### 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. 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. Emerging evidence suggests that the uptake of self-sampling packs, and the return of samples to enable diagnosis, are influenced by various social factors and there are important but potentially modifiable barriers to use, which might amplify health inequalities.

Working closely with the NIHR funded *Limiting Undetected Sexually Transmitted Infections to RedUce Morbidity* research programme, BASHH undertook a highly collaborative, evidence-based, iterative process 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. Emphasis was placed on involvement of the full range of stakeholders and members of the public.

### Recommendations for the design of self-sampling packs and associated support for selfsampling 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 (<u>https://www.learningdisabilities.org.uk/learning-disabilities/a-to-z/e/easy-read)</u>, 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. (<u>https://www.gov.uk/guidance/accessibility-requirements-for-public-sector-websites-and-apps</u>), 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 selfsampling 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: <u>https://www.bashhguidelines.org/media/1069/bashh-eaga-statement-on-hiv-wp-nov-14.pdf</u>

#### 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.

8. 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, <u>https://ispysti.org/</u>)

**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: <u>https://www.bashh.org/about-bashh/publications/standards-for-the-management-of-stis/</u>

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

#### References

- Aicken, C.R.H., Fuller, S.S., Sutcliffe, L.J. et al. Young people's perceptions of smartphone-enabled self-testing and online care for sexually transmitted infections: qualitative interview study. BMC Public Health 16, 974 (2016). https://doi.org/10.1186/s12889-016-3648-y
- Banerjee, P., Thorley, N. & Radcliffe, K. A service evaluation comparing home-based testing to clinic-based testing for Chlamydia and gonorrhoea in Birmingham and Solihull. Int. J. STD AIDS 29, 974–979 (2018) doi: 10.1177/0956462418767180
- Barnard, S. *et al.* (2018) 'Comparing the characteristics of users of an online service for STI self-sampling with clinic service users: A cross-sectional analysis', *Sexually Transmitted Infections*. BMJ Publishing Group, 94(5), pp. 377– 383. doi: 10.1136/sextrans-2017-053302
- 4. BASHH Spring Meeting <u>https://www.bashh.org/events-education/conferences/annual-conference-2020-virtual/</u>
- 5. BASHH Standards for the Management of STIs (2019) Available at: <u>https://www.bashh.org/about-bashh/publications/standards-for-the-management-of-stis/</u>
- Brown, L., Tan, K., Guerra, L., Naidoo, C. and Nardone, A. (2018), Using behavioural insights to increase HIV selfsampling kit returns: a randomized controlled text message trial to improve England's HIV self-sampling service. HIV Med, 19: 585-596. doi:10.1111/hiv.12634
- Estcourt CS, Howarth AR, Copas A, et al. Accelerated partner therapy (APT) partner notification for people with Chlamydia trachomatis: protocol for the Limiting Undetected Sexually Transmitted infections to RedUce Morbidity (LUSTRUM) APT cross-over cluster randomised controlled trial. BMJ Open 2020;10:e034806. doi:10.1136/ bmjopen-2019-034806 (https://bmjopen.bmj.com/content/bmjopen/10/3/e034806.full.pdf).
- 8. Flowers P, Woode Owusu M, Pothoulaki M, Mapp F, Vojt G, Mercer CH, Cassell J, Wayal S, Symonds M, Nandwani R, Howarth, A, Saunders J, Brice, S, Comer-Schwartz, Estcourt CS. **Improving 'home-based' sti/hiv self-sampling and boosting sample return rates.** <u>doi: 10.1136/sextrans-2019-sti.253</u>
- 9. Flowers P, Pothoulaki M, Vojt G, Mapp F, Woode Owusu M, Estcourt CS, Cassell J, Saunders J. Understanding the barriers and facilitators to using self-sampling packs for sexually transmitted infections and blood borne viruses: thematic analyses supporting intervention optimisation. medRxiv 2020.11.22.20230359; doi: https://doi.org/10.1101/2020.11.22.20230359
- 10. Gibbs J, Aicken CRH, Sutcliffe LJ, et al. Mixed-methods evaluation of a novel online STI results service. Sex Transm Infect. 2018;94(8):622-624. doi:10.1136/sextrans-2017-053318
- 11. Gkatzidou, V., Hone, K., Sutcliffe, L. *et al.* User interface design for mobile-based sexual health interventions for young people: Design recommendations from a qualitative study on an online Chlamydia clinical care pathway. *BMC Med Inform Decis Mak* **15**, 72 (2015). <u>https://doi.org/10.1186/s12911-015-0197-8</u>
- 12. Goodwin, B.C., Ireland, M.J., March, S. *et al.* Strategies for increasing participation in mail-out colorectal cancer screening programs: a systematic review and meta-analysis. *Syst Rev* **8**, 257 (2019). https://doi.org/10.1186/s13643-019-1170-x
- 13. Hsu C & Sandford BA. The Delphi Technique: Making Sense of Consensus. Practical Assessment, Research & Evaluation. 2007 Aug;12(10). <u>https://doi.org/10.7275/pdz9-th90</u>
- 14. Kersaudy-Rahib, D. *et al.* (2017) **'Chlamyweb Study II: A randomised controlled trial (RCT) of an online offer of home-based Chlamydia trachomatis sampling in France'**, *Sexually Transmitted Infections*, **93**(3), pp. 188–195. doi: 10.1136/sextrans-2015-052510
- Manavi, K. and Hodson, J. (2017) 'Observational study of factors associated with return of home sampling kits for sexually transmitted infections requested online in the UK', *BMJ Open*. BMJ Publishing Group, 7(10), p. e017978. doi:10.1136/bmjopen-2017-017978
- 16. McCarthy, O., French, R.S., Roberts, I. *et al.* Simple steps to develop trial follow-up procedures. *Trials* **17**, 28 (2016). https://doi.org/10.1186/s13063-016-1155-1
- 17. Middleton, A, Pothoulaki M, Woode Owusu M, Flowers P, Mapp F, Vojt G, Laidlaw R, Estcourt C. **How can we make** self-sampling packs for sexually transmitted infections and blood borne viruses more inclusive? A qualitative study with people with mild learning disabilities and low health literacy. medRxiv 2020.11.06.20217612; doi: https://doi.org/10.1101/2020.11.06.20217612
- 18. Ritchwood, T.D., Selin, A., Pettifor, A. *et al.* **HIV self-testing: South African young adults' recommendations for ease** of use, test kit contents, accessibility, and supportive resources. *BMC Public Health* **19**, 123 (2019). <u>https://doi.org/10.1186/s12889-019-6402-4</u>
- 19. SH24 Blog (2015) Home STI test kit orders hit 3000 and return rate rises to 68% https://business.sh24.org.uk/service-news/2015/8/13/3000-home-sti-kit-orders-and-counting

- 20. Witzel TC, Rodger AJ, Burns FM, Rhodes T, Weatherburn P. **HIV Self-Testing among Men Who Have Sex with Men** (MSM) in the UK: A Qualitative Study of Barriers and Facilitators, Intervention Preferences and Perceived Impacts. PLoS One. 2016;11(9):e0162713.
- 21. Personal communication Prof C Fairley, March 2021, Melbourne Sexual health Centre, https://ispysti.org/

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