

<b>Article details: 2014-0008</b>	
<b>Title</b>	Time to wake up: evidence from British Columbia for implementing take home naloxone programs in Canada
<b>Authors</b>	Oluwajenyo Banjo MPHc, Despina Tzemis MPH, Diana Al-Qutub MPH, Ashraf Amlani MPH, Sarah Kesselring MPH, Jane A Buxton MBBS MHSc
<b>Reviewer 1</b>	Sanju George
<b>Institution</b>	
<b>General comments</b>	I enjoyed reading this paper and have only one comment:  The qualitative analyses need to be more in depth. Why wasn't IPA used as a better methodology for analysis and presentation of qualitative findings?
<b>Reviewer 2</b>	Pierre-Paul Tellier
<b>Institution</b>	McGill University, Students Health Services
<b>General comments</b>	<p>This article describes the evaluation of a take home naloxone program in British Columbia. This is the first evaluation of the BC program and the second in Canada of such a program. The evaluation of a similar program in Edmonton was limited in the number of participants. Therefore, this paper provides relevant information about these programs in Canada.</p> <p>The Abstract describes the project clearly. I would suggest removing or rewording the last sentence in the conclusion. This comment sounds bias and "preachy", which further reinforces the statement in the Limitations researchers being affected by "their subjective experiences" thus potentially decreasing the validity of the study in the eye of the reader.</p> <p>The Introduction reviews the literature pertinent to the subject. The data presented at the end of the first paragraph from the Coroner Services and the BC Ambulance Services is helpful in understanding the scope of the problem in BC at the time of the implementation of the program. In the second paragraph it is said by the author that "naloxone has no pharmacological action", this is accurate according to Health Canada but studies are being performed by various groups to find other uses for this compound. I do not understand the second sentence in the fifth paragraph which should either be rewritten or taken out.</p> <p>Methods. The researchers stated that ethics approval was granted by the University of British Columbia but no mentioned is made that consent was obtained from the participants. The second sentence of the first paragraph indicates that a community advisory board was created. What was the role of this Board? Was this participatory research? If so, then it should be made clearer in this section.</p> <p>A requirement of qualitative research is a variability of participants. However, all the clients are from the same area and most of the individuals who had single interviews were also from the Vancouver area. The development of the interview questionnaires was based on literature and input from the community members which is appropriate. A different questionnaire was developed for each category of participants. It would be useful to know the similarity and dissimilarity of these questionnaires.</p> <p>Results. In reporting results of qualitative data it is customary to provide more identification of the participants, e.g. Nurse 1, Client 5 form group 1, so that the reader can judge that all the quotes are from the same individuals. This provides some evidence of a thorough evaluation of the data. It would be useful to have more quotes from clients for each of the themes. If this makes the article too long then all the quotes could be deleted from the text and placed in a chart.</p> <p>Interpretation: This portion is good but would benefit from a little editing as three paragraph start with "Service providers" and I find the first sentence of the third paragraph confusing and hard to understand.</p> <p>Conclusion: Same comment about the last statement as per abstract</p>
<b>Reviewer 3</b>	Miya Narushima
<b>Institution</b>	Brock University, Community Health Sciences
<b>General comments</b>	<p>Thank you for the opportunity to review this interesting article. I think that the paper should be published by CMAJ Open with substantial revisions. Please see my detailed comments and suggestions for the authors below.</p> <p>I found this a very interesting paper on an important public health issue (harm reduction for prevention of death from opioid overdose). The paper should be published by CMAJ Open with substantial revisions. Given that Take Home Naloxone (THN) programs are still relatively new in Canada, and the number of evaluative studies of the programs is still scarce, this paper presenting both the successes of and challenges facing the British Columbia Take Home Naloxone (BCTHN) program provides a useful reference for health care practitioners and policy makers to plan and implement similar programs in other regions and provinces. The evaluation was conducted in a comprehensive way, using both quantitative (descriptive statistics) and qualitative methods including the direct voices of various stakeholders (i.e., clients, service providers, police, and parents of opioid users), in a community-based research approach including the community advisory board.</p>

	<p>I think the authors can improve this article through: 1) adding a brief description of how reflexivity figures in their research (i.e., the positionality of the authors), 2) elaborating their data collection and analysis strategy, 3) improving their presentation of the results of the qualitative research part, and 4) raising the issue of future research needs in the conclusion.</p> <p>1) Regarding reflexivity, I assume that the authors are front-line practitioners directly involved in the BCTHN. Although the authors mentioned that “our subjective experiences may play a role in the quotes chosen and ideas presented” (l.26-29 in the limitation section), there is no description of who they are, why they did this study, and their relationship with the participants. Clearly positioning themselves should increase the trustworthiness of their qualitative study.</p> <p>2) As for methodology, I would suggest a little more detailed information about their data collection (e.g. How many participants per focus group?, How long did the focus groups and face-to-face interviews take?, Where were they conducted?, etc.). In addition, a more precise description of their coding process for the content analysis should help their audience understand where the major themes in the findings come from (e.g. Were some of the themes identified in advance based on the literature, or were all of them derived from the data?). Also, the authors should add information regarding their research ethics clearance.</p> <p>3) Although I understand the challenges involved in dealing with qualitative results in such limited space, I found the authors presented their results in an over-generalized way. In particular, I wondered whether the results presented under each theme fully captured the voices of as many as 40 client participants. Adding a few negative examples (i.e. deviant cases of people who didn’t fit the generalized pattern) can increase the scope and depth of the findings.</p> <p>In addition, it would be useful if the authors elaborated more on a typical training session (e.g. What do they teach?, How long does it usually take?), and the implementation challenges (e.g. How does the current funding mechanism work? Why is it difficult to identify physicians willing to prescribe Naloxone?). This type of information will increase the practical use of this article for some of its readers.</p> <p>I also found that some statements made in the discussion section were not supported by evidence. For example, the authors mentioned that “clients reported feeling empowered” (l.18, p.8 and l.49, p.11), and that service providers reported that “training increased client engagement and utilization of health care services” (l.11, p.12), without providing quotations to support these statements.</p> <p>4) In the limitations section, the authors should also mention that no clients from rural areas were included in this evaluation. Finally, in their conclusion, instead of enthusing that “it’s time to implement THN programs across Canada and save lives now”, given the limitation of the research, the authors should merely suggest that, based on the success of their program, other similar programs should be attempted. It is also important that the authors call for further research and evaluation to advocate for THN programs in Canada, given the potential personal risks caused by the program (for example, overconfidence resulting in the failure of clients to seek medical attention), and structural challenges (the difficulty in reaching certain clients, including those prescribed opioids for chronic pain, the “sustainability” of this type of program, etc.),</p> <p>I hope that these comments and suggestions will help optimize the effectiveness of this interesting article on a most important topic.</p> <p>Miya Narushima Associate Professor Department of Health Sciences Brock University</p>
<p><b>Author response</b></p>	<p><b>Reviewer 1:</b></p> <p>1. (Methods): Why wasn't IPA used as a better methodology for analysis and presentation of qualitative findings?</p> <p>The authors would like to thank the reviewer for his/her comment. The research team used a broad descriptive qualitative analysis for this manuscript as it is appropriate for this initial evaluation of the BCTHN program. We feel that the results are easy to understand and can help inform future research. We do appreciate the suggestion from the reviewer and in future we will consider using Interpretative Phenomenological Analysis in our methodology.</p> <p><b>Reviewer 2:</b></p>

Comment from Dr. Tellier: The Introduction reviews the literature pertinent to the subject. The data presented at the end of the first paragraph from the Coroner Services and the BC Ambulance Services is helpful in understanding the scope of the problem in BC at the time of the implementation of the program.

Thank you for your comment. We worked with our partners at the Coroner Services and BC Ambulance Services to obtain this data and provide a detailed picture of the situation in BC.

1. (Abstract): I would suggest removing or rewording the last sentence in the conclusion.

The authors have revised the abstract and have removed the last sentence in the conclusion as suggested. See Editor's Comments #6.

2. (Introduction): In the second paragraph it is said by the author that "naloxone has no pharmacological action", this is accurate according to Health Canada but studies are being performed by various groups to find other uses for this compound.

Thank you for your comment. The authors appreciate that there are other studies currently examining naloxone's pharmacological action. Therefore, the authors have removed the statement "naloxone has no pharmacological action..." from the Introduction in order to address the Editor's concerns of the length of the Introduction and the need to keep the background succinct. See Editor's Comments #7.

3. (Introduction): I do not understand the second sentence in the fifth paragraph which should either be rewritten or taken out.

The authors appreciate your insights and have removed this sentence from the manuscript. This also helps address the Editor's comments to shorten the Introduction. See Editor's Comments #7.

4. (Methods): The researchers stated that ethics approval was granted by the University of British Columbia but no mention is made that consent was obtained from the participants.

We have added the following sentence (page 5): "Informed consent was obtained verbally from focus group participants and in writing from individual interviewees."

5. (Methods): The second sentence of the first paragraph indicates that a community advisory board was created. What was the role of this Board? Was this participatory research? If so, then it should be made clearer in this section.

This was not a participatory research project. We have added the following sentence (page 5-6): "A BCTHN community advisory board (CAB) including membership from THN site coordinators, police and people who use drugs was developed. CAB members assisted in developing the question guides and recruiting participants for individual interviews as discussed below." In the subsequent paragraphs, we mention (page 6) "Following a literature review and input from CAB members, we developed semi-structured interview guides...", (page 7) "The Vancouver Police Department member on the CAB identified front line officers to interview".

6. (Methods): A requirement of qualitative research is a variability of participants. However, all the clients are from the same area and most of the individuals who had single interviews were also from the Vancouver area.

Thank you for your comment. The BCTHN program is a relatively new initiative and during its infancy most individual sites were implemented in the Vancouver area. For this initial evaluation (and taking into account funding restrictions) all focus groups and most interviews were conducted in the Vancouver area where the research team was also based. However, this is an ongoing evaluation and in future we will attempt to conduct in person focus groups and interviews in other areas of BC with clients. To help reflect this reality in the manuscript we have added the following:

(page 7 - Methods): Vancouver was chosen as the region for client recruitment since it had the greatest number of BCTHN sites that were actively running at the time of the study, and because these sites are accessed by a diverse clientele.

(page 9 - Results): Although focus group participants were recruited from the Vancouver area, they varied widely in age (24-62 years), sex (28% female, 60% male, 12% unknown), level of education (none – post secondary) and years of substance use (<1 yr to >45 years).

(page 16 - Limitations): Findings from this first evaluation of the BCTHN program may differ from future evaluations when more qualitative data are collected from sites are implemented outside the Vancouver region. Since most BCTHN sites were first implemented in the Vancouver region during its initial roll-out, most qualitative FGs and interviews were conducted in this region; however, the study team did reach out to health workforce in the Interior region, which had the second largest number of participating sites.

7. The development of the interview questionnaires was based on literature and input from the community members which is appropriate. A different questionnaire was developed for each category of participants. It would be useful to know the similarity and dissimilarity of these questionnaires.

Thank you for your comment. The authors have added the following section to provide some clarity around the question posed above (page 7): Interview guides were relatively similar across stakeholder groups. Difference lay in the depth and specificity of some questions that were most relevant to that stakeholder. For example, educators may have expanded on the training materials developed, while police may have focused on misconceptions about the program and community awareness.

8. (Results): In reporting results of qualitative data it is customary to provide more identification of the participants, e.g Client 5 form group 1, so that the reader can judge that all the quotes are from the same individuals. It would be useful to have more quotes from clients for each of the themes. If this makes the article too long then all the quotes could be deleted from the text and placed in a chart.

Thank you for your comments. As suggested we have included Table 5 to highlight a few more quotes to support each theme represented in the results section. We have also taken your suggestion and removed the quotes from the text as we are mindful of the word limit. The following statement has been included in the manuscript (page 9): Key quotes that highlight these themes are shown in Table 5.

In addition, we have now appropriately labeled each quote.

9. (Interpretation): This portion is good but would benefit from a little editing as three paragraph start with "Service providers" and I find the first sentence of the third paragraph confusing and hard to understand.

We have edited the manuscript to improve the writing style as suggested. Edits can be seen on page 15.

The third paragraph now starts off with: Service providers described difficulties Other challenges described by service providers included recruiting engaging people with long-term opioid use to participate in the THN program, because long-term users seem to as they may underestimate their personal risk and believe they have adopted sufficient harm reduction strategies to prevent overdose.

10. (Conclusion): Same comment about the last statement as per abstract

We appreciate your feedback and have revised the concluding paragraph in the following way (page 17): Our findings highlight the success of the BCTHN program and suggest other communities across Canada should consider implementing THN programs to prevent harms from opioid overdoses. Additional research is needed to determine the success of such programs in rural or remote settings, as well as for patients who are prescribed opioids.

**Reviewer 3:**

1. (Methods): Regarding reflexivity, I assume that the authors are involved in the BCTHN. Although the authors mentioned that "our subjective experiences may play a role in the quotes chosen and ideas presented" (ll.26-29 in the limitation section), there is no description of who they are, why

they did this study, and their relationship with the participants. Positioning themselves should increase the trustworthiness of their qualitative study.

Thank you for your insights. We hope the following edits will clarify the author's position to the study and increase the trustworthiness in our results.

Regarding author description: The authors felt that when the article is published their connection to the BCTNH program would be assumed from their affiliation; however, you raise a good point and this should be made clear in the methods section. On page 7, we have now added the following: Two investigators (one graduate student and one BCCDC epidemiologist) conducted each focus group...

Furthermore, the author's affiliation could be linked from the information stated on page 8: DA, OB and JB independently analyzed the data using content analysis and a qualitative descriptive approach which is a low-inference analytic approach.]

Regarding why authors did the study: We hope the clarity around the objectives in the Introduction Section will help readers understand the why the authors did this study (page 5): BC has the only Canadian provincial THN program in continuous operation for over 20 months. Our objective is to report on the BCTHN program's key measures (participation and overdose reversals) and This paper describes the program's successes, challenges, and recommendations from the its first evaluation of the BCTHN program using quantitative and qualitative methods. We present the perspectives of program stakeholders: i.e. clients and service providers, from sites participating in the initial roll-out of the program, and police and parents of people who use opioids. This paper will add to the limited literature available in Canada providing relevant insight for those considering participation in, and implementation of, THN programs in Canada.

Regarding the authors relationship with the participants:

We hoped the revisions around the recruitment strategy has helped clarify this:

(page 6): CAB members assisted in developing the question guides and recruiting participants for individual interviews as discussed below;

(page 7): Clients were recruited by program staff at that BCTHN site

(page 7-8): The Vancouver Police Department member on the CAB identified front line officers to interview. Parents of people who use opioids were recruited through parent support groups.

We have also added Figure 1, which shows the role of, and processes followed by, BCTHN sites and the authors (all affiliated with BCCDC). We hope this addresses concerns about our position and credibility in the study.

2. (Methods): I would suggest a little more detailed information about their data collection (e.g. How many participants per focus group?, How long did the focus groups and face-to-face interviews take?, Where were they conducted?, etc.).

The authors have revised the manuscript to include more detail about the data collection (page 7): Two investigators (one graduate student and one BCCDC epidemiologist) conducted each focus group which took approximately one hour (one moderated while the other took field notes). One investigator conducted 20 minute interviews with clients. Service providers at BCTHN sites, including nurses, coordinators, and physicians, were emailed invitations invited to participate in an interview which took approximately one hour through e-mail. The Vancouver Police Department member on the CAB identified front line officers to interview. Parents of people who use opioids were recruited through parent support groups. Interviews were conducted over the phone or in person at a location which was convenient to the interviewee.

And page 9: Client feedback was gathered from 4 focus groups (4-7 individuals per group) and 20 face-to-face interviews;

3. (Methods): A more precise description of their coding process for the content analysis should help their audience understand where the major themes in the findings come from (e.g. Were some of the themes identified in advance based on the literature, or were all of them derived from the data?).

The authors are mindful of the word count, but to help highlight the where the major themes came from the authors have highlighted segments from our manuscript below and made the following

revisions:

(page 5-6) A BCTHN community advisory board (CAB) including membership from THN site coordinators, police and people who use drugs was developed. CAB members assisted in developing the question guides and recruiting participants for individual interviews as discussed below

(page 6) Following a literature review and input from CAB members, we developed semi-structured interview guides...

(page 8) Initial coding was informed and led by the interview guides but was constantly refined as simultaneous collection and analysis provided new insights that prompted changes in interview guides and analysis.

4. (Methods): The authors should add information regarding their research ethics clearance.

Thank you for your comment. This aligns with the comments from the other reviewer. We have added the following sentence (page 5): Ethics approval was obtained from the University of British Columbia and appropriate health authority Research Ethics Boards. Informed consent was obtained verbally from focus group participants and in writing from individual interviewees.

5. (Methods): I understand the challenges involved in dealing with qualitative results in such limited space, I found the authors presented their results in an over-generalized way. In particular, I wondered whether the results presented under each theme fully captured the voices of as many as 40 client participants. Adding a few negative examples (i.e. deviant cases of people who didn't fit the generalized pattern) can increase the scope and depth of the findings.

We thank you for your comments. Your concerns were similarly expressed by Dr. Tellier and we have made revision to address this concern. Please see Comments to Dr. Tellier Q.#8 for details.

In addition, we must say that there were no deviant cases of 'clients who didn't fit the generalized pattern'. The only negative findings were from those highlighted in the manuscript by police officers who had misconceptions. We have addressed this pattern in our limitations section in the following way: (page 16): Opinions expressed by study participants may differ from those of the general community as they were a convenience sample selected from those currently enrolled in the BCTHN program and may have been most supportive of the BCTHN program.

6. (General): It would be useful if the authors elaborated more on a typical training session (e.g. What do they teach?, How long does it usually take?), and the implementation challenges (e.g. How does the current funding mechanism work? Why is it difficult to identify physicians willing to prescribe Naloxone?). This type of information will increase the practical use of this article for some of its readers.

Thank you for your comments and interest in the BCTHN program.

Regarding Training: The authors have provided some details about the program to set the stage for the study, however, due to word limitation it may be challenging to include details about the training. We have added a figure to the introduction that displays the SAVE ME acronym that describes the overdose response protocol covered in the training. The second paragraph in the introduction (page 4-5) now reads: Training, which includes overdose prevention, recognition and response using the S.A.V.E. M.E. procedure (Figure 2), is provided to people who use opioids, their family and friends, and service providers.

To refer readers who are interested in learning more about the training and the BCTHN program, we have also included the following (page 5): For more information about the BCTHN program visit: [www.towardtheheart.com/naloxone](http://www.towardtheheart.com/naloxone).

Regarding how does the current funding mechanism work? The authors reflected upon this comment and felt it was necessary to not only address the funding mechanism, but to describe the BCTHN program in greater detail. Therefore, a new section was added to the methods (page 6):

#### BCTHN sites/program setting

The BCCDC Harm Reduction Program operates the BCTHN program, which is responsible for developing training materials, enrolling sites and supplying the overdose prevention kits. BCTHN sites are existing health units or community agencies partnered with health care providers (Figure 1). BCTHN sites are responsible for training and dispensing kits to eligible clients, and reporting their

progress to BCCDC. This study took advantage of the existing program structure: administrative records were reviewed for the quantitative component and participants were recruited from existing BCTHN sites for the qualitative component.

In addition, Figure 1 illustrates the relationships and roles of the BCTHN program at the BCCDC, the THN sites, and the Regional Health Authority.

Regarding why is it difficult to identify physicians willing to prescribe Naloxone: To address this question, we have now included a discussion piece around physician willingness to prescribe naloxone (page 15): There are a limited number of physicians in BC's smaller communities that work with people who use psychoactive substances and within a harm reduction model. Without a local champion to support administrative and training activities or any financial incentives, physicians may find the program time-consuming and may be reluctant to participate.

7. (Discussion): Some statements made were not supported by evidence. For example, the authors mentioned that "clients reported feeling empowered" (l.18, p.8 and l.49, p.11), and that service providers reported that "training increased client engagement and utilization of health care services" (l.11, p.12), without providing quotations to support these statements.

Thank you for your comment. We have included a section in the results entitled, "Client Empowerment" in order to support the statements given in the discussion (page 14):

#### Client Empowerment

Clients reported a strong sense of pride for taking part in the BCTHN program and for having learnt the skills to potentially save someone's life. The majority of clients discussed feelings of empowerment and confidence in responding to an overdose event.

In addition, Table 5 has been added which has more quotes to help support statements in the discussion section and the following quote exemplifies utilization of health care services: one fellow revealed that he hadn't had a physical exam for 6 years so there are other things, other opportunities to talk about health issues. " – Coordinator [Educator] #1, Rural

However, the authors do agree it was not our main objective/findings and have removed the following statement about service utilization from the abstract (page 2-3): Service providers found the program training materials easy to use and that training increased improved client engagement and increased utilization of healthcare services.

8. (Limitations): Authors mentioned that no clients from rural areas were included in this evaluation. Finally, in their conclusion, instead of enthusing that "it's time to implement THN programs across Canada and save lives now", given the limitation of the research, the authors should merely suggest important that the authors call for further research and evaluation to advocate for THN programs in Canada, given the potential personal risks caused by the program (for example, overconfidence resulting in the failure of clients to seek medical attention), and structural challenges (the difficulty in reaching certain clients, including those prescribed opioids for chronic pain, the "sustainability" of this type of program, etc.)

We appreciate your feedback and the above comment was also suggested by Dr. Tellier. We have revised the concluding paragraph in the following way (page 17): Our findings highlight the success of the BCTHN program and suggest other communities across Canada should consider implementing THN programs to prevent harms from opioid overdoses. Additional research is needed to determine the success of such programs in rural or remote settings, as well as for patients who are prescribed opioids.