could also include physical advertising in the public domain, such as on public transport. This is especially useful for reaching those who are potentially not engaged with services and do not access LGBT venues, either online or offline.

Novelty may be a key driver for people accessing HIV self-tests, especially in earlier stages of service delivery. During these campaigns very simple messaging may suffice in creating substantial demand.

As a general approach, it is likely helpful to highlight HIV self-testing facilitators (e.g. ease of use, convenience, confidentiality) while addressing potential barriers (e.g. capability concerns, support concerns).

A further approach is to highlight public health messaging around HIV testing among groups at increased risk and the links of this with altruism. This also can tap into norms around HIV testing prevalent in the community.

If using people in advertisement imagery it is important that these are tailored to the population groups that the services seek to reach. For national campaigns, highlighting diversity in age, ethnicity and gender is important. Example messages are provided in figure 4 below, advertising examples from SH:24 and the English National Programme in figures 5-7, and a leaflet from THT (figure 8).

Messaging highlighting intervention novelty

Interested in HIV self-tests? Click below to find out more.
Would you like to test yourself for HIV? Find out more today.
We're giving away free self-tests to gay and bi men in England. Sign-up today

Messaging highlighting facilitators while responding to barriers

HIV self-testing is easy and private. Ever been interested? To find out more, click here.
Test yourself for HIV – it's fast and easy. Sign-up by clicking here.
Ever wondered about taking an HIV test on your own? With HIV self-testing you can at home and find out your result in minutes. Sign-up up for free today.

Figure 4: Example messaging that can be used to promote HIV self-testing interventions

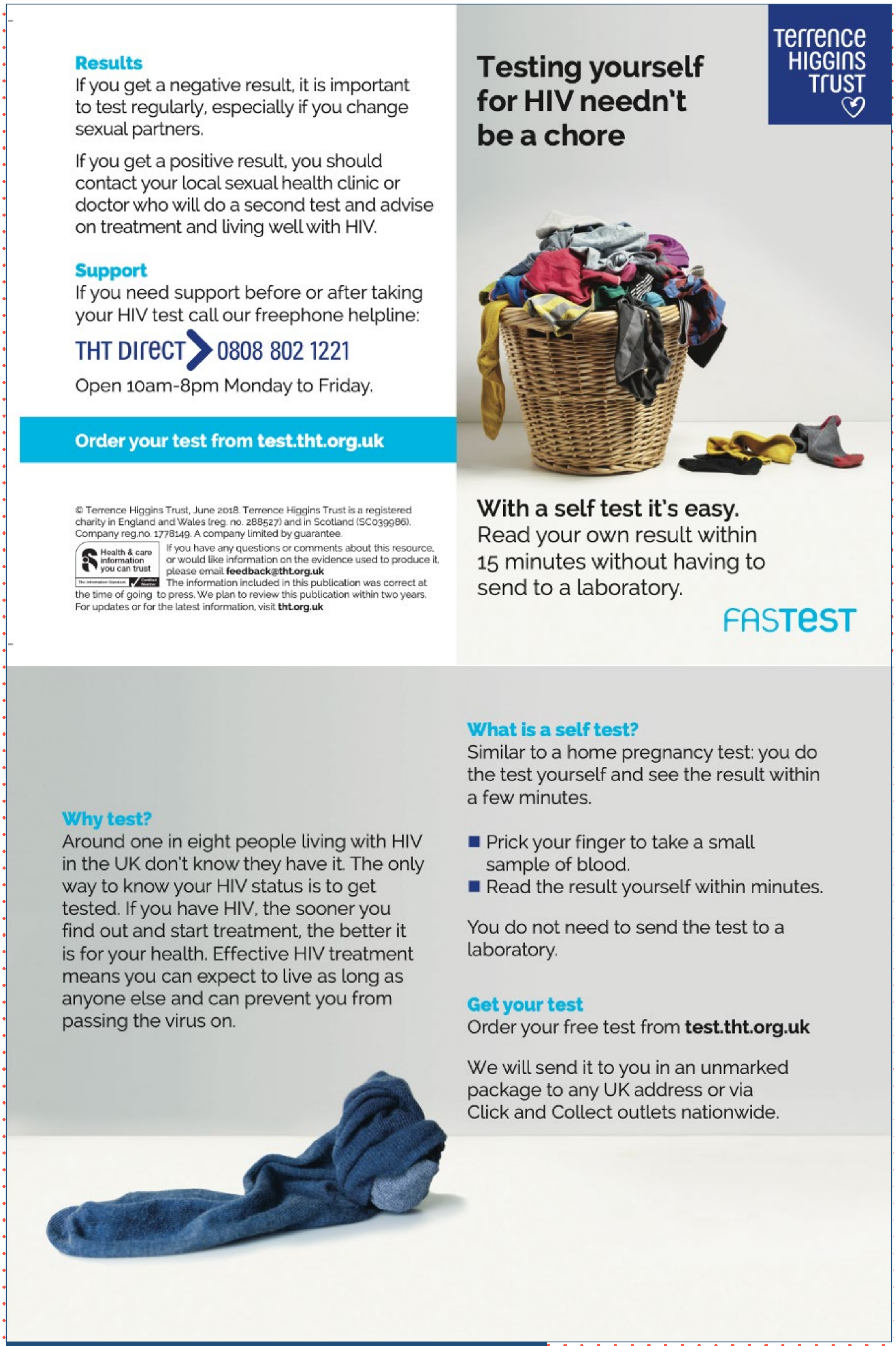

Sexual health
24 hours a day

Free, discreet, confidential

Figure 5: SH:24 web-portal

Figure 6: English National HIV Testing Week campaign

Figure 7: English National HIV Testing Week campaign



Results
If you get a negative result, it is important to test regularly, especially if you change sexual partners.

If you get a positive result, you should contact your local sexual health clinic or doctor who will do a second test and advise on treatment and living well with HIV.

Support
If you need support before or after taking your HIV test call our freephone helpline:

THT Direct 0808 802 1221

Open 10am-8pm Monday to Friday.

Order your test from test.tht.org.uk

Health & care information you can trust

If you have any questions or comments about this resource, or would like information on the evidence used to produce it, please email **feedback@tht.org.uk**
The information included in this publication was correct at the time of going to press. We plan to review this publication within two years. For updates or for the latest information, visit **tht.org.uk**

Testing yourself for HIV needn't be a chore

With a self test it's easy.
Read your own result within 15 minutes without having to send to a laboratory.

Why test?
Around one in eight people living with HIV in the UK don't know they have it. The only way to know your HIV status is to get tested. If you have HIV, the sooner you find out and start treatment, the better it is for your health. Effective HIV treatment means you can expect to live as long as anyone else and can prevent you from passing the virus on.

What is a self test?
Similar to a home pregnancy test: you do the test yourself and see the result within a few minutes.

- Prick your finger to take a small sample of blood.
- Read the result yourself within minutes.

You do not need to send the test to a laboratory.

Get your test
Order your free test from **test.tht.org.uk**

We will send it to you in an unmarked package to any UK address or via Click and Collect outlets nationwide.

Figure 8: Example of HIV self-testing leaflet distributed by THT

5.2 Service enrolment questions

Most HIV self-testing services will enable people to sign up through online platforms. This is a useful source of monitoring and evaluation data, and for those implementing self-testing to understand who is accessing the services. Information collected at this stage should be limited to what is strictly necessary for monitoring and for addressing safeguarding issues. It is not envisaged that services will include all examples below as collecting large volumes of data will reduce intervention acceptability, especially for those with heightened concerns around privacy who are less likely to test through conventional services. Below (table 7) we include some options which can be used to ask about gender, sexual orientation, ethnicity, testing recency and sexual behaviours. These questions can also gather monitoring information for services with passive results reporting systems, however the number used should be limited to what is strictly necessary in these interventions in order to avoid negatively impacting on intervention acceptability. All questions are also available in appendix 3.

Table 7: Example service enrolment survey questions

Question	Options
How do you describe yourself?	**Single choice drop-down**
	Man (including trans man)
	Woman (including trans woman)
	Non-binary
	Other
What sex were you assigned at birth?	**Single choice vertical**
	Male
	Female
	Indeterminate
Which of the following options best describes how you think of yourself?	**Single choice drop-down**
	Gay or lesbian
	Bisexual
	Straight or heterosexual
	Any other term
	I don’t usually use a term
Were you born in the UK?	**Single choice vertical**
	Yes
	No
How long have you lived in the UK?	**Single choice drop-down**
	Less than 1 year
	1-3 years
	3-5 years
	5-10 years
	More than 10 years

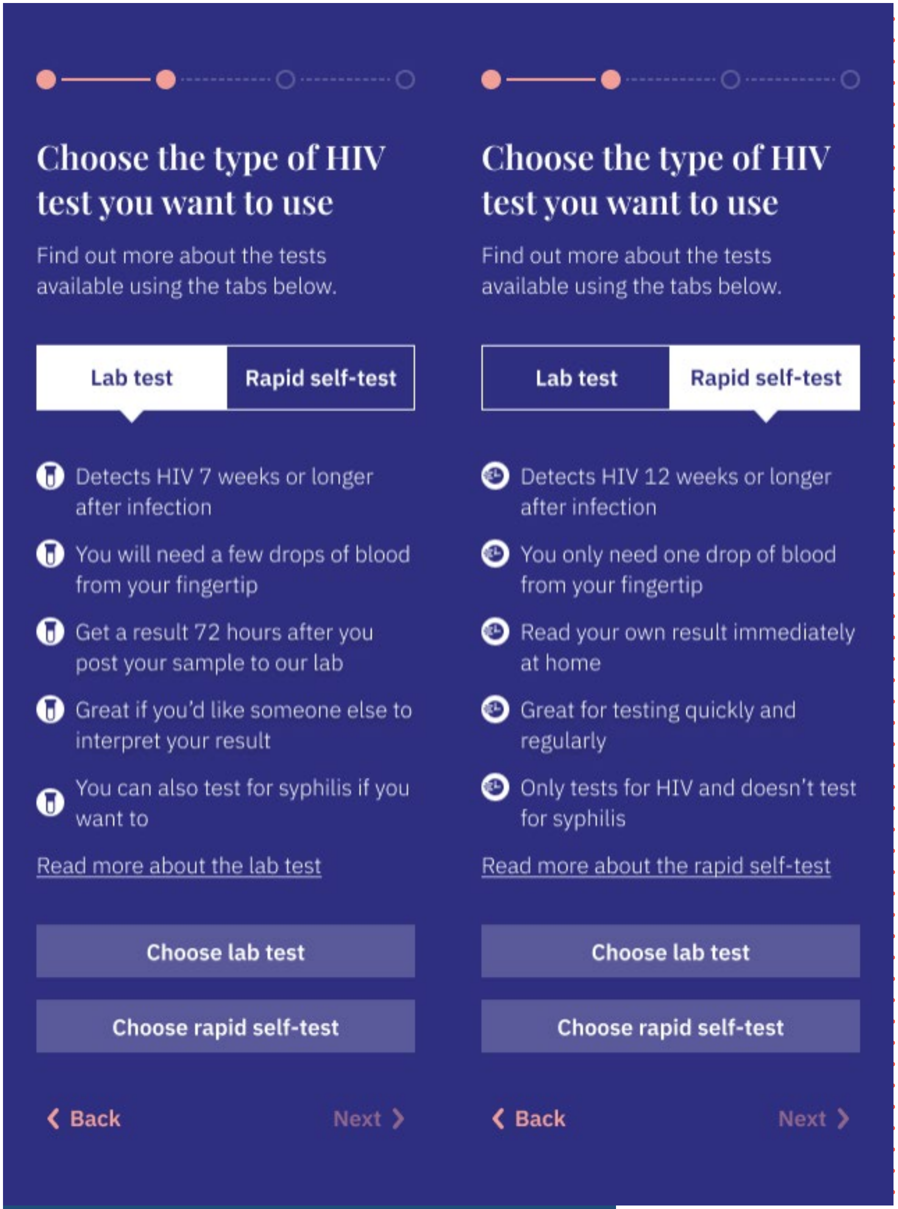
Which country were you born in? If it does not exist any more, please select the country that best applies.	**Single choice drop-down**
	List of countries
How would you describe your ethnicity?	**Single choice drop-down**
	White - English/Welsh/Scottish/Northern Irish/British
	White - Irish
	White - Gypsy or Irish Traveller
	White - Any other White background
	Mixed - White and Black Caribbean
	Mixed - White and Black African
	Mixed - White and Asian
	Mixed - Any other Mixed/Multiple ethnic background
	Asian or Asian British - Indian
	Asian or Asian British - Pakistani
	Asian or Asian British - Bangladeshi
	Asian or Asian British - Any other Asian background
	Black or Black British - African
	Black or Black British - Caribbean
	Black or Black British - Any other Black/African/ Caribbean background
	Arab
	Chinese
	Latin/South/Central American
	Any other ethnic group
	I don't know
	I'd rather not say
Please say which 'other' ethnicity?	**Write-in 1 line**
What is your highest educational qualification?	**Single choice drop-down**
	I have no educational qualifications
	GCSEs/CSEs/O-Levels or equivalent
	A-Levels or equivalent
	Higher education (eg. HNC, HND)
	University Degree or higher
	Other
***[if other ethnicity]* Please say which other?**	**Write-in 1 line**
When did you last have an HIV test?	**Single choice drop-down**
	Within the last 3 months
	Within the last 12 months
	Within the last 5 years
	More than 5 years ago
	Never
Where did you go for your last HIV test?	**Single choice drop-down**
	At a sexual health clinic
	At hospital - as an inpatient or outpatient
	A community HIV testing service
	I used a self-sampling kit (I took my own sample and sent off for the results)

	I used a self-testing kit (I took a sample and found out the result on the spot)
	In a bar/pub, club or sauna
	At a General Practitioner/family doctor
	Somewhere else
When did you last have a test for sexually transmitted infections (STIs) such as syphilis or gonorrhoea?	**Single choice drop-down**
	Within the last 3 months
	Within the last 12 months
	Within the last 5 years
	More than 5 years ago
	Never
Can you tell us the total number of partners that you have had sex with in the last 3 months?	**Single choice drop-down**
	None
	1
	2
	3-4
	5-6
	7-9
	10-30
	More than 30
How many partners have you had sex with without a condom in the last 3 months?	**Single choice drop-down**
	None
	1
	2
	3-4
	5-6
	7-9
	10-30
	More than 30
PrEP stands for pre-exposure prophylaxis. PrEP is taken by HIV negative people before sex to protect against HIV. PrEP usually involves two HIV drugs combined in a single pill. For example, Truvada or Tenvir-EM.	**Medium text**
Have you ever taken any PrEP (e.g. Truvada or Tenvir-EM)?	**Single choice vertical**
	Yes
	No
Do you currently use PrEP?	**Single choice vertical**
	Yes
	No
***[if yes to currently taking PrEP]* How do you take your PrEP?**	**Single choice vertical**
	Every day
	When I need to (on-demand dosing)
	In another way

5.3 Test choice

Services which provide multiple types of testing, such as both self-testing and self-sampling or multiple choices of kits (e.g. both blood and oral fluid options), should provide clear information on the benefits and drawbacks of each type of test. This will include information on ease of use, window period as well as sensitivity and specificity.

It is also important to highlight what else might accompany the different options provided. Below (figure 9) is an example from SH:24 which outlines the differences between their self-sampling and HIV self-testing approaches.



Choose the type of HIV test you want to use

Find out more about the tests available using the tabs below.

- Detects HIV 7 weeks or longer after infection
- You will need a few drops of blood from your fingertip
- Get a result 72 hours after you post your sample to our lab
- Great if you'd like someone else to interpret your result
- You can also test for syphilis if you want to

Read more about the lab test

Choose the type of HIV test you want to use

Find out more about the tests available using the tabs below.

- Detects HIV 12 weeks or longer after infection
- You only need one drop of blood from your fingertip
- Read your own result immediately at home
- Great for testing quickly and regularly
- Only tests for HIV and doesn't test for syphilis

Read more about the rapid self-test

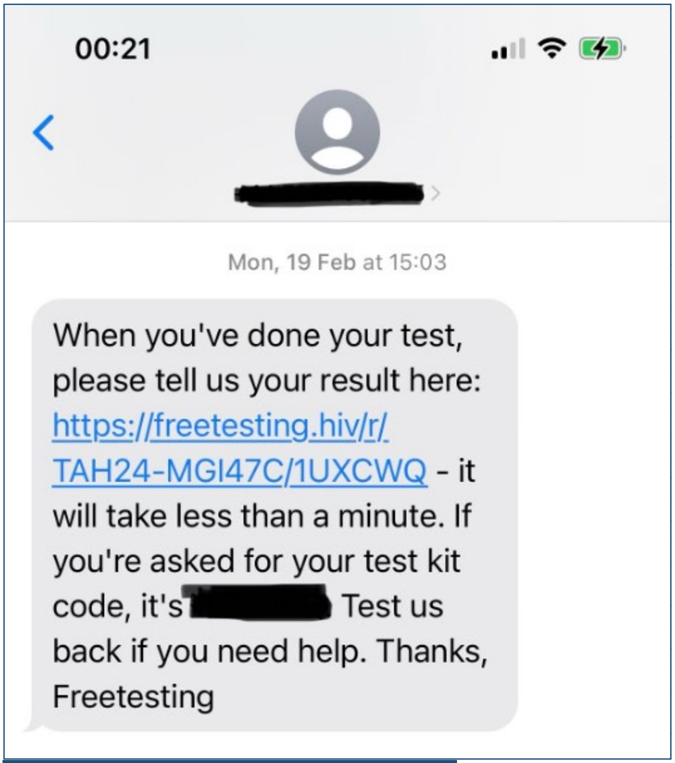
Figure 9: Differences between testing options on SH:24

5.4 Results reporting system

Nearly all HIV self-testing services will have a results reporting system of some kind. Many of these will use prompts via SMS and email asking people to fill in a brief survey with their results. An example of an invitation to complete this from SH:24 is provided in figure 10. We also provide example questions which can be used to ask for HIV self-testing results in table 8. These questions will likely be useful not just for results reporting, but also potentially for monitoring purposes after individuals have received their tests.

Note that services can employ active or passive approaches to results reporting depending on how it is being delivered, and that service beneficiaries should have the option to opt-out, in line with the minimum standard of support described in chapter 4. For passive approaches a physical card can be sent with the pack containing a QR code with a link to the results reporting system.

A further approach to asking test results which may be useful is to provide images of the possible results received to help service beneficiaries accurately report their results. Below is an example from SH:24 (figure 11).

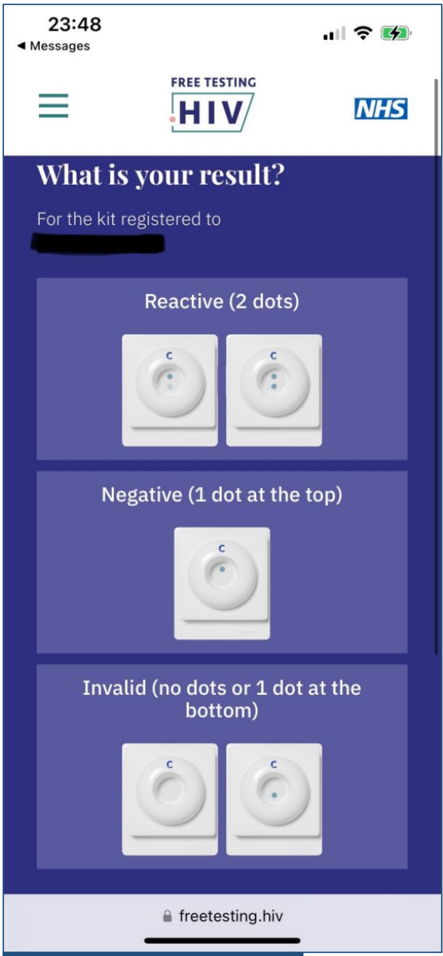


[redacted]

Mon, 19 Feb at 15:03

When you've done your test, please tell us your result here: https://freetesting.hiv/r/TAH24-MGI47C/1UXCWQ - it will take less than a minute. If you're asked for your test kit code, it's [redacted] Test us back if you need help. Thanks, Freetesting

Figure 10: Results reporting SMS prompt



What is your result?

For the kit registered to
[redacted]

Reactive (2 dots)

Negative (1 dot at the top)

Invalid (no dots or 1 dot at the bottom)

freetesting.hiv

Figure 11: results reporting question in picture form

Table 8: Results reporting survey questions

Question	Options
Have you received your free HIV self-test kit?	**Single choice vertical**
	Yes
	No
Have you used the kit to test yourself?	**Single choice vertical**
	Yes
	No
***[if No to used test yourself]* Why not?**	**Single choice drop-down**
	I tested somewhere else instead
	I didn’t know how to use the test
	I changed my mind about self-testing
	The instructions were too difficult
	I gave the test to someone else
	Not yet, but I still plan to use it later
	Other
***[If Other to Why not?]* Please give more details**	**Write-in 3 line**
What was the result?	**Single choice vertical**
	Negative (one line appeared)
	Positive (two lines appeared)
	My test did not work (no lines appeared or there was another problem with the test)
***[if My test did not work]* Please give more details**	**Write-in 3 line**
***[if Positive]* Have you been to a clinic or doctor to have this result confirmed?**	**Single choice vertical**
	Yes
	No
	I already knew my HIV positive status
***[If Yes to Confirmed result]* Which clinic did you attend?**	**Write-in 3 line**
***[If Yes to Confirmed result]* What was the confirmed result?**	**Single choice vertical**
	Positive
	Negative
	I’m waiting for the result
***[If No to Confirmed result]* Present link to NAM HIV clinic finder widgit**	

5.5 Supportive resources

Resources to link individuals who use HIV self-testing to support, including HIV prevention opportunities will be useful for most intervention designs. These can be provided either online in routine communications to end users, or be included in physical form with the self-testing kits.

These supportive resources are most likely to be used by those who do not have supportive networks on which they can rely. Figures 12 and 13 provide examples of supportive information which accompanies HIV self-test kits distributed through an initiative from THT.

Testing yourself for HIV is easy with our support

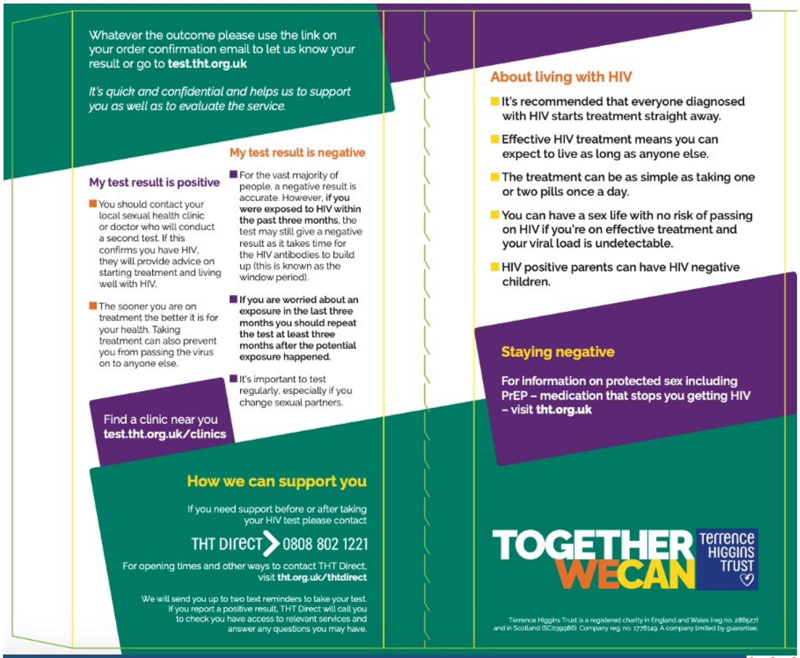
Read your own result within 20 minutes without sending it back to a laboratory.

A donation of £10 could help us continue to support those living with HIV and reach our goal of ending HIV transmission and HIV stigma in the UK.

Support our work by donating today

tht.org.uk/donate

Figure 12: outside sleeve of test from THT emphasising immediacy and convenience of using HIV self-testing



Whatever the outcome please use the link on your order confirmation email to let us know your result or go to **test.tht.org.uk**

It's quick and confidential and helps us to support you as well as to evaluate the service.

My test result is positive

- You should contact your local sexual health clinic or doctor who will conduct a second test. If this confirms you have HIV, they will provide advice on starting treatment and living well with HIV.
- The sooner you are on treatment the better it is for your health. Taking treatment can also prevent you from passing the virus on to anyone else.

My test result is negative

- For the vast majority of people, a negative result is accurate. However, **if you were exposed to HIV within the past three months**, the test may still give a negative result as it takes time for the HIV antibodies to build up (this is known as the window period).
- **If you are worried about an exposure in the last three months you should repeat the test at least three months after the potential exposure happened.**
- It's important to test regularly, especially if you change sexual partners.

Find a clinic near you
test.tht.org.uk/clinics

How we can support you

If you need support before or after taking your HIV test please contact

THT Direct > 0808 802 1221

For opening times and other ways to contact THT Direct, visit **tht.org.uk/thtdirect**

We will send you up to two text reminders to take your test. If you report a positive result, THT Direct will call you to check you have access to relevant services and answer any questions you may have.

About living with HIV

- It's recommended that everyone diagnosed with HIV starts treatment straight away.
- Effective HIV treatment means you can expect to live as long as anyone else.
- The treatment can be as simple as taking one or two pills once a day.
- You can have a sex life with no risk of passing on HIV if you're on effective treatment and your viral load is undetectable.
- HIV positive parents can have HIV negative children.

Staying negative

For information on protected sex including PrEP – medication that stops you getting HIV – visit **tht.org.uk**

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Figure 13: supportive resources, including linkage to care information, provided on inside of sleeve accompanying THT test

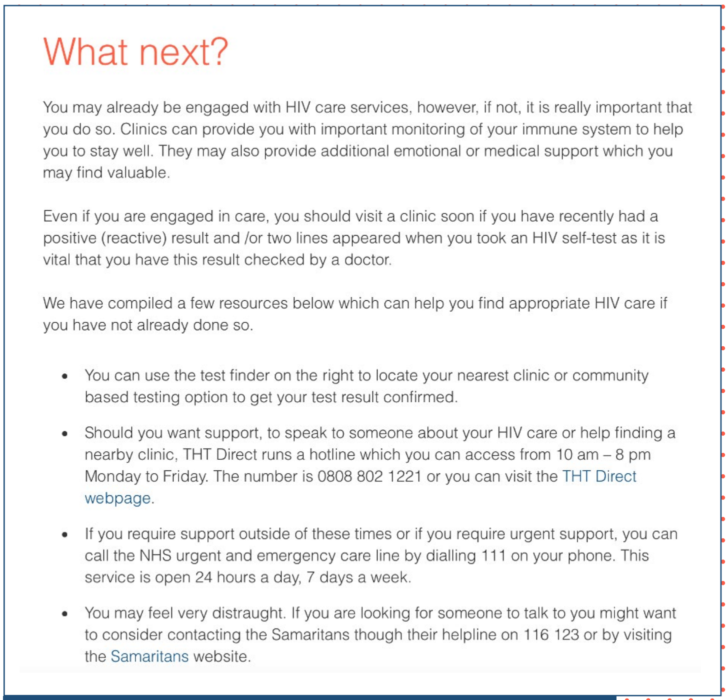
Table 9: Supportive information provided by the SELPHI study

Scenario	**Text Support**	**Routing**
Self-reported Positive Test Result confirmed with clinic or doctor	The answers you have given indicate that you have tested HIV positive. If you require any further advice, please call THT Direct at 0808 802 1221, open 10am – 6PM Monday to Friday We also have information on the [service name] website [include webpage in hyperlink] that will tell you what to do now and how to find support	Reactive Test Page
Self-reported Positive Test Result unconfirmed with doctor/clinic.	The answers you have given indicate that you have tested HIV positive. It's important to have any positive result from a selftest confirmed by a doctor. You can get support to access services by calling THT Direct at 0808 802 1221. We also have information on the [service name] website that will tell you what to do now and how to find support. If you would like us to help you have your result confirmed by a doctor, please click here.	

For those who report a positive result on an online system a version of the supportive information provided by SELPHI (table 9) can be provided.

Below are examples of additional information from the SELPHI trial and from SH:24 to those who reported a positive HIV self-test result (figures 14-16. Future similar support information should also highlight the importance of beginning antiretroviral treatment as soon as possible. This can be adapted depending on the context in which interventions are being delivered. For example, if interventions are geographically specific, service names and contact details can be provided along with relevant local voluntary organisations.

Supportive information can also be provided in physical form with the kit. Below is an example from the SELPHI RCT.



What next?

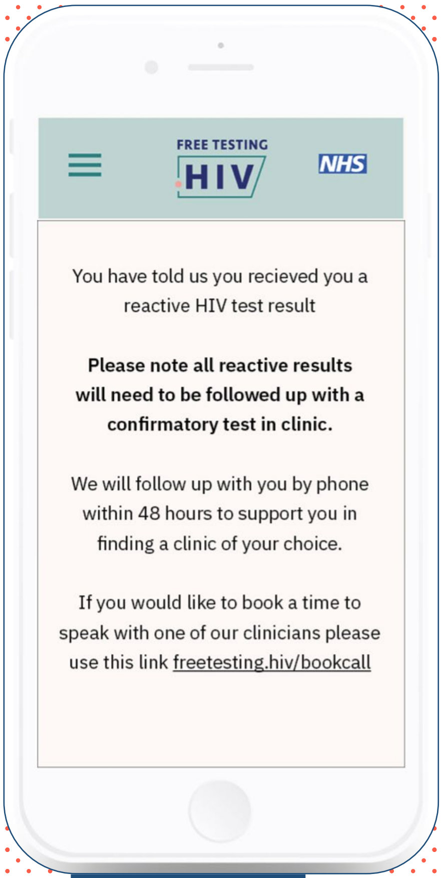
You may already be engaged with HIV care services, however, if not, it is really important that you do so. Clinics can provide you with important monitoring of your immune system to help you to stay well. They may also provide additional emotional or medical support which you may find valuable.

Even if you are engaged in care, you should visit a clinic soon if you have recently had a positive (reactive) result and /or two lines appeared when you took an HIV self-test as it is vital that you have this result checked by a doctor.

We have compiled a few resources below which can help you find appropriate HIV care if you have not already done so.

- You can use the test finder on the right to locate your nearest clinic or community based testing option to get your test result confirmed.
- Should you want support, to speak to someone about your HIV care or help finding a nearby clinic, THT Direct runs a hotline which you can access from 10 am – 8 pm Monday to Friday. The number is 0808 802 1221 or you can visit the THT Direct webpage.
- If you require support outside of these times or if you require urgent support, you can call the NHS urgent and emergency care line by dialling 111 on your phone. This service is open 24 hours a day, 7 days a week.
- You may feel very distraught. If you are looking for someone to talk to you might want to consider contacting the Samaritans though their helpline on 116 123 or by visiting the Samaritans website.

Figure 14: Supportive resource for individuals reporting a reactive self-test result from the SELPHI RCT



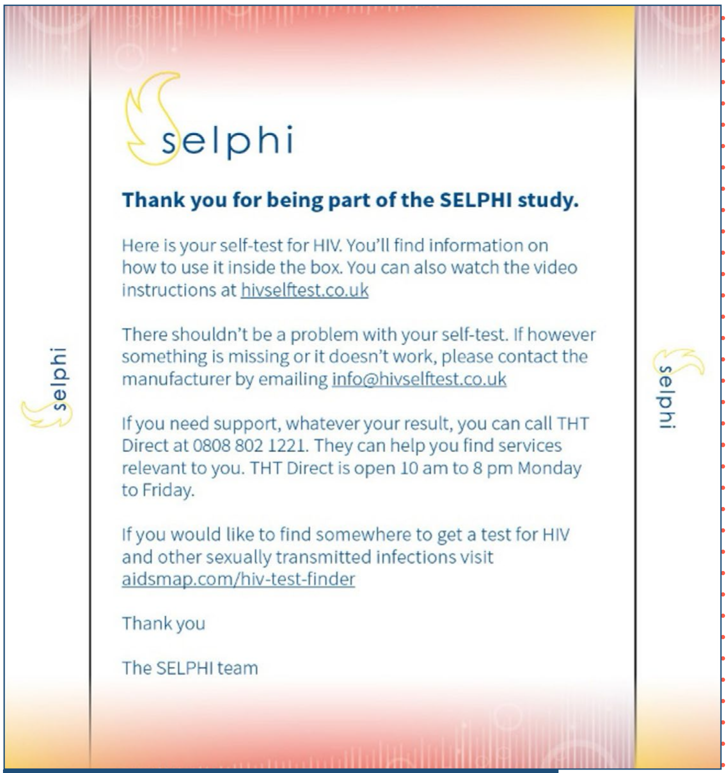
You have told us you recieved you a reactive HIV test result

Please note all reactive results will need to be followed up with a confirmatory test in clinic.

We will follow up with you by phone within 48 hours to support you in finding a clinic of your choice.

If you would like to book a time to speak with one of our clinicians please use this link freetesting.hiv/bookcall

Figure 15: Supportive information from free testing



Thank you for being part of the SELPHI study.

Here is your self-test for HIV. You'll find information on how to use it inside the box. You can also watch the video instructions at hivselftest.co.uk

There shouldn't be a problem with your self-test. If however something is missing or it doesn't work, please contact the manufacturer by emailing info@hivselftest.co.uk

If you need support, whatever your result, you can call THT Direct at 0808 802 1221. They can help you find services relevant to you. THT Direct is open 10 am to 8 pm Monday to Friday.

If you would like to find somewhere to get a test for HIV and other sexually transmitted infections visit aidsmap.com/hiv-test-finder

Thank you

The SELPHI team

Figure 16: Supportive information provided on HIV self-testing kit sleeve through the SELPHI trial

5.6 Evaluation domains

When evaluating their approaches, services can draw on the following examples to develop bespoke evaluations for their HIV self-testing initiatives. Those seeking to implement evaluation of the HIVST service should be cautious when deciding on the amount of data to collect, as onerous evaluation processes will reduce intervention acceptability for many. In addition, different types of evaluation will have different requirements around what data to collect. For example, early formative evaluation should be focused on how the intervention is performing in the context of the service beneficiaries' needs (e.g. ease of use, usability, overall experience) and make amendments to the intervention where necessary. Monitoring will be more concerned with understanding outcomes, including potential HIV self-testing harms.

Both approaches can be supplemented with (qualitative) interviews with service beneficiaries. This will likely only be useful when there the experiences of beneficiaries are less well known. Examples of when this might be useful are when implementing HIV self-testing with new populations, in new areas or using new kits. Below we include some examples of survey questions which can be used in an evaluation, as well as a brief topic guide which can be adapted for use in interviews in early evaluation.

Early, formative evaluation

This type of evaluation is best used early in intervention implementation when seeking to understand what is working well with the intervention, and what isn't working as well. This will enable those delivering HIV self-testing services to adapt the approaches they are currently taking in response to beneficiary feedback. Formative survey evaluation questions (table 10) should be kept brief and focused, to ensure that acceptability is not negatively impacted. This will also lead to improved survey response rates.

Table 10: Formative evaluation questions

Did you use the kit to test yourself?	**Single choice vertical**
	Yes
	No
Why not?	**Single choice drop-down**
	I tested somewhere else instead
	I didn't know how to use the test
	I changed my mind about self-testing
	The instructions were too difficult
	I gave the test to someone else
	Not yet, but I still plan to use it later
	Other
Please give more details	**Write-in 4 line**

Which instructions did you use? Select all that apply	**Multiple choice vertical**
	The instructions that came with the kit
	The online video
	I didn't use any instructions
How much do you agree with the following statements?	
I received the kit without any problems	**Single choice drop-down**
	Strongly Agree
	Agree
	Neither Agree nor Disagree
	Disagree
	Strongly Disagree
The instructions were easy to use	**Single choice drop-down**
	Strongly Agree
	Agree
	Neither Agree nor Disagree
	Disagree
	Strongly Disagree
Performing the test was simple	**Single choice drop-down**
	Strongly Agree
	Agree
	Neither Agree nor Disagree
	Disagree
	Strongly Disagree
I was able to access the support I needed	**Single choice drop-down**
	Strongly Agree
	Agree
	Neither Agree nor Disagree
	Disagree
	Strongly Disagree
My overall experience with the self-test kit was good	**Single choice drop-down**
	Strongly Agree
	Agree
	Neither Agree nor Disagree
	Disagree
	Strongly Disagree

Qualitative questions

Although this situation will be rare, if concerns exist around how HIV self-testing is being received by service beneficiaries, qualitative interviews can be conducted by those implementing the intervention. Service beneficiaries who agree to follow-up can be contacted by email or SMS. When doing so, they should be provided with comprehensive information about the interview process. Individuals taking part in this type of evaluation should always be compensated for their time. £30/hour is a reasonable rate for an interview lasting up to an hour. An example topic guide is provided below (table 11).

Table 11: Qualitative interview questions

1. HIV testing history

- Had you tested for HIV before you accessed [name of HIV self-testing service]?

If no

- Have you considered HIV testing before?
- What has stopped you?
- Have you ever considered testing but not gone?
- Have you ever tested for STIs?

If yes

- Can you tell me about the first time you tested for HIV?
- Can you remember what prompted you to seek testing the first time you went?
- What was the experience like? Where did you go? How did you choose to test that way?
- What kind of support were you provided with? Was this what you wanted?

2. Engagement with HIV self-testing

- When did you first hear about HIV self-testing?
- What were your initial thoughts?
- How did you hear about the [service name]? What make you decide to access it?
- How did you feel about filling in details about yourself when signing up to the service?

3. Using the HIV self-test

- This is the same version of the test we sent you. Can you remember what your first impressions of it were? (Make sure support information and kit itself are covered in conversation)
- Thinking back to when you first took the self-test, what was going through your mind? Tell me everything you can about the first time you used HIVST (*Prompt*: Where were you? did you think there was a possibility of a positive result?).
- Did you decide to take the test by yourself or was there someone with you?
- Did you read the instructions? How many times?
  (*Prompt:* if not answered: What did you make of them? Did you watch any of the videos online? Did the kit look easy to use?)
- How was your overall experience of using the test kit?
  (*Prompt*: Do you think you made any mistakes? Was it difficult to use the lancet?)
- Describe your experience of reading the result.
- How did you feel after using HIVST? Did you trust the result that your test gave you?
- After using the test, did you know where to get support if you felt you needed it?
- Did you seek support from anywhere?
- *[If yes]* How did you choose that source of support? Did it meet the needs you had at the time?
- Did you feel like you had the support you needed? What else might have been helpful in your situation?
- Do you remember receiving a follow-up about two weeks after you took the test? What were your impressions of that?

4. After HIVST

- What are your thoughts on using an oral fluid test rather than blood [or vice versa depending on the test received]?
- Would you use HIVST again?
- [If yes] how often? Would this be the main way you would test for HIV?
- [If no] can you tell me more about why not?
- Are there any changes we could make to the self-testing offer that would make it easier for people to use self-testing?

Intervention monitoring (summative evaluation)

This type of evaluation typically comes at the end of a beneficiaries journey an intervention or at the end of a discreet project. As such, different services will implement this type of evaluation at different time points. Individuals contacted for these purposes should be those who have previously provided consent for this type of follow-up. As in all HIV self-testing services, questions asked should only be those directly relevant to evaluating the service itself, and superfluous questions should not be asked. In addition to the questions below (table 12), results reporting questions can be asked again during this monitoring if this process is separate.

Table 12: intervention monitoring survey questions

Question	**Options**
The following questions refer only to other HIV tests you might have taken not the free HIV self-test kit from [name of this service].	
Have you had any HIV tests in the last 3 months?	**Single choice vertical**
	Yes
	No
How many tests did you have in the last 3 months?	**Single choice drop-down**
	1
	2
	3
	More than 3
Where did you go for your last HIV test?	**Single choice drop-down**
	At a sexual health clinic
	At hospital - as an inpatient or outpatient
	A community HIV testing service
	I used a self-sampling kit (I took my own sample and sent off for the results)
	I used a self-testing kit (I took a sample and found out the result on the spot)
	In a bar/pub, club or sauna
	At a General Practitioner/family doctor
	Somewhere else
Were any of the HIV tests positive?	**Single choice vertical**
	Yes
	No
***[if reports an HIV positive test]* Are you now under the care of an HIV doctor?**	**Single choice vertical**
	Yes
	No
Have you had a test for sexually transmitted infections (STIs) such as syphilis or gonorrhoea in the last 3 months?	**Single choice vertical**
	Yes
	No

Were you diagnosed with an STI in the last three months?	**Single choice vertical**
	Yes
	No
Please select from the list any STIs you have been diagnosed with in the last 3 months **Select all that apply**	**Multiple choice vertical**
	Chlamydia
	Gonorrhea
	Non-specific urethritis (NSU)
	Genital warts
	Herpes
	Syphilis
	Hepatitis B
	Hepatitis C
	Other
	I don't know
Please specify	**Write-in 1 line**
Where did you go for your last STI test?	**Single choice drop-down**
	At a sexual health clinic
	At hospital - as an inpatient or outpatient
	A community HIV testing service
	I used a self-sampling kit (I took my own sample and sent off for the results)
	I used a self-testing kit (I took a sample and found out the result on the spot)
	In a bar/pub, club or sauna
	At a General Practitioner/family doctor
	Somewhere else
Did you feel like you needed support after using your HIV self-test?	**Single choice drop-down**
	Yes
	No
[if yes to needed support] **Were you able to get the support you needed?**	**Single choice drop-down**
	Yes
	No

Harms questions

Harms from HIV self-testing are very rare. Nevertheless it is worth monitoring harms from self-testing services proactively as these are less likely to be identified during routine service provision because of the dislocated nature of the intervention. In table 13 we include questions which can be incorporated into formative or summative evaluation covering the three primary types of HIV self-testing harms: technological, intervention and socially emergent harms. Those implementing services which may be more likely to engage vulnerable people may wish to consider including these in results reporting system.

Table 13: Harms questions

Question	**Responses**
Did your HIV self-test give you a result which was later confirmed to be incorrect through another test?	**Multiple choice vertical**
	Yes
	No
***[if yes to incorrect HIV self-test]* What was the result from your HIV self-test?**	**Multiple choice vertical**
	Positive (I had a positive HIV self-test which was confirmed to be negative)
	Negative (I had a negative HIV self-test which was confirmed to be positive)
Has using HIV self-testing or accessing this service had a negative impact on your wellbeing?	**Multiple choice vertical**
	Yes
	No
***[if yes to negative impact on wellbeing]* Can you tell us more about what happened?**	**Free text box**
Has using HIV self-testing or accessing this service had a negative impact on your relationships?	**Multiple choice vertical**
	Yes
	No
***[if yes to negative impact on relationships]* Can you tell us more about what happened?**	**Free text box**
Has someone pressured or persuaded you to use HIV self-testing when you did not want to?	**Multiple choice vertical**
	Yes
	No
***[if yes to negative pressured/persuaded]* Can you tell us more about what happened?**	**Free text box**

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