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Title	Service delivery models for injectable opioid agonist treatment in Canada: two environmental scans
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Reviewer 1	Dr. Richard Elliott
Institution	Canadian HIV/AIDS Legal Network, Toronto, Ont.
General comments (author response in bold)	<p>Does the background accurately represent current knowledge in this field? To the best of my knowledge, yes.</p> <p>Do the authors explain why they conducted the study? Yes, clearly.</p> <p>Is there a clear research question? Yes.</p> <p>Is the study design appropriate? Yes.</p> <p>Are the methods described in enough detail? Did you find anything confusing? Yes, the methods are described clearly; nothing was confusing.</p> <p>You may wish to consider: participants, intervention, exposure, comparator, outcome, confounders, bias Given the nature of the research and the manuscript, these aren't particularly significant or relevant considerations in this case. The selection of participants (one key informant from each program) seems appropriate. Most of the data gathered is objective and quantitative and there is little reason informants would provide anything other than the most accurate data (about program type and details) they have. The "lessons learned" portion of the survey necessarily elicits more subjective, qualitative data, but the perspectives of the (appropriately-selected) key informants from each program is part of the added value of this research. I note that for this part of the data collection, the selected key informant was asked to liaise with other staff in the program to represent a range of perspectives. The authors note this in their description of the methods, which is good, as well as noting as a limitation that "data accuracy was reliant on key informant engagement with other staff." Given this, it might be good to report in a sentence or two somewhere (in the methods section, presumably), on the extent, if known, to which the key informant(s) did in fact engage other program staff in providing their assessment of barriers and facilitators</p> <p>EXCERPT FROM PEER REVIEWER 1 COMMENT above: "Given this, it might be good to report in a sentence or two somewhere (in the methods section, presumably), on the extent, if known, to which the key informant(s) did in fact engage other program staff in providing their assessment of barriers and facilitators."</p> <p>RESPONSE TO PEER REVIEWER 1 COMMENT above: We thank the reviewer for this useful feedback. We note your suggestion to</p>

provide further detail on program staff consultation. Unfortunately, we do not have this data for the baseline and follow-up scans, however, based on your suggestion, we will amend the survey to capture this information in the future. We have added new text in the Limitations to this effect:
“Data accuracy was reliant on program records and key informant engagement with other staff. Future follow-ups will solicit disclosure of this engagement (number and professional designation) for improved accountability.” Pg. 10

Are the results reasonable? Interesting? Surprising?

The results are informative, not surprising, and interesting - and useful for future policy development, program planning and delivery, and advocacy.

Is the interpretation supported by data in the results?

Yes.

Do tables and figures accurately represent the data? Would some other visual be more helpful?

The tables and figures are helpful.

Are any important limitations not mentioned?

None that I can think of.

Did you spot any fatal flaws? That is, errors you do not believe the authors could overcome. Please explain clearly.

No.

For whom are these findings relevant?

Policy makers, health services providers, and advocates.

Do the authors place their findings in the context of the literature?

Yes.

OTHER COMMENTS

1. Page 7 -- The phrase "meet clients where they are <u>at</u>" is grammatically incorrect; perhaps this can be corrected to simply "meet clients where they are", since it doesn't appear to be a direct quote, but rather invoking a commonly-used phrase. Picayune, I know.

We thank the reviewer for picking up on this error. On checking the data, we can confirm that it is a quote used by several programs and apologize for not using quotation marks in the first instance. This omission has now been corrected. (Pg. 9)

2. Page 5: The observation is made that the only one of the iOAT programs in which nurses administered doses was the hospital-based one. It invites the question as to why none of the other programs, in which nurses (and doctors) work, include this feature. Is this worth a comment?

We thank the reviewer for this feedback and agree that this is worth a comment. Next text has been added to the Clinical and Operational Characteristics subsection of the Results:

	<p>“The only exception was nurse-administered doses within a hospital-based program to meet institutional protocols prohibiting self-injection of drugs on-site.” (Pg. 6)</p>
Reviewer 2	Dr. Fady Hannah-Shmouni
Institution	National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, Md.
General comments (author response in bold)	<p>Eydt et al conducted a descriptive environmental scan of iOAT programs to support national expansion activities occurring as a part of the opioid overdose response and to address ongoing gaps in care. These findings are relevant to the government and associated entities responsible for developing iOAT programs. The study design is appropriate and the manuscript is well written.</p> <p>1. It would be helpful to clarify details of the phone interviews. Were the survey questions asked over the phone, or did the informants have access to a hard copy of the survey to answer questions prior to the phone interview? How many informants completed a phone interview vs. returned a written survey? For questions requiring consultation with other staff, were phone interviewees requested to follow up with this information? I think this is important to clarify because otherwise it is unclear if participants completing phone interviews had comparable opportunity to consult with staff and review the survey questions compared to those who completed a hard copy of the survey. We are grateful for these suggestions, and agree that this is indeed a highly important consideration. We hope that our response to the editors in Editors: Comment 3b has fully addressed this comment. (NA)</p> <p>2. The first paragraph under design (page 4 lines 6-14) could be moved to background information since it is not specific to the methods used in the study. We thank the reviewer for this suggestion and have moved this paragraph to the Introduction. (Pg. 3)</p> <p>3. Results on the number of programs analyzed could be improved. I think making the distinction between active and non-operational programs will mitigate this. It needs to be explicitly stated 11 programs participated at baseline, at follow-up three new programs were added and two were on-hold, for a total of 12 active programs at follow-up and overall 14 (active and non-operational) analyzed. We thank the reviewer for highlighting the need for further clarity in this description. To provide the reader with a clear understanding of the number of programs analysed as well as the number identified in the search strategy, we have revised text within the Programs subsection of the Results to report on each of these components separately. We have included your suggestions within this new text. “Fourteen eligible programs were identified; 11 at baseline, 12 at follow-up (three new programs identified, two baseline programs on-hold). Online searching yielded nine of these programs (1 primary, 8 grey literature). All nine programs were known to our service provider networks, which identified five additional eligible programs not found online. (Pg. 6) All 14 programs were invited to participate and all responded (Table 1).” We have also added new text within the Design subsection of the Methods to improve clarity on the status of non-operational programs at follow-up: “Non-operational programs at follow-up were ineligible to participate but were asked about discontinuation rationale. (Pg. 4)</p>

4. Regarding the barriers and facilitators section, the description “pharmacy issues” (page 6 line 36) is vague, please include a specific example of what is meant.

We thank the reviewer for this feedback and have amended the term “pharmacy issues” to “pharmacy operations” with examples:

“Limited program capacity, pharmacy operations (e.g. dispensing delays for programs with an internal pharmacy and paucity in community pharmacy partnership options for other programs) and lack of diacetylmorphine access were most commonly reported as barriers.” (Pg. 7)

The term “pharmacy operations” has also been revised in Table 4. (Table 4 (tracked))

5. It might be interesting for the authors to discuss their thoughts on why the two programs that were non-operational at follow-up were of the same service delivery model. Are there barriers specific to this model? Did the programs state how they plan to return to operation?

We thank the reviewer for this feedback and are pleased to provide further information on this situation.

The two pharmacy-based programs were both located in the Downtown Eastside in Vancouver and partnered with the same community pharmacy for iOAT maintenance doses. In this way, rather than two separate programs within the same model going on hold, issues within a single pharmacy necessitated these two programs going on hold.

To provide clarity, the relevant text has been revised within the Barriers and Facilitators subsection of Results to read:

“Rationale for the operational hold on two pharmacy-based programs included inadequate missed dose protocols, and challenges with dose adjustments at the shared community pharmacy; this created significant workload for staff and delays for clients.” (Pg. 7)

Changes have also been made elsewhere to reinforce this concept of a shared community pharmacy:

1. Service Delivery Models subsection in the Results:

“Four service delivery models were identified: 1) comprehensive/dedicated (wrap-around care exclusively for iOAT clients, two programs); 2) embedded/integrated (incorporation of iOAT within existing health and social services, eight programs); 3) hospital-based (iOAT provision during inpatient acute care, two programs); and 4) pharmacy-based (iOAT induction at a community health clinic with pharmacy maintenance, two programs sharing a community-based pharmacy). Appendix 2 has additional detail.” (Pg. 6)

2. Interpretation:

“Two pharmacy-based programs with a shared community pharmacy partner provided treatment to stabilized clients who did not require the more intensive wrap-around care offered in other models.¹⁴ (Pg. 9)

6. Regarding Table 1: Determining which programs were included at baseline, and those added at follow-up is confusing. Consider adding an additional table or flow diagram listing programs included at baseline, then at follow up. For the programs included at follow-up, distinguish which were active and which were non-

operational.

We thank the reviewer for this suggestion and acknowledge the importance of providing clarity on this point. To address this we have created a new Figure (now Figure 1) to visualise the start / end dates for all programs and to illustrate which participated in baseline and/or follow-up.

We kindly request that you also refer to our response to Peer Reviewer 2: Comment 3 for new text for clarity around participation of non-operational programs. (Figure 1)

7. No client feedback on how the services met their needs was requested.

We thank the reviewer for highlighting omission of this highly important perspective in the manuscript. Work in this area is already underway outside of the environmental scan. New text has been added to inform the reader about these activities in the Future Directions subsection of the Interpretation:

Interpretation:

“Comprehensive mixed methods evaluation of client experience is underway in British Columbia with national expansion anticipated.” (Pg. 10)

8. Citation #15 “Heroin-Assisted Treatment and Supervised Drug Consumption Sites” could be utilized more to provide context to how the structure and implementation of Canadian iOAT programs compare to other countries. This document provides valuable detail on programs specific to each country, client characteristics, drug administration, clinic set-up, etc. that would be interesting to compare with information obtained from the environmental survey.

We appreciate the reviewers’ suggestion to draw more thoroughly on this useful citation and have included new text to more firmly place Canadian iOAT service delivery within the international landscape. Similarly, we have also included additional context from the 2018 RAND Group working paper titled: ‘Heroin-assisted treatment and supervised drug consumption sites’ as the most recent publication providing a similar country based review of iOAT service delivery in Switzerland, the Netherlands, UK and Canada’.

This new text has been added to the Interpretation:

“Even where urban programs exist, capacity is commonly inadequate. This contrasts with many jurisdictions outside Canada; a 2012 European monitoring report noted that four out of six countries offering injectable heroin as routine treatment were not operating at capacity (Switzerland, the Netherlands, Spain and Denmark).¹²”

“Identified service delivery models are consistent with the Canadian Research Initiative in Substance Misuse iOAT guideline recommendations.⁴ The comprehensive/dedicated model mirrors the approach widely employed in Europe and the United Kingdom until 2013 (when national funding for supervised iOAT clinics was discontinued; injectable heroin can still be legally prescribed as a take-home medication though it rarely is).^{4,12,15} The most prevalent model, embedded/integrated, also exists in European jurisdictions, where injectable heroin is typically offered alongside other treatment modalities in addiction centres.^{12,15} Notably, implementation in Canada has extended the services in which iOAT was embedded (e.g. community health centre, supported housing, hospice, shelter). Adoption of this model enabled organizations to leverage existing infrastructure, resources and relationships to facilitate timely set-up and “meet clients

where they are at” in the community.”

“The others represent emerging models, that to our knowledge, were first implemented in Canada. Two pharmacy-based programs with a shared community pharmacy partner provided treatment to stabilized clients who did not require the more intensive wrap-around care offered in other models.¹⁴ Though on hold at follow-up, barriers associated with dose adjustments and missed-doses appear amenable to mitigation with robust clinical protocols. This model may offer a feasible, lower-cost approach to expansion, particularly in rural settings.²⁷ Injectable heroin has been available within a hospital-based outpatient setting in Europe,¹² however, inpatient iOAT appears to be novel and may be a valuable tool for client engagement in both acute care and opioid use disorder treatment.²⁸ Not identified in Canada are prison-based programs.^{12,15”}

“Co-prescription of oral OAT reflected practice in other jurisdictions.^{12,15} A central element of care was the provision of other health and social supports whether direct or indirect, such as referrals to nearby services, which aligns with the policy and practice outside of Canada.^{12,15} To achieve this approach to care, multi-disciplinary teams were the norm, though they varied in size and composition, both in Canada and elsewhere.¹² Interestingly, peer support workers were not reported in any programs outside of Canada.^{12,15”}

“Diacetylmorphine, the mainstay of iOAT programs internationally, has only been available in Canada outside of a clinical trial setting since September 2016, through Health Canada’s Special Access Program.³⁰ Access has remained limited to Vancouver’s Crosstown Clinic, a trial site,³¹ primarily because of regulations and reliance on diacetylmorphine importation from Switzerland.⁴ In contrast, hydromorphone is widely available, thus uniquely forming the foundations of iOAT in Canada. Widespread availability of two to three injections daily is aligned with other countries (except Spain which offers treatment on weekdays only).¹² Driven by client experience and advocacy, prescription of tablet hydromorphone was initiated as a pilot primarily for individuals who use illicit prescription opioids.^{32”} (Pg. 8-10)