PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	An observational study of factors associated with return of home sampling kits for sexually transmitted infections requested online in the UK
AUTHORS	Manavi, Kaveh; Hodson, James

VERSION 1 – REVIEW

REVIEWER	Paul Flowers Glasgow Caledonian University Scotland, UK
REVIEW RETURNED	03-Jul-2017

GENERAL COMMENTS	Within the summary at the start; what kind of factors are being addressed? Within the introduction- can you situate to the wider readership of BMJ Open? So how is online service provision within Sexual health interesting to other health arenas? Also can you indicate a better description of the population being served here. Is referral all self-referral? what are economic drivers behind the service change? Is there provider referral? Does the service only address those who know they are at risk? are those at risk who do not recognise it not served by the service? Methods Perhaps a table could cover the content of the kits more succinctly? Is there a possibility of a figure depicting how to use the kits? what were levels of missing data and how were they dealt with analytically? Why is the EU defined like this? what is the rationale? Discussion I found the discussion a little disappointing (sorry). I think it could be improved if it was widened and we heard more about the teams thoughts concerning what the findings might mean and why they may be important. For example the potential of amplifying health inequalities, the implications of assuming digital and health literacy within services and how the findings suggest the need for further research. How might the service be improved? How might behavioural theory and approaches be useful for service improvement (e.g. engaging heterosexual men). If we knew more about how the service was advertised we could hear more about population targeting or how wider interventions could enable targeting and tailoring of people who should use the service but don't know their risks

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REVIEWER	Rihcard Gilson Institute for Global Health UCL UK
REVIEW RETURNED	10-Jul-2017

| GENERAL COMMENTS | This report describes an analysis of routinely collected data to evaluate factors associated with returning samples by individuals who have requested a self-sampling kit for STI/HIV testing. There are a number of points which should be addressed.

1. This is referred to as a cohort study but then also a 'service improvement analysis'. The authors (page 7) say that they did not seek review by an ethics committee. The authors need to make clear that the study fell outside the requirements for HRA review, if that is the case.

2. The authors refer variously to 'home testing' and 'home sampling'. There is a convention that distinguishes home testing from home sampling and it would be helpful if the authors were consistent in this respect.

3. The authors refer in their abstract and elsewhere to 'sex groups' and later refer to 'gender group' (results paragraph 2). This is confusing. Furthermore in their results they report differences in the return rate between females and males (results paragraph 2) and then later (paragraph 5) report the differences by 'type of kit'. I think it would be more straightforward if the results were presented for women, heterosexual men, and MSM. Comment can then be made about any differences between the two groups of women i.e. whether they reported anal sex.

4. The authors report 'a multivariable analysis' and then refer to odds ratios. It needs to be made clear that these are adjusted odds ratios, if this is the case

5. Two outcomes of interest are not commented upon. One is the time to the receipt of the sample by the laboratory from the time of logging the request in those who did return their samples. The other is the proportion of incomplete or inadequate samples. Both these would be important aspects of evaluation of the service, although not strictly about factors associated with return.

6. In their conclusion the authors state that 'improved instructions for groups less likely to return their kits would be beneficial'. The authors have not presented any data in support of this.

7. Other points for clarification include:
• Can the authors explain their choice of countries (page 6 paragraph 7)? The list which is described as 'EU' appears not to be a complete list of EU countries.
• In the abstract the authors refer to the service being limited to residents of Birmingham but in the methods it refers to Birmingham and Solihull.
• In their abstract the authors repeat the time period unnecessarily
• There are a number of typos in particular a lack of definite or indefinite articles, 'rolled over' (article summary), 'volvo-vaginal' (methods paragraph 5) |

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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Comment: Can you situate to the wider readership of BMJ Open? So how is online service provision within Sexual health interesting to other health arenas? Also can you indicate a better description of the population being served here. Is referral all self-referral? what are economic drivers behind the service change? Is there provider referral? Does the service only address those who know they are at risk? are those at risk who do not recognise it not served by the service?

Response: We thank the reviewer for their comments. We have added the following statement to the manuscript: "Because of savings on the cost of clinical overheads, home sampling STI testing services may be more cost effective compared with traditional services.".
The service is promoted online and through a number of local media outlets and venues including community partnerships and primary care centres for the benefit of all adult residents of Birmingham and Solihull. Individuals are encourage to visit the service's website and request a testing kits at the time of their convenience.
The service is available for anyone irrespective of their risk for STI. Patients with symptoms are encouraged to attend the clinics.

Comment: Perhaps a table could cover the content of the kits more succinctly? Is there a possibility of a figure depicting how to use the kits?

Response: We have added in a table (Table 1) to help clarify the contents of the various kits. With this new table, and the information reported in the text, we feel that it is now clear how the kits would be used, but would be willing to add a figure if you feel that this is still necessary.

Comment: What were levels of missing data and how were they dealt with analytically?

Response: When registering on the website to receive a kit, individuals must answer all questions in order to progress to the order page. As a result, complete data were available for all patients included in the study. The only instance of missing data were in the IMD scores for N=39 patients, which was due to the fact that the given postcodes could not be matched to the published IMD lookup tables. These patients were excluded from the univariable analysis of IMD, and from the multivariable analysis (as IMD was an included factor), but the remainder of the analysis included all patients.

We have added details to the methods/results sections to clarify these points.

Comment: Why is the EU defined like this? what is the rationale?

Response: We thank the reviewer for their comment. We have amended the definition to "Northern EU". We consider the 16 Northern European countries to have low over all prevalence of hepatitis B infection. Individuals born and bred in or having sex with partners from outside Northern EU may be at risk of hepatitis B infection. In accordance with NICE guidelines, the website advises those individuals to attend one of Umbrella Health clinics for hepatitis B screening and vaccination. We have amended the manuscript with the information. [reference 12: https://www.nice.org.uk/guidance/qs65/chapter/Quality-statement-1-Testing-and-vaccination-for-hepatitis-B.]

Comment: I found the discussion a little disappointing (sorry). I think it could be improved if it was widened and we heard more about the teams thoughts concerning what the findings might mean and why they may be important.

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For example the potential of amplifying health inequalities, the implications of assuming digital and health literacy within services and how the findings suggest the need for further research. How might the service be improved? How might behavioural theory and approaches be useful for service improvement (e.g. engaging heterosexual men). If we knew more about how the service was advertised we could hear more about population targeting or how wider interventions could enable targeting and tailoring of people who should use the service but don't know their risks
We thank the reviewer for their comments. We agree that the aspects they have highlighted are significant in uptake of the service. Our paper is on non-return of the testing kits by individuals who made an effort and filled in the mandatory fields for request of the testing kits and yet did not return their kits. For this reason, we don't think that the cause of non-return could be because of lower digital or health literacy. We have updated the discussion section with our intention to survey patients who do not return their kits to better understand the possible reasons for the non-return of their testing kits.

Reviewer 2
Comment: This is referred to as a cohort study but then also a 'service improvement analysis'. The authors (page 7) say that they did not seek review by an ethics committee. The authors need to make clear that the study fell outside the requirements for HRA review, if that is the case.

Response: We thank the reviewer for their comment. We have amended the manuscript to clarify that the study is an evaluation of a service already in full operation. We refer to HRA's document in this regard:[HRA. Does my project require review by a Research Ethics Committee?http://www.hra.nhs.uk/documents/2013/09/does-my-project-require-rec-review.pdf].

Comment: The authors refer variously to 'home testing' and 'home sampling'. There is a convention that distinguishes home testing from home sampling and it would be helpful if the authors were consistent in this respect.

Response: We thank the reviewer for highlighting this point. We have amended the discrepancies and used home sampling throughout the manuscript.

Comment: The authors refer in their abstract and elsewhere to 'sex groups' and later refer to 'gender group' (results paragraph 2). This is confusing. Furthermore in their results they report differences in the return rate between females and males (results paragraph 2) and then later (paragraph 5) report the differences by 'type of kit'. I think it would be more straightforward if the results were presented for women, heterosexual men, and MSM. Comment can then be made about any differences between the two groups of women i.e. whether they reported anal sex.

Response: We have reworded the results section to clarify.

Comment: The authors report 'a multivariable analysis' and then refer to odds ratios. It needs to be made clear that these are adjusted odds ratios, if this is the case

Response: The odds ratios relating to the multivariable analysis are adjusted odds ratios, as you suggest. We thought that the fact that the odds ratios came from a multivariable model was a sufficiently clear implication that they were "adjusted". However, we have updated the text to use the acronym ORadj when referring to the adjusted odds ratios, in order to make this explicitly clear

Comment: Two outcomes of interest are not commented upon. One is the time to the receipt of the sample by the laboratory from the time of logging the request in those who did return their samples. The other is the proportion of incomplete or inadequate samples. Both these would be important aspects of evaluation of the service, although not strictly about factors associated with return.

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Response: We thank the reviewer for the two pertinent points. Our data are on return of the STI kits within 30 days of their online request. We have amended the methodology (sub-section Study design and abstract) accordingly. We did not collect the information on proportion of kits returned with incomplete or inadequate specimens. We have added this point as a study limitation.

Comment: In their conclusion the authors state that 'improved instructions for groups less likely to return their kits would be beneficial'. The authors have not presented any data in support of this.

Response: The last sentence read: "Further research in improvement of return rate of the testing kits among individuals with those factors would be beneficial.". We have changed the sentence to "…. with those factors may be beneficial". At the time of the write of the manuscript we did not have data on initiatives that improve return rate of the testing kits.

Comment: Can the authors explain their choice of countries (page 6 paragraph 7)? The list which is described as 'EU' appears not to be a complete list of EU countries.

Response: We thank the reviewer for their comment. We have amended the definition to "Northern EU". We consider the 16 Northern European countries to have low over all prevalence of hepatitis B infection. Individuals born and bred in or having sex with partners from outside Northern EU may be at risk of hepatitis B infection. In accordance with NICE guidelines, the website advises those individuals to attend one of Umbrella Health clinics for hepatitis B screening and vaccination [reference 12: https://www.nice.org.uk/guidance/qs65/chapter/Quality-statement-1-Testing-and-vaccination-for-hepatitis-B.]

Comment: In the abstract the authors refer to the service being limited to residents of Birmingham but in the methods it refers to Birmingham and Solihull.

Response: The service applied to both Birmingham and Solihull. We have corrected the abstract to clarify.

Comment: In their abstract the authors repeat the time period unnecessarily

Response: We have amended the abstract to remove duplication.

Comment: There are a number of typos in particular a lack of definite or indefinite articles, 'rolled over' (article summary), 'volvo-vaginal' (methods paragraph 5)

Response: Thank you for pointing this out. We have proof-read the resubmission version more thoroughly, and should now have hopefully dealt with these issues.

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VERSION 2 – REVIEW

REVIEWER	Paul Flowers Professor of Public Health Psychology Glasgow Caledonian University Scotland, UK
REVIEW RETURNED	17-Aug-2017

GENERAL COMMENTS	As requested in my previous comments the manuscript should clearly state that the service is accessed through self referral, or prompting through marketing, and via direct referral from health professionals. This is an important distinction as the former manage their own sexual health and the latter do not. I find the term 'sex groups' hard to understand. Sounds like sex parties etc The introduction still doesnt really capture and reflect the policy context of the study or explain why the appear may be interesting to wider readers of BMJ Open. How might the findings and approach be of relevance to other health care settings? Why should non sexual health readers read the paper? What do they need to know about the background epidemiology of sexual ill-health to understand the context of the study? It might be helpful to the readers to include a figure (If word limit permits) of the 'pictorial information' or a link to such information. if I have understood things correctly, the description 'The rates of return were similar for females without or with history of anal sex ' seems inaccurate as the distinction relates to women who ordered, or didnt order a kit with anal tests. Maybe some epidemiological rationale could help explain this focus? I still found the discussion a little disappointing. There is a lot of literature and theory relating to health inequalities and masculinities that could easily be drawn upon to discuss the findings here.

VERSION 2 – AUTHOR RESPONSE

Comment: “the manuscript should clearly state that the service is accessed through self referral, or prompting through marketing, and via direct referral from health professionals.”

Response: we agree with the statement. Sexual health services in the UK are open access. Patients do not require referral fro their GPs or other doctors. We have added the following statement to the methodology section (page 5, first paragraph) that we think would address the issue:
“This offers an online service for requesting home sampling kits for STI and HIV, which can be used by any adult residents of Birmingham and Solihull and without the need for direct referral from their general practitioners. The service is promoted online and through a number of local media outlets and venues, including community partnerships and primary care centres. Individuals are encouraged to visit the service’s website and request a sampling kit at the time of their convenience.”

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Comment: The term ‘sex group’ is hard to understand: [
Response: this is the term widely used in clinical settings to refer to the categories of sexual orientation of patients. We do not think the term would be mis-understood.

Comment: The introduction still doesnt really capture and reflect the policy context of the study or explain why the appear may be interesting to wider readers of BMJ Open. How might the findings and approach be of relevance to other health care settings? Why should non sexual health readers read the paper? What do they need to know about the background epidemiology of sexual ill-health to understand the context of the study?

Response: the use of internet may offer an opportunity for delivering new models of clinical service in other medical specialities. Colleagues may find similarities between our model described in the manuscript and their specialty services. We strongly believe the data would be received with interest.

Comment: Including a figure of pictorial information:

Response: : we do not think the information would be necessary. An interested reader could access the website through the web address provided for the information at any time. We would be prepared to add the pictorial guide if required.

Comment: if I have understood things correctly, the description 'The rates of return were similar for females without or with history of anal sex ' seems inaccurate as the distinction relates to women who ordered, or didnt order a kit with anal tests. Maybe some epidemiological rationale could help explain this focus?

Response: The reason we have emphasised the distinction is that women with history of anal sex would have to take one extra swab (anal swab). Having to take this extra intrusive self collection of the sample did not act as a barrier to the return rate of the kits when compared with that for women without history of anal sex.

Comment:I still found the discussion a little disappointing. There is a lot of literature and theory relating to health inequalities and masculinities that could easily be drawn upon to discuss the findings here.

Response: we are sorry for the comment. We have attempted to focus on possible causes of lack of return of STI testing kits and have referred to a number of publications. The issue of health inequalities and masculinity is not our area of expertise for which we are sorry. Our results certainly support higher rate of non return of STI kits among heterosexual men and among individuals living in lower income neighbourhoods. We are however cautious with generalising our results because the patients included in this study voluntarily requested the testing kits in the first place. That a proportion of those patients did not return their kits suggests a more logistical issue with the kits. We have nevertheless finalised a survey of all service users to investigate the possible linkage between background knowledge and health literacy and the return of STI testing kits.

I hope you would find the above descriptions satisfactory.
Please do not hesitate to contact me for further information.

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VERSION 3 – REVIEW

REVIEWER	Paul Flowers Glasgow Caledonian University Scotland, UK
REVIEW RETURNED	04-Sep-2017

GENERAL COMMENTS	Overall not much has changed since my last comments so I dont feel I can make any further suggestions. An editorial decision, or another reviewer, might move things forward more efficiently. Overall, this is a really useful paper with wide appeal but could be improved with a few tweaks. I feel Ive made my suggestions and the authors have engaged with them. I still think the introduction should be improved by the authors spelling out the wider relevance of the paper to a wider pool of readers. So I agree completely with the authors which is why I made the suggestion to include new text as not all readers may join the dots and see the relevance of this paper to their wider work in digital health. Equally, with regard to the figure, again, I think an editorial decision is needed. I think the paper would benefit the manuscript and the authors do not think this is necessary. An interested reader could access the website through the web address provided for the information at any time. We would be prepared to add the pictorial guide if required. I still think the discussion could be improved but the authors dont. So other than these issues Ive got nothing further to add. Really enjoyed it and think its very useful. Very happy for the editors to make the decisions on these last few matters.

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