ORIGINAL RESEARCH

Preparedness for use of the rapid result HIV self-test by gay men and other men who have sex with men (MSM): a mixed methods exploratory study among MSM and those involved in HIV prevention and care

P Flowers,¹ J Riddell,² C Park,^{1,2} B Ahmed,¹ I Young,² J Frankis,¹ M Davis,³ M Gilbert,⁴ C Estcourt,⁵ L Wallace⁶ and LM McDaid²

¹School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, UK, ²MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, Glasgow, UK, ³School of Social Sciences, Monash University, Melbourne, Vic., Australia, ⁴Applied Epidemiology Unit, Ontario HIV Treatment Network, Toronto, ON, Canada, ⁵Barts and the London School of Medicine and Dentistry, Barts Sexual Health Centre, Blizard Institute, London, UK and ⁶Health Protection Scotland, Glasgow, UK

Objectives

The aim of the study was to explore preparedness for the HIV self-test among men who have sex with men (MSM) and those involved in HIV prevention and care.

Methods

A mixed methods exploratory research design was employed, detailing awareness and willingness to use the self-test and the perceived barriers and facilitators to implementation. Quantitative and qualitative data collection and analysis were completed in parallel. Descriptive and inferential analysis of cross-sectional bar-based survey data collected from MSM through a self-completed questionnaire and oral fluid specimen collection (n = 999) was combined with qualitative, thematic, analysis of data collected through 12 expert focus groups (n = 55) consisting of gay men, National Health Service (NHS) staff, community organizations, entrepreneurs and activists. Findings were subsequently combined and assessed for synergies.

Results

Among MSM, self-test awareness was moderate (55%). Greater awareness was associated with increased educational attainment [adjusted odds ratio 1.51; 95% confidence interval (CI) 1.00–2.30; P = 0.05] and previous history of sexually transmitted infection (STI) testing (adjusted odds ratio 1.63; 95% CI 1.11–2.39; P = 0.01). Willingness to use the test was high (89%) and associated with meeting sexual partners online (unadjusted odds ratio 1.96; 95% CI 1.31–2.94; P < 0.001). Experts highlighted the overall acceptability of self-testing; it was understood as convenient, discreet, accessible, and with a low burden to services. However, some ambivalence towards self-testing was reported; it could reduce opportunities to engage with wider services, wider health issues and the determinants of risk.

Conclusions

Self-testing represents an opportunity to reduce barriers to HIV testing and enhance prevention and access to care. Levels of awareness are moderate but willingness to use is high. Self-testing may amplify health inequalities.

Keywords: HIV prevention, HIV testing, men who have sex with men, sexual health, sexual risk behaviour

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Correspondence: Professor Paul Flowers, School of Health and Life Sciences, Glasgow Caledonian University, Cowcaddens Road, Glasgow G4 OBA, UK. Tel: +44 (0)141 331 8617; fax: 00441413313000; e-mail: P.Flowers@gcu.ac.uk

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Introduction

Gay and other men who have sex with men (MSM) are the group at highest risk of acquiring HIV infection

within the UK. In 2013, they represented 54% of all new diagnoses. HIV testing rates amongst MSM overall have increased [1,2] and increasing the frequency of testing to 3-monthly for men at higher risk of HIV infection is recommended in UK national guidelines [3,4]. Scottish data for 2005-2009 showed a relatively stable incidence rate among MSM of around 15.3/1000 person-years [5]. UK data show there were 3250 new HIV diagnoses in MSM in 2013 (1) and an estimated one in five HIV positive MSM remain undiagnosed [6] with approximately 1000 late diagnoses each year [1]. Delayed diagnosis is associated with poorer health outcomes and treatment response, increased mortality and health care costs, and increased levels of onward transmission [7,8]. Given that men living with HIV who are taking effective antiretroviral therapy are highly unlikely to transmit HIV [9], it is clear that undiagnosed infection, particularly primary infection (when individuals are most infectious), is responsible for most new infections [10]. Mathematical modelling suggests that increased testing, linkage to care and early treatment could significantly reduce the HIV incidence in MSM [11]. Furthermore, currently within the UK we know that most undiagnosed infections have occurred recently [1], and the proportion of new diagnoses associated with recent transmission has increased in some parts of the UK between 2011 to 2013 from 23% to 30% [6]. In this way, getting men at high risk to test, to test regularly, and, if they test positive, to remain in care with controlled HIV is central to HIV prevention. Yet, recommendations regarding the frequency of testing are not being followed [12] and significant barriers to HIV testing endure [2]. However, rapid result HIV self-tests (or "home tests") may offer new ways of reducing barriers to testing.

In the UK, rapid result HIV self-test kits became legally available in April 2014, and subsequently (April 2015) commercial products became available. While self-testing has been available in the USA for some time, it is not yet available in other national settings such as Canada, Australia or New Zealand. The international literature from countries where self-testing has been available shows that the key facilitators to implementing, and scaling up, programmes of HIV self-testing interventions are that they are convenient [13,14]; are quick and easy to use (15,16); offer privacy and discretion [15,17]; are accurate and trustworthy [18]; have the ability to increase knowledge of one's HIV status in resource-limited settings [17]; potentially encourage communication about HIV among potential partners [19]; are acceptable to high-risk groups [20,21]; potentially encourage more frequent testing among men with high-risk behaviours [19]; and offer immediate results [15,22]. The studies also show that key barriers to effective implementation are the lost

opportunities to test for other sexually transmitted infections (STIs) [15,23]; cost issues [18,20,24]; and perceptions of the lack of professional support available [15,18,24].

Here, we present findings from the first UK study of self-testing and explore three key research questions vital for future policy and practice development in the UK with potential transferability to other international settings where HIV self-tests may be implemented.

(1) Which factors are associated with levels of awareness of the HIV self-test among MSM?

(2) Which factors are associated with willingness to use the HIV self-test among MSM?

(3) What are the key barriers and facilitators to the effective use of the rapid result HIV self-test among the MSM population?

Methods

Twin studies were combined and respective findings integrated to provide synergistic interpretations regarding preparedness for self-testing across both MSM and those involved in providing HIV prevention and care services.

Quantitative study

The University of Glasgow's triennial Gay Men's Sexual Health Survey was implemented in Glasgow, Edinburgh and Dundee in 17 venues (including two saunas) within the commercial gay scene in May 2014. Ethical approval was granted by the College of Social Sciences Ethics Subcommittee at the University of Glasgow (ref: 400130179). Data collection was similar to that in previous surveys [25,26]. Men completed an anonymous, self-completed questionnaire and provided an oral fluid specimen (using OraSure[®] Oral Specimen Collection Devices; OraSure Technologies, Inc, Bethlehem, PA, USA). Oral fluid specimens were analysed at the West of Scotland Specialist Virology Centre. These were tested for anti-HIV using the Vironostika HIV Uni-Form II Ag/Ab enzyme immunoassay (Organon Teknika, Boxtel, Netherlands). Positive samples were re-tested and, if repeatedly reactive, were confirmed using western blot. Overall, 1340 men completed the questionnaire [45% response rate (RR)], with 1151 also providing oral fluid samples (38.6% RR). Men were excluded from the analysis if they: tested positive for HIV via the oral fluid sample (n = 61); did not provide a specimen (n = 189); had missing data on all self-testing questions (n = 58); or did not selfidentify as being gay or bisexual (n = 33). This resulted in an overall sample size of n = 999.

The key measures included were as follows

Demographic and behavioural characteristics: Variables included were age, educational level and frequency of visits to the "gay scene" (i.e., bars, clubs and saunas).

Sexual behaviour: Respondents were asked "With how many men have you had anal sex WITHOUT a condom in the last 12 months?" and those who reported at least one unprotected anal intercourse (UAI) partner were asked: "How often was this with a casual partner?"; "How often did you know these partners' HIV status?" and "Were any of your partners HIV positive?" A single measure of higher risk sexual behaviour was derived from the above to include men who reported UAI with at least two casual, and/or unknown/discordant partners in the previous 12 months (compared with men reporting fewer than two regular, or known/concordant partners only).

Self-testing awareness: Men were introduced to questions regarding the self-test with the following text: "HIV selftesting kits were licensed in the UK in April. This will enable men to do a test themselves and get the result immediately. This is different from self-sampling, when you do the test at home but send the sample to a laboratory for testing." They were then asked about awareness of self-testing kits by answering the question "Have you heard of self-testing kits?" with the options of yes, no or don't know. This was then recoded to "yes" (original "yes" response) and "no"/"don't know" (combined "no"/"don't know" responses).

Willingness to use self-testing: Men were also asked about the likelihood of using self-testing kits in various settings: if it was freely available on the NHS; in a community clinic or supervised location; on their own; with a partner; and if they had to pay for it. Finally, men were asked to indicate if they would be willing to use self-testing kits under the following conditions: after a condom burst or after an episode of unprotected sex; instead of going to a clinic; before having sex with a new partner; and instead of a self-sampling kit.

Statistical analysis

Data were entered and analysed using spss version 21 (Armonk, NY: IBM Corp.). Chi squared tests were used for bivariate comparisons and binary and multivariate logistic regression models were used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) to explore factors associated with awareness of and willingness to use self-testing kits. The final model contained all variables significant at the bivariate level (P < 0.05) in order to assess which remained statistically significant.

Qualitative study

Twelve focus groups (FGs) were conducted with 55 multiprofessional, patient and provider "expert" participants between October 2014 and February 2015 in a range of settings (e.g. NHS offices, voluntary organizations and university settings). Group members were all involved in using, offering, or implementing self-testing, or providing associated pathways into HIV care, and/or prevention. Recruitment used (1) the project funders, who assisted with local NHS recruitment within each respective health board, and (2) the research teams' existing connections with a range of organizations. Sampling balanced recruitment across urban and rural NHS board areas, and included heterogeneous groups of gav men (three FGs), a range of NHS staff (six FGs), and a range of staff from community organizations, activists and people working for businesses with vested interests in MSM (i.e. sex shop and sex sauna staff) (three FGs). An interview topic guide facilitated discussion regarding the barriers and facilitators to the implementation of self-testing within the MSM population. Focus groups were conducted by a number of team members, primarily by CP but assisted by PF, JF, IY. Thus, facilitators were all white and included mixtures of straight, lesbian and gay researchers.

Data were transcribed and analysed thematically using NVIVO 10 qualitative data analysis software (QSR International Pty Ltd. Version 10, 2012) by three of the research team (PF, BA and CP). The analytic focus was primarily descriptive, identifying areas of commonality in experts' beliefs. Ethical approval was given by Glasgow Caledonian University and NHS R and D approval for NHS Project ID: 164239; R&D2014AA089.

Integration of findings

Following parallel and independent quantitative and qualitative data analysis, the key findings from each study were positioned within a single matrix, with a focus upon integration and synthesis. Given the differences in underlying epistemologies of each research approach (quantitative and qualitative), valuable knowledge was generated both within each study and across respective studies. As such, the matrix was interpreted by the first and last authors in relation to the complementarity and unique contribution of respective findings as patterned across various inter-related and overlapping descriptions of context. A consensus was reached via iterative analysis and discussion. For ease of reading, the results of data integration are presented within the Discussion section of this paper.

Results

Quantitative study

Sample characteristics

The average age of participants was 34 years (range 18– 82 years; standard deviation (SD) 10.96 years) with the majority identifying as gay (92.5%). Most reported post-secondary school education (86.7%), with 34.9% reporting further/vocational-level education, and 51.8% reporting degree/postgraduate-level education. Almost all reported sexual contact with a man in the previous 12 months (94.0%) and 53.7% reported higher risk sexual behaviours (UAI with at least two, casual, and/or unknown/discordant partners in the previous 12 months). Only 15.4% had never had an HIV test, while 39.8% had tested in the previous 6 months and 10.1% reported having a sexually transmitted infection (STI) in the previous 12 months (Table S1, available as an online resource).

Factors associated with awareness of HIV self-testing kits Binary logistic regression compared men who had heard of self-testing kits (n = 599; 60.0%) and those who had not or did not know if they had (n = 400; 40.0%) (Table 1). The odds of having heard of HIV self-testing kits were significantly higher for men who identified as gay, were from Glasgow as opposed to elsewhere, reported post-secondary school education, did not report higher risk sexual behaviours, had tested for HIV in the previous 6 months, and had ever had an STI test. When these factors were included in a multivariate logistic regression model, only having post-secondary school education and ever having had an STI test remained significant.

Factors associated with willingness to use HIV self-testing kits

The majority of men (n = 887; 88.8%) reported that they would be willing to use HIV self-testing kits in at least one circumstance. Of these men, 77.3% (n = 686) reported that they would use a kit after a condom burst or after an episode of unprotected sex, 74.9% (n = 664) would use a kit instead of going to a clinic, 65.2% (n = 578) would use a kit before having sex with a new partner, and 59.9% (n = 531) would use one instead of a self-sampling kit (Fig. 1).

Men were also asked about the likelihood of using selftesting kits in various settings. Of those who were willing to self-test in least once circumstance (n = 887), 79.9% (n = 709) reported that they were very likely/likely to use self-testing kits if they were freely available on the NHS, 68.0% (n = 603) were very likely/likely to use the kit on their own, 65.3% (n = 579) were very likely/likely to use the kit in a community clinic or supervised location, 57.5% (n = 510) were very likely/likely to use the kit with a partner, and 45.2% (n = 401) were very likely/ likely to use the kit if they had to pay for it (Fig. 2).

The characteristics of men who reported that they would be willing to use self-testing kits are shown in Table 2. Men who reported that they ever went online/ used an app to meet sexual partners were significantly more likely to report that they were willing to use selftesting kits. There were no other significant demographic, testing, or sexual risk behaviour differences between men who were and were not willing to use self-testing kits.

Exploratory qualitative study

Table 3 illustrates the major themes that the participants raised concerning the key facilitators and barriers to the uptake and use of the self-test.

Facilitators to uptake and use of rapid result HIV self-test The convenience, immediacy, discretion and privacy of testing within one's own home were important factors in facilitating the likely implementation of the self-test and understanding how the self-test could reduce barriers to testing. Autonomy regarding decisions on when to test and dramatically reduced waiting times for results figured strongly within the discussions as other key facilitators. Self-testing was welcomed in terms of cost-efficiency and the rationalization of limited NHS resources; for example, "how expensive is it to post a kit as opposed to half an hour of a consultant's time?" (NHS staff FG). Self-testing was also described as potentially reaching new populations by reducing perceived barriers to testing, such as the stigma associated with use of traditional genitourinary medicine (GUM) services:

- P7 ...there are people who don't engage with sexual health services, so anything that maybe makes them test would surely be worthwhile, for these people who will never engage with us.
- P2 Yes, it's still got a terrible stigma, it's still the clap clinic, people come in they were like, "Oh it's awful in the waiting room" and "I hate being here", "I never thought I would have to come to a place like this", and people always say stuff like that.(NHS staff FG)

Discussions also detailed how the self-test facilitated testing and would reduce barriers to testing by accommodating the hectic reality of many people's lives. It could

	Have you heard of HIV self-testing kits?									
	Yes (<i>n</i> = 599)		No/don't know (n = 400)		Unadjusted odds ratio			Adjusted odds ratio		
	n	0/0	n	%	OR	95% Cl	<i>P</i> -value	OR	95% Cl	<i>P</i> -value
Sexual orientation										
Gay	562	60.8	362	39.2	1		1			
Bisexual	37	49.3	38	50.7	0.63	0.39-1.01	0.05	0.78	0.46-1.34	0.37
Age										
<25 years	144	55.6	115	44.4	1					
26-35 years	221	62.6	132	37.4	1.34	0.96-1.85	0.08			
36–45 years	135	63.4	78	36.6	1.38	0.95-2.00	0.09			
\geq 46 years	94	55.6	75	44.4	1.00	0.68-1.48	1.00			
Area of residence										
Glasgow	236	64.1	132	35.9	1			1		
Edinburgh	178	58.6	126	41.4	0.79	0.58-1.08	0.14	0.82	0.58-1.17	0.28
Elsewhere	165	56.5	127	43.5	0.73	0.53-1.00	0.05	0.71	0.50-1.01	0.06
Post secondary school educ		00.0	127	10.0	0.75	0.00 1.00	0.00	0.71	0.00 1.01	0.00
No	58	51.3	55	48.7	1			1		
Yes	457	62.2	278	37.8	1.56	1.05-2.32	0.03	1.51	1.00-2.30	0.05
Employment status	+57	02.2	270	57.0	1.50	1.05 2.52	0.05	1.51	1.00 2.30	0.05
Not employed	95	56.9	72	43.1	1					
Employed	502	60.8	324	39.2	1.17	0.84-1.64	0.35			
1 /	302	00.8	324	33.Z	1.17	0.04-1.04	0.35			
Commercial gay scene use	202	CO 1	240	20.0	1					
Low use	362	60.1	240	39.9	1	0.75 1.00	0.04			
High use	232	59.5	158	40.5	0.97	0.75–1.26	0.84			
Do you ever go online/use										
No	274	57.7	201	42.3	1					
Yes	324	62.4	195	37.6	1.22	0.95–1.57	0.13			
Higher risk sexual behaviou										
No	298	64.4	165	35.6	1			1		
Yes	301	56.2	235	43.8	0.71	0.55-0.92	0.01	0.81	0.60-1.08	0.15
Number of HIV tests in pre	,									
< 4	417	60.5	272	39.5	1					
\geq 4	132	66.7	66	33.3	1.30	0.94-1.82	0.12			
More recent HIV test										
Not in last 6 months	337	56.4	260	43.6	1			1		
In last 6 months	257	65.1	138	34.9	1.44	1.10-1.87	0.01	1.22	0.89-1.67	0.21
STI in previous 12 months										
No	529	59.5	360	40.5	1					
Yes	66	66.0	34	34.0	1.32	0.86-2.04	0.21			
Ever had STI test										
No	86	49.1	89	50.9	1			1		
Yes	507	63.1	296	36.9	1.77	1.28-2.46	< 0.001	1.63	1.11-2.39	0.01

Table 1 Demographics of those who had heard of self-testing kits versus those who had not/did not know if they had, with unadjusted and multivariate logistic regression (n = 999)

Cl, confidence interval; OR, odds ratio; STI, sexually transmitted infection.

*Unprotected anal intercourse with at least two, casual, and/or unknown/discordant partners in the previous 12 months.

be easily used by men who had busy lives, who lived rurally, and who would struggle to use traditional clinics for a range of reasons: "I think it's good, because some people, for example, they're married and they have children, for example, some men. But they still engage, like, in gay sex. Obviously, they're not going to their doctor to get a test, a blood test" (Gay men's FG). In this way, the self-test could enable high-risk men to test more frequently and could enable more vulnerable men to engage in testing for the first time. For example, "So what better way of actually taking away any stigma about it than to have something as regular where you might actually go to pick up paracetamol?" (Non-NHS stakeholder FG).

Barriers to uptake and use of rapid result HIV self-test

Key barriers to the uptake and use of self-testing focussed upon lost opportunities to engage with a wide range of services, staff and holistic understandings of health and the actual determinants, as opposed to the consequences, of risk behaviour, as the following extract shows: "very rarely is it just about... When someone goes to, even a sexual health clinical, very rarely is it just about sexual

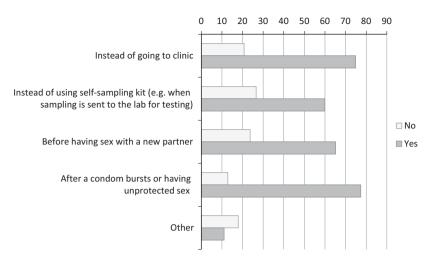
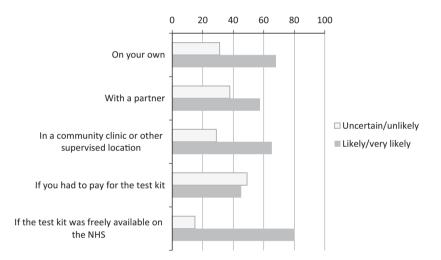


Fig. 1 Percentages of those who would self-test by circumstance in which they would self-test (n = 887).



P1

Fig. 2 Percentages of those who would self-test by likelihood of setting in which they would self-test (n = 887).

health. There are other support needs" (Non-NHS stakeholder FG). Primarily among NHS staff, there was some resistance to the idea that the decoupling of testing from traditional services was beneficial or warranted. Participants outlined the lost opportunities that self-testing technologies herald; there is no guaranteed continuity of care, no easy access to the full range of clinical expertise (e.g. in mental health, wellbeing, relationship concerns, drugs, and alcohol), no partner notification, and no opportunity for additional risk reduction and intervention. Similarly, major concerns were articulated about the test users discovering their reactive results when alone.

- F1 Uh-huh. What are your concerns, P2?
- P2 Just the one o'clock in the morning stuff.

- I know, and go and jump off a bridge or something.
- P2 Yeah, and I suppose that is...
- P1 That is the worry.
- P2 ...I suppose that is the difference between home testing and home sampling, is, okay, you've got the advantage that you've got it within 20 minutes, half an hour, whatever it might be, which is great. The disadvantage is just that lack of connection with other people, and that support.(NHS staff rural areas)

The discussions also outlined barriers to the effective use of self-testing in relation to health inequalities and

	Wou kits	ld use s	elf-tes	sting				
	Yes		No		Unadjusted Odds Ratio			
	n	(%)	n	%	OR	95% Cl	<i>P</i> -Value	
Sexual Orientation								
Gay	819	88.6	105	11.4	1			
Bisexual	68	90.7	7	9.3	1.25	0.56-2.78	0.59	
Age								
< 25	236	91.1	23	8.9	1			
26–35	311	88.1	42	11.9	0.72	0.42-1.23	0.23	
36-45	187	87.8	26	12.2	0.70	0.39-1.27	0.24	
46+	150	88.8	19	11.2	0.77	0.41-1.46	0.42	
Area of residence								
Glasgow	326	88.6	42	11.4	1			
Edinburgh	269	88.5	35	11.5	0.99	0.61-1.60	0.97	
Elsewhere	263	90.1	29	9.9	1.17	0.71-1.93	0.54	
Post secondary scho	ol educ	ation						
No	99	87.6	14	12.4	1			
Yes	652	88.7	83	11.3	1.11	0.61-2.03	0.73	
Employment status								
Not employed	152	91.0	15	9.0	1			
Employed	730	88.4	96	11.6	0.75	0.42-1.33	0.32	
Commercial gay scer	ne use							
Low Use	533	88.5	69	11.5	1			
High Use	347	89.0	43	11.0	1.04	0.70-1.56	0.83	
Ever go online/use a	n app				ers			
No	405	85.3	70	14.7	1			
Yes	477	91.9	42	8.1	1.96	1.31-2.94	< 0.001	
Higher risk sexual be						1101 2101	0.001	
No	405	87.5	58	12.5	1			
Yes	482	89.9	54	10.1	1.28	0.86-1.89	0.22	
Number of HIV tests				10.1	1.20	0.00 1.00	0.22	
<4	610	88.5	79	11.5	1			
4+	174	87.9	24	12.1	0.94	0.58-1.53	0.80	
More recent HIV tes		07.5	24	12.1	0.54	0.50 1.55	0.00	
Not in last 6	536	89.8	61	10.2	1			
months	550	05.0	01	10.2				
In last 6 months	345	87.3	50	12.7	0.79	0.53-1.17	0.23	
STI in previous 12 m		07.5	50	12.7	0.75	0.00-1.17	0.23	
No	786	88.4	103	11.6	1			
Yes	93	00.4 93.0	103	7.0	1.74	0.79–3.86	0.17	
Ever had STI test	53	53.0	/	7.0	1.74	0.75-3.00	0.17	
No	160	01 /	15	8.6	1			
	160	91.4				0.41 1.00	0.07	
Yes	711	88.5	92	11.5	0.72	0.41-1.28	0.27	

Table 2 Demographics and unadjusted odds ratios of those who would use self-testing kits versus those who would not (n = 999)

Cl, confidence interval; OR, odds ratio; STI, sexually transmitted infection.

*Unprotected anal intercourse with at least two, casual, and/ or unknown/discordant partners in the previous 12 months.

health literacy. Key concerns focussed upon the skills, abilities and knowledge levels among those who were testing and their accurate interpretation of test results:

P1 The test is going back to the timing from infection date to it being shown, showing up in your blood. So, I think the errors that can be involved in self-testing are with yourself, you know, wait until you, what do you call it, your viral load becomes testable. There's no like pregnancy wait for two weeks [....]. Table 3 Overview of perceived barriers and facilitators to self-testing among men who have sex with men (MSM)

Facilitators to the uptake and use of the self-test	Barriers to the uptake and use of the instant result HIV self-test
Consensus regarding Convenience	Provider perceptions of the lost
/Speed of testing and	opportunities for engagement
accessing test results	with range of services and staff
Consensus regarding perceptions of high discretion and privacy	Consensus regarding concerns relating to deracinating HIV from wider and holistic health
Provider perceptions of the need to rationalise clinical time and resources	Consensus regarding perceived negative consequences of receiving reactive test results (suicide, distress, isolation)
Consensus regarding the test's	MSM perceptions of poor trust
ability to reach new and	and low perceived accuracy
potentially vulnerable populations	of the kit
MSM perceptions that self-testing	Consensus regarding high levels
avoided the stigma of utilising	of health literacy and skills
GUM services	required to use the kit correctly

GUM, genitourinary medicine.

P4 I think this probably then also depends on how educated you are about it in the first place, rather than, okay, you know everything about it, so we'll take a test and that's your result. It depends on how educated you are about when your potential exposure was(Gay men rural area)

Discussion

This work has explored preparedness for self-testing and describes the overall acceptability of the self-test in the UK for the first time. The triangulation and integration of key constructs from the two constitutive studies reported here are shown in Table 4. This suggests the overall acceptability of the self-test and highlights its potential to increase HIV testing among some, but not all, MSM. It also suggests that the optimization and subsequent effective implementation of self-testing will change HIV prevention policy and practice. In turn, this will have an impact upon how HIV care and surveillance should also be considered.

At the individual level, health and HIV literacy were important, with awareness of self-testing associated with level of educational attainment. Concerns were also expressed about the accuracy of interpreting test results in relation to the window period and to specific risk events. Preferences to use the self-test rather than visiting a clinic or using self-sampling, combined with perceptions of convenience and ease of use and potential reductions in stigma, suggest that it is highly likely that the

Key contexts	Quantitative study	Qualitative study	Interpretation and synthesis		
Technological level – the acceptability of the self-test	Although awareness was low, willingness to use self-tests was high	Self-tests were considered to reduce barriers to testing and have the ability to reach new and potentially vulnerable populations	Self-tests are a tool with the potential to increase testing		
Individual level	Awareness of self-testing was associated with post-secondary school education and ever having had an STI test. The self-test offers new opportunities for self-management of HIV risks, with 77.3% reporting that they would use a kit after a condom burst or after an episode of unprotected sex and 65.2% reporting that they would use a kit before having sex with a new partner	Using the kit correctly was regarded to require high levels of health literacy and skills, and perceptions of poor trust and low perceived accuracy of the kit were expressed by MSM. While self-tests were perceived to offer high discretion and privacy, there are potentially negative consequences of receiving reactive test results alone (suicide, distress and isolation)	Health and HIV literacy is important in terms of using and understanding the results of the kit. There is also potential vulnerability of men receiving reactive results on their own and risk of men being misinformed by taking the self-test at the wrong time (i.e. immediately after a risk event)		
Service/community evel	Self-tests offer an alternative to clinic testing, with 74.9% reporting that they would use a kit instead of going to a clinic. While 68.0% were likely to use the kit on their own, 57.5% reported that they were likely to use the kit with a partner and 65.3% were likely to use the kit in a community clinic or supervised location	There was consensus among stakeholders regarding the convenience and speed of testing and accessing results and, for MSM, avoiding the perceived stigma of using GUM services. However, providers highlighted lost opportunities for engagement with a range of services and staff	The self-test could lead to a lack of engagement with traditional NHS services, but could be provided in alternative community settings to relieve pressure on the NHS. Testing between partners could facilitate discussions on HIV status, but this could leave men at risk of violence and abuse		
Social level	Most men (79.9%) reported that they were likely to use self-tests if they were freely available on the NHS, while only 45.2% were willing to pay for the tests. Willingness to use the self-test was only associated with the use of the internet and phone apps to meet sexual partners	Additional social and geographical factors, such as relative isolation, may also influence who might be more likely to use the test and digital media. Although self-tests could relieve pressures on clinical time and resources, deracinating HIV from wider and holistic health is contrary to the existing policy landscape	The social and economic context in which self-tests are provided, and existing inequalities among MSM, are likely to shape uptake, but a move towards self-testing could have unintended consequences for broader sexual health and wellbeing by amplifying health inequalities		

Table 4 Integration of the main findings across the constitutive studies

self-test will reduce some barriers to testing. However, use of the self-test may therefore lead to a lack of engagement with traditional NHS services. While this may rationalize limited NHS resources, it was also concerning from both the patient and provider perspectives, particularly in relation to follow-up of reactive results and the accuracy of epidemiological surveillance, but also in relation to lost opportunities for prevention such as interventions that address the determinants of on-going risk behaviour, or partner notification.

The synthesis also indicates the likely importance of social and economic factors in shaping the kinds of men who may use the self-test. It illuminates the complexity of these issues; the quantitative findings representing bar-based urban populations of MSM suggest the potential importance of digital and social media use in the likelihood of using the self-test, with concomitant

repercussions extending to service redesign for accessing future regular testing, the provision of prevention interventions, accessing confirmatory testing, and on-going care for those who test positive. These findings could reflect the role of digital literacy, or a propensity to engage with innovation or online consumerism; yet, tellingly, patterns in likelihood of use also relate to whether the test would be provided free by the NHS. The qualitative findings, which reflect perspectives from both urban and rural areas, highlighted how additional social and geographical factors, such as relative isolation, may also influence who might be more likely to use both the test and indeed the digital media. Although self-tests could relieve pressures on clinical time and resources, deracinating HIV from wider and holistic health is contrary to the existing policy landscape and could have unintended consequences for broader sexual health and wellbeing.

Strengths and weaknesses

The strengths of this study were its originality and its effective use of exploratory mixed methods. These maximized the strengths of the qualitative analysis which both captured the complexity of the issue and inductively identified areas of concern (e.g. the amplification of health inequities). The study also consolidated the benefits of quantitative research approaches, illuminating population means and other nomothetic insights (e.g. apparent preferences for self-testing over self-sampling). Its weaknesses relate to its exploratory cross-sectional design and its geographical reach (Scotland only), its sole focus upon the MSM population rather than other populations such as black Africans in the UK, its use of a sample of MSM who mostly identified as gay and were highly educated, and the temporal collection of data prior to self-testing products becoming commercially available. Recent surveys of MSM recruited via other approaches also suggest that our sampling strategies may well oversample those already engaged with testing behaviours per se; for example, only 52% of MSM in the general population report having an HIV test within the past 5 years and comparison of population-based probability surveys and venue-based convenience surveys has shown increased recent testing in the latter [27,28]. Selftesting may well be more relevant for MSM populations not currently using traditional testing services or enrolling in venue-based convenience samples and our work here may underestimate the potential value of self-testing. The findings have international relevance for countries with similar epidemics among MSM where the selftest has yet to be made available (e.g. Canada) or where it is currently becoming available (e.g. New Zealand and Australia).

Importance and implications

Self-testing represents a relatively new development within the HIV prevention and care tool kit. Our integrated exploratory findings anticipate that it has great potential to shape HIV prevention and care. Yet, our findings also suggest that its potential will not be realized if it is not considered in relation to the heterogeneity of MSM and the diversity of their needs and preferences. Self-testing has the capacity to be a transformative technology, potentially, a core part of an integrated online HIV prevention and care system for men who choose this approach and have the requisite digital and health literacy [this could combine access to pre-exposure prophylaxis (PrEP) and other behavioural prevention initiatives]. However, our integrated analysis also suggests the particular vulnerability of some MSM populations and the potential for further isolation if shifts to digital technologies and self-managed diagnostic testing reduce provision for other testing opportunities.

Further research

Further research must examine self-testing at the individual, organisational and social levels. For example, at the individual level, who will use it? Why do they choose it, rather than, for example, self-sampling, and indeed which type of self-test do they prefer (blood or oral)? How will they use it? When, in which circumstances, and with what consequences (e.g. delayed confirmation, "loss to follow-up" or suicide) will they use it? At the organizational level, questions of the effectiveness and cost-effectiveness of self-testing become important; how can it be optimized to reduce barriers to testing? Can it reduce undiagnosed infection and late diagnosis? What, if any, are the health economic benefits of self-testing and how can they be enhanced (e.g. by targeted self-testing)? How should the NHS and other services be redesigned to accommodate the way in which self-testing is decoupled from existing services? To what extent can online prevention and care services complement the self-management of these diagnostic technologies, and would such online services improve patient experience and contribute to health improvements? With regard to the social consequences of selftesting, research is needed that examines how self-testing may amplify health inequities, enabling MSM with good health and digital literacy skills to improve their health while investment in more traditional services and their service users (e.g. with poorer health and digital literacy) reduces.

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Author contributions

PF and LM devised the study, and PF and JR wrote the first draft of the manuscript. PF led the qualitative analysis with assistance from CP and BA; JR undertook quantitative data analysis and contributed to drafts of the manuscript. PF and LM integrated the data analysis. All authors contributed to interpretation of the data, contributed revisions, and approved the final version of the manuscript.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1. Sample characteristics of men (n = 999).