

BASHH Guidance for the design of self-sampling packs and associated support for self-sampling processes within Sexually Transmitted Infection and Blood Borne Virus testing

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Background

Over recent years, sexual health services have offered an increasing proportion of care remotely through a variety of mixed online and in person clinical care pathways. This has accelerated during the Covid-19 pandemic in an attempt to provide access to testing whilst reducing face-to-face care. BASHH has placed digital services at the core of its guidance for recovery planning. As services are restored, growing emphasis on online care pathways raises serious concerns about the widening of health inequalities. The groups most at risk of poor sexual health are less likely to engage with online / self-managed care (*Manavi et al, 2017*).

Much innovation has focussed on postal self-sampling for sexually transmitted infections (STIs) and blood borne viruses (BBVs). This relies on the use of self-sampling packs. Packs and their components have mostly been developed by laboratory staff and others whom they may have chosen to consult. In-depth assessment of user engagement or application of theories of behaviour or reference to an evidence base have not been possible. This has implications for their effectiveness. Emerging evidence suggests that the uptake of self-sampling packs, and the return of samples to enable diagnosis, are influenced by various social factors (*Banerjee et al, 2018*) and need to be optimised based on these factors and with user engagement.

Within the LUSTRUM programme, the NIHR has funded extensive research into prevention of transmission of STIs and HIV (*lustrum.org.uk*) including the role and design of self-sampling and treatment packs. Qualitative studies aimed to optimise the design, contents and support needed for self-sampling packs for sex partners of people with chlamydia, as part of a trial of Accelerated Partner Therapy (APT) (*Estcourt et al, 2020*). Views of people of particular concern and vulnerability were sought. This included people with previous STIs, others who had not had experience of sexual health services, and people with mild learning disabilities (*Middleton et al, 2020*). Findings suggested that self-sampling packs offer a widely acceptable means to enabling STI and BBV testing and diagnosis as they remove many barriers to testing in sexual health services. However, there remain important but potentially modifiable barriers to use, which might amplify health inequalities.

The LUSTRUM team proposed to develop evidence-based recommendations for the optimal design of STI & BBV postal self-sampling packs and the user support required for maximal inclusivity and reach, on behalf of BASHH.

This report describes the development process and the resulting recommendations.

Process

We used a highly collaborative, evidence-based, iterative process with an emphasis on involvement of the full range of stakeholders and members of the public.

1. We undertook a **rapid literature review** to determine current evidence on the acceptability, reach, and most importantly, design of self-sampling kits and their instructions and supporting materials. Studies on the circumstances around the remote self-sampling process aided understanding of the sampling process as understood by the user, and also highlighted how to reduce barriers to uptake. In particular, we were keen to explore how to make the kits accessible to those with lower health and digital literacy. Literature on specific design elements to enhance the user experience was limited, further emphasising the need for evidence-based recommendations. We used these findings to create draft recommendations.
2. We **convened and consulted with a panel of experts**. The panel consisted of sexual health practitioners, commissioners, academics, providers, three members of a patient and public involvement (PPI) panel, laboratory providers and a pharmacist, to ensure that input from a wide range of stakeholders, spanning all stages of the user journey was possible. Members were recruited through BASHH newsletter advertisements, personal networks and PPI contacts.
3. We circulated the draft recommendations, along with the literature review and rationale, to all panel members as an **online survey** ahead of an online group meeting. All members voted on whether they liked the recommendation as it is, wanted to adapt it, or remove the recommendation altogether, and commented on their decisions. The survey allowed us to hear all voices and reduced any possible reticence which individual members may have felt about speaking up during the panel meeting. This was a particular priority for our PPI members. This step also gave us an indication of which recommendations would benefit most from in depth group discussion subsequently.
4. We held an **online panel meeting** in which we discussed each recommendation until agreement was reached, using a modified Delphi technique (Hsu & Sandford, 2007).
5. We **redrafted the recommendations** following the advice gleaned from the panel. The panel was then invited to comment in writing on these recommendations, prior to their final iteration in which 15 recommendations were created.

Recommendations for the design of self-sampling packs and associated support for self-sampling processes within Sexually Transmitted Infection and Blood Borne Virus testing

The scope of the recommendations includes:

- Self-sampling pack design
- Information included in the pack
- Self-sampling components
- Packaging materials
- Support services

The recommendations are mapped to the user/patient journey for someone seeking STI & BBV testing.

R1. The name, branding and links into and out of the test kit request website should make it easy for the user to both locate and establish that it is part of free NHS/ local authority /commissioned sexual health services.

Note: For people to feel confident in engaging with online care, the credibility of the system is important. People have confidence in NHS branding and this should be prominent.

R2. There is easy-to-find telephone support, and alternative options such as online support, provided by sexual health teams throughout the week to assist with use of the service and related sexual health concerns.

R3. All information and instructions within every stage of the self-sampling process should be easy to access and written as clearly as possible to enable a wide range of people, including those with low literacy / health literacy to use it.

Desirable: Some information could be provided in an Easy Read format (<https://www.learningdisabilities.org.uk/learning-disabilities/a-to-z/e/easy-read>), and in different languages, in line with local need, to enable people with learning disabilities and more limited English reading skills to use the service. If videos are used, subtitles should be included and British Sign Language (BSL) interpretation should be considered.

Note: Useful resources include: Understanding accessibility requirements for public sector bodies. Government Digital Service. (<https://www.gov.uk/guidance/accessibility-requirements-for-public-sector-websites-and-apps>), and the checkpoints developed by the World Wide Web Consortium (W3C) in order to maximise access by people with disabilities (<http://www.w3.org/>)

R4. The test kit request website should include a simple explanation of the whole self-sampling process, from start to finish, including the steps that the user needs to take, exactly how and when the service provider will communicate with the user, and what happens when results are available.

Note: Some people have privacy concerns and may worry about receiving unanticipated texts from the service. Services may use a number of text communications e.g. to acknowledge safe receipt of the completed test kit, to remind users to return their kit, and to provide results. The type and timing of any such communication should be made clear to users early on.

R5. The test kit request website should have a robust, easy to follow process to enable the user to receive the appropriate self-sampling kit in relation to their demographics, sexual behaviour and risk-related needs. This should include an explanation of window periods where relevant.

Note: Please see the BASHH position on HIV window periods here:

<https://www.bashhguidelines.org/media/1069/bashh-eaga-statement-on-hiv-wp-nov-14.pdf>

R6. The user should be offered a range of options for obtaining the self-sampling kit.

Desirable: Options should include posting to a home address, and/or address of the user's choice, and collection e.g. from a sexual health clinic or community pharmacy.

Note: Recorded/ tracked or other signed for delivery options should not be used as this reduces acceptability. Some people may not want the kit to be delivered to their home address for privacy reasons.

R7. The self-sampling kit should be tailored to the individual user's needs so that the kit a person receives contains only the items the user will need.

Note: Extra items in a kit can be very confusing for the user and increase the likelihood of incorrect self-sampling and or failure to use the kit at all. However, where only a limited range of kits can be provided for logistical reasons, the inclusion of items that may not be needed by some users is acceptable if it ensures access for people who might otherwise be excluded.

R8. Kit packaging should be discreet and small enough to fit through a standard letterbox.

R9. The kit should contain a labelled diagram illustrating the different components. The kit components themselves should be organised such that the user can identify "at a glance" the type and number of components.

R10. Instructions for use of the kit should be set out as a series of numbered steps.

R11. Diagrams, especially those depicting anatomical sites for swabbing, should be simple and clear.

Desirable: Consider use of photographs of anatomical sites for swabbing instead of / as well as diagrams. This has been shown to be highly acceptable (as part of a self-diagnosis system) in an Australian sexual health setting (Personal communication Prof C Fairley, Melbourne Sexual health Centre, <https://ispysti.org/>)

Note: Many people have a limited understanding of their own anatomy. Some people find anatomical diagrams too abstract and so they are unable to relate them to their own bodies. Photographs can make interpretation easier.

R12. An accompanying online video showing how to use the kit should be available. The items used (e.g. swabs, blood collection materials) in the film should be identical to those in the kits to avoid confusion.

Note: Some people find it difficult to follow instructions if what they see in front of them does not exactly match diagrams or video content.

R13. A pre-paid envelope or box that will fit into a post box should be provided for the user to return the completed kit for laboratory processing.

Desirable: A text should be sent to the user acknowledging safe receipt by the laboratory but this may not be necessary if laboratory turnaround times are short. Services may choose to send a reminder text if the completed kit has not been returned within a given timeframe e.g. two weeks from kit mail out.

Note: Some people have concerns about the safety of their sample when sent through the post. Users should be informed that the most efficient way for their samples to be returned is by post. Other options risk delays which could cause samples to deteriorate, which could reduce test performance and/or render a sample unviable for testing. Information about the rationale for returning the kit in the post should be provided to the user.

R14. Results should be provided in line with existing standards on turnaround times.

Note: Please see: <https://www.bashh.org/about-bashh/publications/standards-for-the-management-of-stis/>

R15. There should be a range of options for the user to access their test results. These could include SMS (text) messaging, email, or access to an online portal

Summary

These recommendations have been created within a robust process of evidence synthesis and expert review. They may be used in isolation and could form part of future wider BASHH guidance, adding to and/or updating existing work and complimenting ongoing work by Public Health England, BASHH & FRSH quality standards for online services. A natural next step would be the development of a set of evidence based, BASHH exemplar materials for local adaptation. These materials could include self-sampling diagrams, user information sheets, packaging, and short “how to do it” videos.

Acknowledgements

Thank you to our panel members for their input over the process: Mr Tim Alston, Ms Erna Buitendam, Mr Rob Carroll, Prof Jackie Cassell, Dr Darren Cousins, Paul Flowers, Dr Gillian Holdsworth, Ms Portia Jackson, Dr Danial Leahy, Ms Ruth Lowbury, Mr Alan Middleton, Ms Ruth Poole, Dr Johnathan Ross, Dr John Saunders, Mr Merle Symonds.

In particular, thank you to our PPI members: Ms Christen Dali, Ms Yasmin Rahman, and Mr Harri Williams.

Appendices

Appendix 1 - Members of the expert panel

Appendix 2 - The initial project proposal

Appendix 3 - The user journey, and initial recommendations

Supplementary files

1. BASHH self-sampling guidance survey results
2. BASHH self-sampling guidance meeting minutes – November 2020
3. BASHH self-sampling guidance meeting presentation – November 2020
4. Revised recommendations v1 – December 2020
5. Revised recommendations v2 – February 2021.

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Appendix 1 - Members of the expert panel

Member	Role
Prof Claudia Estcourt	Professor of Sexual Health & HIV, Glasgow Caledonian University
Mr Tim Alston	Co-founder, Preventx
Ms Erna Buitendam	Head of quality and standards on chlamydia screening, PHE
Mr Rob Carroll	Commissioner, Chair of the English HIV & Sexual Health Commissioners Group
Prof Jackie Cassell	Professor of Public Health, Brighton and Sussex Medical School
Dr Darren Cousins	Consultant, in Sexual Health and HIV, Cardiff Royal Infirmary
Ms Christen Dali	PPI panel member
Prof Paul Flowers	Professor of Health Psychology, University of Strathclyde
Ms Lily Freeman	Research Assistant, Institute of Global Health, UCL
Dr Jo Gibbs	Senior Clinical Researcher and Honorary Consultant in Sexual Health and HIV Institute of Global Health, UCL
Dr Gillian Holdsworth	Director, SH24
Ms Portia Jackson	Lead Pharmacist, ICaSH
Dr Danial Leahy	GP, Park Medical Centre, London
Ms Ruth Lowbury	Lay Trustee, BASHH
Mr Alan Middleton	Senior Lecturer in Learning Disability Nursing, Glasgow Caledonian University
Ms Ruth Poole	CEO, Preventx
Ms Yasmin Rahman	PPI panel member
Dr Johnathan Ross	Consultant and Professor in Sexual Health and HIV, University of Birmingham and UHB NHSFT
Dr John Saunders	Clinical Academic Consultant, Institute for Global Health, UCL
Mr Merle Symonds	Head of Health Advisory Service, St Barts NHS Foundation Trust
Mr Harri Williams	PPI panel member

Appendix 2 – Initial project proposal

Development of BASHH Guidance for the design of self-sampling packs and associated support for self-sampling processes within Sexually Transmitted Infection and Blood Borne Virus testing

Prof Jackie Cassell, Prof Claudia Estcourt, Dr Jo Gibbs, Dr Melvina Woode Owusu, Dr Fiona Mapp, Dr John Saunders, on behalf of LUSTRUM, (Limiting Undetected Sexually Transmitted Infections to RedUce Morbidity).

Over recent years, sexual health services have offered an increasing proportion of care remotely through a variety of mixed online and in person clinical care pathways. Much innovation has focussed on postal self-sampling for sexually transmitted infections (STIs) and blood borne viruses (BBVs). This relies on the use of self-sampling packs. Packs and their components have mostly been developed by laboratory staff and others whom they may have chosen to consult. In-depth assessment of user engagement or application of theories of behaviour or reference to an evidence base have not been possible. This has implications for their effectiveness. Emerging evidence suggests that the uptake of self-sampling packs, and the return of samples to enable diagnosis, are influenced by various social factors (Banerjee et al, 2017) and need to be optimised based on these and user engagement.

The Covid-19 pandemic has led to a dramatic reduction in sexual health service provision across the UK. BASHH has placed digital services at the core of its guidance for recovery planning. As services are restored, growing emphasis on online care pathways raises serious concerns about the widening of health inequalities. The groups most at risk of poor sexual health are less likely to engage with online / self-managed care (Manavi & Hodson, J, 2017).

Within the LUSTRUM programme, the NIHR has funded extensive research into prevention of transmission of STIs and HIV (lustrum.org.uk) including the role and design of self-sampling. We conducted qualitative studies aimed at optimising the design, contents and support needed for self-sampling packs for sex partners of people with chlamydia, as part of a trial of Accelerated Partner Therapy (APT) (Estcourt et al 2020).

Importantly in relation to post-Covid-19 restoration, we included people of particular concern and vulnerability. This included people with previous STIs, others who had not had experience of sexual health services, and people with mild learning disabilities. We analysed findings using The Behaviour Change Wheel. We found that that self sampling packs offer a widely acceptable means to enabling STI and BBV testing and diagnosis as they remove many barriers to testing in sexual health services. However, there remain important but potentially modifiable barriers to use, potentially reducing sample return and amplifying health inequalities.

On behalf of BASHH, we propose to develop evidence-based recommendations for the optimal design of STI & BBV postal self-sampling packs and the support required for maximal inclusivity and reach. These recommendations could form part of future wider BASHH guidance, adding to and /or updating existing work and complimenting ongoing work by Public Health England on quality standards for online services.

We propose an expert Task-and-Finish group, which would meet remotely to discuss and agree recommendations, following a modified Delphi process (Hsu & Sandford, 2007). We anticipate one virtual meeting to derive a draft shortlist of recommendations which would be refined and finalised through email discussion.

Our LUSTRUM research findings, together with any other relevant evidence obtained from a rapid literature review, undertaken as part of this proposal, would form the empirical data on which the recommendations are based.

The Task-and-Finish group would include 10-12 people with expertise in clinical sexual health medicine, public health, health services research, laboratory medicine, learning disabilities, commissioning, health psychology, general practice, pharmacy, eHealth (from our newly awarded NIHR Programme Grant, “Improving care for people with Sexually Transmitted Infections and their sex partners in a digital NHS”), and at least one lay member. We would also consult with members of the public and expert and lay BASHH representatives as key stakeholders.

The scope of the recommendations includes:

Pack design

- Infection specific information
- Self-sampling components
- Packaging materials
- Support services

Future work beyond the scope of this project could include:

- Recommendations on the design of the self-sampling website
- A set of evidence-based, BASHH exemplar materials for local adaptation. These could include self-sampling diagrams, user information sheets, packaging, short “how to do it” films.

Project time plan:

For these recommendations to be of most use, they need to be developed in a short timeframe. We propose to have recommendations within 4 months of project start.

Resources required:

As this work will be largely conducted online, costs are restricted to project support and reimbursement of lay participants’ time.

Research associate for 15 working days to conduct rapid scoping review, arrange meetings, write up meeting notes and draft the recommendations under supervision of the senior team. £2500

Public / patient involvement: three people providing involvement in a task or activity which equates to approximately half a day’s activity @ £75 per person plus an additional £25 per person for reviewing of draft recommendations (<https://www.invo.org.uk/wp-content/uploads/2016/05/INVOLVE-internal-payment-policy-2016-final-1.pdf>): £300

Total: £2800

Appendix 3 - The user journey, and initial recommendations

Stage of user Journey	Possible provider service intervention	Evidence informing process	Recommendation
<p><i>The user decides to test and is signposted to the service online</i></p> <p>User requests kit online</p>	<p>Ensure the user can easily access/ find the website and guide the user to select most appropriate testing kit for their needs</p> <p>Website is easy to find and linked to local sexual health service/ easily identifiable as “credible”</p>	<p>Potential difficulties in ensuring that users get the right kit – for example if there is a pack particularly for people with mild learning difficulties, how are these people identified? (Middleton et al 2020)</p> <p>Requesting kits online can overcome geographical access inequality (Kersaudy-Rahib <i>et al.</i> 2017, Witzel et al 2016)</p> <p>Users aged between 20-30 were more likely to use online services than the over 35s and under 20s (Barnard, S. <i>et al.</i> 2018)</p>	<p>The website name, branding and links make it easy for the user to a) locate and b) establish that it is part of NHS/ local authority sexual health services</p> <p>The website contains a robust, easy to follow process to enable the user to choose the appropriate self-sampling kit according to demographic, sexual behaviour and risk.</p>
<p>Kit dispatched to user’s home/preferred pickup location</p>	<p>Kit to be sent to user’s home</p> <p>Option to collect kit in a pharmacy or clinic</p>	<p>Sending kits directly to users’ homes seemed to be the most acceptable delivery method (Witzel et al 2016)</p> <p>Recorded delivery was not seen to be helpful (it was not discreet enough) but a text notification when the kit was likely to be delivered was seen as useful so people (especially young people) knew to look out for it (McCarthy et al 2016).</p> <p>Manavi and Hodson (2017) found that kits were more likely to be returned if they were delivered directly to a home, rather than clinic or pharmacy.</p>	<p>A range of kit delivery / collection options are provided.</p> <p>The user has a range of options for obtaining the kit. These should include:</p> <p>a) Posting to a home address and b) collection e.g. from a SH clinic / pharmacy NB Recorded delivery / tracked / signed for kits should NOT be the sole home postal option as this may limit acceptability</p> <p>The user should be alerted to the likely arrival date by text or website information.</p>
<p>Kit arrives with user</p>	<p>External packaging should be appropriate and discreet</p>	<p>Boxes needed to be discreet and must fit through letterboxes (Witzel et al 2016)</p>	<p>Kit packaging should be bland and discrete. It should fit though letter box without requiring a signature</p>

Stage of user Journey	Possible provider service intervention	Evidence informing process	Recommendation
User opens Kit	Lay out of contents	<p>Potential users suggested that the kit be laid out so all components could be seen when the box was opened – eg like a “Graze box” / iPhone packaging (Flowers et al 2020a)</p> <p>The components of the pack could have numbers which match up to the instructions to make it easier to use. (Middleton et al 2020)</p>	<p>The kit components should be organised such that the user can see “at a glance” the type and number of components.</p>
User reads Instructions/literature (including diagrams).	<p>Might be some further instruction or advice</p> <p>Introduction to the pack</p> <p>instructions (verbal and diagrams) are clear</p>	<p>Flowers et al 2020a suggested that detail on the risks of not getting treated could increase engagement. However, Goodwin et al 2019 (in bowel cancer screening kits) found that this did not increase uptake</p> <p>Small significant decrease in uptake if narrative leaflets are sent (Goodwin et al 2019)</p> <p>Instructions –</p> <ul style="list-style-type: none"> • clear information on how long it would take to complete the test was needed (Flowers et al 2020a) • explain why people should use the kits, not just how to do it (Flowers et al 2020c) • Clear diagrams are essential (Flowers et al 2020a), women with mild learning difficulties in particular found the vulvo-vaginal swab diagrams difficult to understand (Middleton et al 2020) • Possible video support to show people how to use the tests would be helpful 	<p>At the beginning of the instructions, have a labelled diagram illustrating the components. Ideally these should be numbered.</p> <p>Instructions should be set out as a series of numbered steps, with simple, clear illustrations that are clearly representative of the sampling kit and the anatomical site.</p> <ul style="list-style-type: none"> • Instructions • Diagrams • Accompanying support <p>All instructions should be written as simply as possible, avoiding small font size, following “Easy Read” principles.</p> <p>Different languages should be available if requested</p> <p>Diagrams, especially those depicting anatomical sites for swabbing, should be simple and clear.</p>

Stage of user Journey	Possible provider service intervention	Evidence informing process	Recommendation
User undertakes self-sampling		<p>Concerns about lack of privacy, especially for young people or people with mild learning difficulties living with parents (Middleton et al 2020, McCarthy et al. 2016).</p> <p>However, testing in the home environment was also seen to boost confidentiality (Flowers et al 2016), especially among rural populations people who were yet to ‘come out’ and British South Asians (Witzel et al 2016)</p>	
User repackages kit to send it for testing		<p>For bowel cancer screening, digital reminders of any kind did not yield any significant increase in returned kits (Goodwin et al 2019)</p> <p>SH24 send an SMS reminder at day 16 to those yet to return kits</p> <p>Brown et al 2018 that ‘behaviourally informed’ reminder and primer text messages can increase return rates.</p>	<p>People who have not returned their kit after 10 days or more after of receipt should be sent a reminder text</p>
User returns kit for testing	<p>Drop off in clinic</p> <p>Take to post office</p>	<p>Flowers et al 2020a found posting it back to be a barrier: concerns around stigma of it being obvious, postal staff not handling it correctly, and it not arriving in time. Possible solution is to allow user to drop sample off at clinic</p> <p>Socioeconomic conditions also potential barriers – kits less likely to be returned when user lives in a less affluent area (Barnard <i>et al</i>, 2018), user is born outside of EU, or a Heterosexual man with symptoms. White British were group most likely to return kits (Barnard <i>et al</i>, 2018)</p> <p>Transgender users showed very low return rates in Manavi and Hodson’s study, only one sent the kit back. However, the group was very small (n=10).</p>	<p>A range of options for returning the completed kit for laboratory processing should be provided. These should include:</p> <p>a) Posting back in a pre-paid envelope which will fit into a street letter box</p> <p>b) drop off at SH clinic / pharmacy</p>

Stage of user Journey	Possible provider service intervention	Evidence informing process	Recommendation
		More work will need to be done to work out how to engage with this demographic.	
Laboratory staff receive kit			A text should be sent to the user acknowledging safe receipt by the laboratory.
Laboratory staff process kit	Lab does the testing and contacts patient etc		This should be done within existing guidelines on turnaround time
Laboratory / service provider gives user their results.	Ensure timelines and protocols are within BASHH Standards for the Management of STIs – Currently 97% reports issued within 4 working days, final reports on supplementary testing or referral issued in 9 working days.	It is more acceptable to use text messages that don't mention sexual health, rather a text message to prompt a user to log on to a results portal (Gibbs et al. 2018)	<p>There should be a range of options for test results to be returned, such as letter, email or SMS. User preference can be recorded when ordering a test.</p> <p>Where results are provided by text (SMS), an alert discrete “your results are ready” text which does not mention specific STIs should be sent with a link to specific test results for privacy reasons.</p>
User links to care pathway if necessary	Further support and advice if needed e.g. telephone helpline etc	<p>A key barrier to testing at home was the lack of access to professional support and knowledge (Flowers et al 2016) (Ritchwood 2019) this is self-testing for HIV so a bit different, but I still think it's relevant</p> <p>Goodwin et al. (2019) found that a live phone conversation with someone taking the user through how to use the kit showed a significant increase in uptake, Witzel et al (2016) also found that users would find this beneficial</p>	<p>There are easy to access routes to access support to assist with use of the service and related sexual health concerns. Telephone support should be available (in addition to alternative options e.g. online) from specialist sexual health teams.</p> <p>The pathways to support should be easy to find and provided at accessible times</p>