Author’s response to reviews

Title: Understanding how, why, for whom, and under what circumstances opt-out blood-borne virus testing programmes work to increase test engagement and uptake within prison: a rapid-realist review

Authors:

Seth Francis-Graham (seth.francis-graham.16@ucl.ac.uk)
Nnenna Ekeke (nnenna.ekeke@nhs.net)
Corey Nelson (corey.nelson01@gmail.com)
Tinny Lee (tinnytylee@gmail.com)
Sulaima Haj (salima.elhaj@nhs.net)
Tim Rhodes (Tim.Rhodes@lshtm.ac.uk)
Cecilia Vindrola (c.vindrola@ucl.ac.uk)
Tim Colbourn (t.colbourn@ucl.ac.uk)
William Rosenberg (w.rosenberg@ucl.ac.uk)

Version: 1 Date: 04 Feb 2019

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Editor Comments

1. Headers and footnotes

Please note that our current production process does not support headers or footnotes. To prevent delays during the production process, please remove all headers and footnotes, and insert the information in the main text body instead.

Response: Page numbering has now been removed from the document. No other headers or footnotes in use.
2. Figure legends

Your figure legends are currently inserted within the main text body. Please remove the figure legends from your main text, and list them separately at the very end of your manuscript instead.

Figure files should contain the figures only. Please remove all figure legends from your figure files (and as stated above, list them at the very end of your manuscript instead).

Response: Figure legends have now been moved to the very end of the manuscript. All figure legends have been removed from figure files.

3. List of abbreviations

Please remove your list of abbreviations from the declarations section, and insert it as a separate section located between your conclusions and your declarations.

Response: Abbreviations have been removed from the declaration section and inserted as a separate section located between conclusions and declarations.

Requested Revisions

***All amendments to the manuscript have been highlighted using red text***

1. As previously mentioned, more details are needed to further define terminology and methods, including RRR, CMO and Nudge Theory.

Response: Thank you for this comment. Table 1 has been converted into a glossary of terms, including definitions for rapid-realist review, context-mechanism-outcome configurations, and Nudge Theory (see pg. 4). We hope that this will be a sufficient source of information for readers.
Minor cosmetic changes and additions have been made throughout the manuscript, in an attempt to make the methods used more transparent. These include referring to different stages of the review process as “phases” rather than “iterations” (see pg 5 line 69). Under “Review process”, an additional figure has been created, presenting the different phases of the review and their relationship graphically (pg 5 line 68). Search and appraisal processes are now discussed under each phase in the methods section, with the intention of walking the reader step by step through the review process, in tandem with the additional figure.

2. Additionally, during the authors' search, they use any physical disease though the stated outcome specified in throughout is opt-out BBVs. There is not sufficient justification as to why the authors included any physical disease as part of their search strategy.

Response: Thank you for raising this point. It was felt during the development of the search strategy that certain cousin interventions (such as opt-out testing for STI’s, TB, or other physical diseases within prison) may provide information relevant to understanding how opt-out programmes work in the prison setting more generally.

For example, an article looking at opt-out testing for TB may have a nuanced description of difficulties faced by healthcare in accessing prisoners, issues of informed consent, or issues with the fidelity of the opt-out offer, which would have been valuable in refining CMOcs related to these aspects of BBV opt-out testing. Other information, for example confidentiality issues if a prisoner was made to wear a mask, would however have been deemed inappropriate for inclusion. This approach to what is considered “relevant” relates back to the realist approach of judging relevance and quality based on the contributing evidence and not the article itself (as outlined on pg. 7 line 111).

That being said, almost all of the articles that were identified and included within phase two were focused on testing for at least one of the BBVs of interest (i.e. HIV, HCV, HBV). The following justification: “The search did not specify testing for HCV, HBV, or HIV, meaning articles discussing cousin interventions, which nonetheless could be useful for theory refinement, would be identified” has been added on pg. 6 line 87 as requested.
3. Further, among BBVs, more clarity would offer a more precise focus--there are a multitude of BBVs and significant variability with respect to screening. Thus, the differences with respect to screening for HIV, viral hepatitis or sexually transmitted infections may influence some of the conclusions drawn about opt-out testing feasibility and acceptability.

Response: Thank you for drawing our attention to this. The opening paragraph (pg. 2 line 2) has been edited to make it more explicit that the reviews interest, when referring to BBVs, is HCV, HBV, and HIV. We hope that the amendment clarifies our focus on these specific BBVs.

In terms of the different methods of screening (i.e. oral, dried blood spot, venous blood test), the impact of different approaches on acceptability was considered in the review under “CMOc 3: fear of invasive procedure” (pg. 15, line 296).

The majority of data identified during phase 2 came from opt-out testing for HIV in US prisons. The impact of this on the generalisability of context-mechanism-outcome configurations developed has been fully acknowledged as a limitation (pg. 21 line 435). Although the authors agree that it would be preferable to have used data from a UK setting, where HCV, HBV, and HIV are being tested for together, the literature available did not permit this. It is worth noting however that these CMOcs were validated during observation of opt-out testing for HCV, HBV, and HIV within two London prisons and with stakeholders involved in opt-out BBV testing within English prisons.

4. The content experts for the London BBV Core Steering Group is unclear--is this an existing body or one that was convened for the purposes of the reported project? Given that the first review iteration was performed with input from this group, more details are warranted.

Response: Additional information on the London BBV Core Steering Group has been added (pg. 4, line 50. We hope that this addition provides sufficient clarification.

5. Also, the authors do not provide sufficient details regarding what they mean by purposive unstructured searches via the second iteration.

Response: Additional information has been added on pg. 8 line 126. These additional searches were conducted in line with RAMESES best practice recommendations (Wong et al., 2017) and were inspired by realist reviews conducted by Papoutsi et al. (2017) and Gee et al. (2016).
6. More information is needed regarding the subjective review specified on page 6, line 105. What criterion, if any, was this scale based on?

Response: Because realist reviews and rapid-realist reviews are more flexible in terms of what information is interpreted as relevant, there is a risk that the review will produce an unmanageably large sample. In fact, realist reviews have been criticised for being too expansive and that sampling could be near inexhaustible.

The subjective scoring and colour assignment process was a method used by the authors to organise and prioritise the articles identified during phase two. Those articles that received low scores were reviewed again and a team decision was made about their inclusion. There was no “official” criterion, reviewers simply provided a value from 1-10 to signify how useful they thought the article would be.

This approach was also developed by the review team as a deliberate attempt to enhance the transparency of what reviewers deemed as “relevant to programme theory refinement”. Often research papers will say things like “retrieved the full texts and classified them into categories of high and low relevance, depending on their relevance to programme theory development” (Papoutsi et al., 2017). Authors hoped the colour and numbering system would allow readers to better assess what papers the team were considering important in the analysis.

The following information has been added on pg 7 line 107: “Articles designated red and with a low score (≤4), were reviewed by authors again and their inclusion discussed.”

7. The details about provisional program theory are quite vague. Much of what the authors’ term theory presented in the results is quite confusing. It is not clear how the provisional and/or refined program "theories" are in fact theories. The italicized statements read more as summary statements and/or hypothesized bases for theoretical development. To state these as distinct theories is very confusing. This needs further clarification. If Nudge Theory is to be the primary theoretical basis for the authors conclusions, a much more robust discussion, including a review of the components of this theory, is needed. In general, Nudge Theory is insufficiently integrated throughout. If this is the primary theory around which the provisional/refined programmatic "theories" revolve, there needs to be much better integration of this.

Response: Details of the provisional program theory have been removed as an additional file and included as a figure (pg. 9 line 156). Authors have also included additional information about the provisional programme theory (see pg. 9 and 10).
Definitions for the terms “provisional” and “refined” programme theory have been provided (see glossary on pg. 4). Italicized statement are no longer referred to as “theories” but as CMOcs.

Definition of nudge theory and the default effect included within glossary of terms (pg. 4). Additional information on the default effect added (see pg. 9 line 165). Additional information added to CMOc headings, linking them to aspect of the default effect (see pg. 14 line 268 for example). CMOc related to cognitive effort separated from “CMOc: early testing and capacity to consent” and presented individually under test uptake (see pg. 17 line 332).

We hope we have now sufficiently integrated discussion of the default effect into the paper, we also use it to frame the discussion of test uptake (see pg 19 starting line 396).

8. The authors mention mediation a couple of times, what do they mean by this given in behavioural research the term has very specific connotations (which do not fit the way in which the term is used here).

Response: These terms have been removed from the manuscript.

Other comments

Page 13: In the section on theory one it would be interesting to know if any studies addressed issues/concerns of confidentiality with sharing of information to health care services (in particular GPs) based in the community

Response: Thank you for this comment. We reviewed included articles again and found little discussion surrounding the sharing of information to community services. Focus was placed on issues of confidentiality and stigma within the prison context. Authors feel that a discussion around information sharing would merit more space and time than can be provided within this section.
Page 18: line 372 some discussion of the implications of imposing an intervention that would not be currently mandated in a community setting would be useful

Response: Thank you for identifying this important point. We have added additional information as advised (pg 19, line 403).

Line 384: dried blood spot testing mentioned here but not in the results. Some discussion of the role of dried blood spot testing (as opposed to venepuncture or oral testing would be helpful in the introduction given its role, certainly in the UK context, of diagnoses within prison

Response: Thank you for this comment. Additional information has been included in the background (pg 2, line 20) and results section (pg 15, line 303).