Author’s response to reviews

Title: A type II implementation-effectiveness hybrid quasi-experimental pilot study of a clinical intervention to re-engage people living with HIV into care, ‘Lost & Found’: an implementation science protocol

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Author’s response to reviews:

Hamde Nazar
Pilot and Feasibility Studies

December 30, 2019

Dear Hamde Nazar and Vichithranie Madurasonghe,

Re: PAFS-D-19-00134

A type II implementation-effectiveness hybrid quasi-experimental pilot study of a clinical intervention to re-engage people living with HIV into care, 'Lost & Found': an implementation science protocol. Joseph Cox, MD MSc FRCPC; Blake Linthwaite, MScPH; Kim Engler, PhD; David Lessard, PhD; Bertrand Lebouché, MD PhD; Nadine Kronfli, MD MPH DTM&H FRCPC
Thank you for your review and related comments/questions. I am re-submitting the protocol taking into consideration your feedback, with tracked changes in the re-submitted documents and direct responses to your comments below.

Comment 1: “page 11 & 12, Aim 1 and 2: please can you add what you mean by the interim and cumulative effectiveness.”

RESPONSE: By ‘interim’, as detailed in Aim 1, we report on effectiveness and implementation outcomes during the delivery of the Lost & Found intervention. As such, we expect to report on how effectiveness and implementation outcomes changed over time based on data collected at time points detailed in Table 2: Data collection schedule. By ‘cumulative’, as detailed in Aim 2, we refer to the overall effectiveness of Lost & Found after implementation during a 12-month period. As a pre-post design, the pre-intervention level of reengagement for the year prior to delivery of Lost & Found will be compared with the overall level of reengagement during the year Lost & Found was delivered. An explicit definition for each has been added on page 13.

Comment 2: “please add the details of how OOC patients were identified and followed-up before the 'Lost and Found' implementation.”

RESPONSE: Additional details regarding how OOC patients were identified and followed-up before Lost & Found implementation have been added to Background (page 5).

Comment 3: “Authors described that 'Lost and Found' have two core elements 1) identifying and documenting OOC patients 2) contacting OOC patients. But the analysis model (i.e. Equation 1) proposed to use in the analysis, include only those patients identified as OOC (the offset), not all eligible for 'Lost and Found'. Please explain the reasons for this and add how authors proposed to assess the effectiveness of the first core element of this intervention.”
RESPONSE: Due to lacking information in the pre-implementation period (e.g., number of patients identified as OOC, contact efforts) it is not possible to consider the relative effectiveness of each core element. Nonetheless, we can still conduct an analysis of the overall effectiveness of the combined intervention. Our analysis retrospectively applies the RPT to the pre-implementation phase to determine a number of OOC patients expected. Then, based on clinical visits and the date the patient is marked OOC by the RPT, we can determine re-engagement rates in the pre-implementation phase, for comparison with rates in the implementation phase. Therefore, the proposed analysis model (i.e., Equation 1) is to determine the combined overall effectiveness of the whole intervention, both core elements (1. Identifying and documenting OOC patients and 2. Contacting OOC patients). It is limited to those patients flagged as OOC by the RPT because they are the only patients who could have received both core elements of the intervention. However, the nurse validation step, a peripheral component of the intervention, was excluded from this analysis. As discussed in ‘ii) Pre-post analysis: Implementation phase’ in section ‘Data analysis’ (page 19), limiting the determination of OOC to only those confirmed by nurses would have biased the pre-post comparison favoring the implementation period; fewer patients would be considered OOC following nurse validation, reducing the denominator in the implementation period and introducing bias. Additional clarifications were added to the protocol (pages 18-20).

Comment 4: “sustainability of 'Lost and Found' is assessed through quantitative analysis only? If not what other analysis methods are used, and why.”

RESPONSE: A combination of quantitative and qualitative data will be used for the sustainability analyses (the first three months of the sustainability phase, months 13 to 15, are included in Aim 1 analyses). However, given the short time frame, the primary focus of this analysis will be the quantitative pre-post analysis in Aim 2, and possibly complemented with the qualitative focus group information in Aim 1.

Again, thank you for this additional feedback. I hope the revised manuscript is acceptable for publication in Pilot and Feasibility Studies.

Best wishes,

Joseph Cox, MD MSc FRCP(C)

Associate Professor