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# BMJ Open

## Rates of opioid agonist treatment prescribing in provincial prisons in Ontario, Canada, 2015 to 2018: A repeated cross-sectional analysis

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|-------------------------------|---|
| Journal:                      | <i>BMJ Open</i>   |
| Manuscript ID                 | bmjopen-2021-048944   |
| Article Type:                 | Original research   |
| Date Submitted by the Author: | 11-Jan-2021   |
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| Keywords:                     | MENTAL HEALTH, PRIMARY CARE, Forensic psychiatry < PSYCHIATRY,<br>Substance misuse < PSYCHIATRY, PUBLIC HEALTH, FORENSIC<br>MEDICINE  |
|                               |   |

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3 **Rates of opioid agonist treatment prescribing in provincial prisons in Ontario,**  
4 **Canada, 2015 to 2018: A repeated cross-sectional analysis**  
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L8P1H6  
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34 Manuscript Word Count: 2608  
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**Abstract****Objective:**

To describe opioid agonist treatment prescribing rates in provincial prisons and compare with community prescribing rates.

**Design:**

We used quarterly, cross-sectional data on the number and proportion of people prescribed opioid agonist treatment in prison populations. Trends were compared with Ontario surveillance data from prescribers, reported on a monthly basis.

**Setting:**

Provincial prisons and general population in Ontario, Canada between 2015 and 2018.

**Participants:**

Adults incarcerated in provincial prisons and people ages 15 years and older in Ontario.

**Main Outcomes and Measures:**

Opioid agonist treatment prescribing prevalence, defined as treatment with methadone or buprenorphine/naloxone.

**Results:**

In prison, 6.9% to 8.4% of people were prescribed methadone; 0.8% to 4.8% buprenorphine/naloxone; and 8.2% to 13.2% either treatment over the study period. Between 2015 and 2018, methadone prescribing prevalence did not substantially change in prisons or in the general population. The prevalence rate of buprenorphine/naloxone prescribing increased in prisons by 1.70 times per year (95%CI 1.47-1.96), which was significantly higher than the increase in community prescribing: 1.20 (95%CI 1.19-1.21). Buprenorphine/naloxone prescribing prevalence was significantly different across prisons.

**Conclusions:**

Opioid agonist treatment prescribing increased between 2015 and 2018 in provincial prisons in Ontario, Canada due to increased buprenorphine/naloxone prescribing, and increased more in prisons than in the general population.

**Article Summary:**

Strengths of this study

- 1  
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3 - This is the first study describing the rates of opioid agonist treatment prescribing  
4 in a prison population over time and during the opioid overdose crisis.  
5  
6 - We used whole population prescribing rates for people in prisons and in the  
7  
8 community.  
9

#### 10 Limitations of this study

- 11  
12 - We lack data on the prevalence of opioid use disorder to determine opioid agonist  
13 treatment coverage for people with opioid use disorder.  
14

#### 15 **Keywords:**

16 Opioid-Related Disorders, Addiction Medicine, Prisons, Prisoners, Opiate Substitution  
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18 Treatment  
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## Background

There is a substantial burden of opioid-related morbidity and mortality in people who experience incarceration in Canada.<sup>1-4</sup> Research consistently identifies high rates of substance use disorders in this population,<sup>5-10</sup> and a majority of people report recent drug use at the time of admission to custody,<sup>7,8,11-14</sup> including use of opioids,<sup>12</sup> and a substantial proportion use drugs in custody.<sup>8,13,15-17</sup> People who experience incarceration commonly engage in behaviours such as injecting drugs,<sup>5,11,12,14,16,18-23</sup> sharing needles and other paraphernalia,<sup>5,18,20,23-25</sup> and polysubstance use,<sup>7,11</sup> which increase the risk of harms such as overdose and bloodborne infections. Further, evidence from Ontario reveals that the risk of death from overdose is high in this population compared to the general population, in particular at the time of release.<sup>1,2</sup> Not only do people in prison have higher rates of illicit substance use, but people who use drugs have higher rates of incarceration in the context of the criminalization of drug use.<sup>26</sup>

Opioid agonist treatment (OAT) is the first line treatment for opioid use disorder (OUD), and the standard of care across Canada.<sup>27</sup> OAT provides a long-acting opioid medication that binds to opioid receptors and prevents drug cravings and opioid withdrawal symptoms. OAT reduces both all-cause and overdose mortality.<sup>28</sup> In incarcerated populations, OAT reduces HIV transmission and complications, hepatitis C transmission and complications, and mortality after release, and improves a host of other health, social, and psychological outcomes.<sup>29-32</sup> Implementation of a state-wide correctional OAT program in Rhode Island produced a 60.5% reduction in overdose mortality rates within 1 year of release from prison.<sup>33</sup> OAT may also positively impact recidivism, but available evidence is limited in quantity and quality.<sup>34</sup>

Though challenges to access remain, OAT is widely available in the community and is being rapidly scaled in response to the current opioid overdose crisis. Canadian and international law confers an obligation to provide equivalent care in prison. The United Nations Standard Minimum Rules for the Treatment of Prisoners, also known as the Nelson Mandela Rules, were adopted by the UN General Assembly in 2015 and call for prison health care services that are comparable to community services and continuity of care from the community to prison and back again.<sup>35</sup> Despite the burden of opioid-related morbidity and mortality, evidence of OAT effectiveness, and the principle of

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3 equivalence, access to OAT in correctional facilities is often limited. A recent qualitative  
4 study of OAT prescribing in provincial correctional facilities in Ontario demonstrated  
5 that many physicians working in this setting do not prescribe OAT, and a minority  
6 initiate OAT for patients in custody.<sup>36</sup> Quantitative data from Vancouver, British  
7 Columbia revealed that among 597 recently incarcerated people with opioid use disorder,  
8 only 35% were prescribed OAT while in custody, and less than 10% of those prescribed  
9 OAT in custody were new initiations.<sup>37</sup>

10 Information on OAT use in people in prison is important to understand whether this  
11 population has access to this evidence-based treatment, which could mitigate the risk of  
12 harms for people who experience incarceration. We aimed to describe rates of OAT  
13 prescribing in provincial prisons in Ontario, Canada between 2015 and 2018, and  
14 compared this with rates of OAT prescribing in the community.

## 25 **Methods**

### 26 *Context*

27  
28 Provincial prisons in Canada hold adults aged 18 years and older who are awaiting trial  
29 or sentencing, or who are sentenced to less than 2 years in prison. In Ontario, provincial  
30 prisons are publicly funded and administered by the Ministry of the Solicitor General. We  
31 use the term “provincial prison” to represent all provincial correctional facilities, and  
32 “people who experience incarceration” to represent the population of those who  
33 experience detention and incarceration in provincial prisons, and “in custody” to refer to  
34 the time while in a provincial prison.

35  
36 For Ontario residents, hospitalizations and medically necessary physician services are  
37 paid for through the public health insurance system, the Ontario Health Insurance Plan  
38 (OHIP), including while in provincial prison. In custody, prescribed medications are paid  
39 for by the Ministry of the Solicitor General. In the community, a subset of OHIP-eligible  
40 people are eligible for coverage of prescribed medication costs through the Ontario Drug  
41 Benefit (ODB) program, including people aged 65 years or older, and people who receive  
42 benefits based on financial need and employment status or disability.

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44 Regarding health care in Ontario provincial prisons, people are routinely assessed by a  
45 nurse on admission, which includes a history of prescribed medications and substance  
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3 use. They are then seen by a physician or nurse practitioner in the ensuing weeks or  
4 sooner if medically indicated. The physician or nurse practitioner may order prescribed  
5 medications without seeing a patient, e.g., at the time of admission for continuity of  
6 medication, or after assessing the patient. The model of care in Ontario prisons requires  
7 that every facility have at least one OAT prescriber but does not require all primary care  
8 physicians to prescribe OAT, which may represent a barrier to accessing OAT. As this  
9 study was a review of administrative health data, patients and the public were not  
10 consulted in the development of this study.  
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### 19 ***Data Sources***

20 The Ministry of the Solicitor General provided quarterly snapshot data between 2015 and  
21 2018 on the number and proportion of people in each provincial prison who were  
22 prescribed buprenorphine/naloxone and methadone, which were the two forms of OAT  
23 available during the period under study. These snapshots were aggregate cross-sectional  
24 data of people prescribed these treatments on a single day. These data are routinely  
25 reported by health care staff in each provincial prison to the Ministry of the Solicitor  
26 General. The Ministry of the Solicitor General also provided data on the number of  
27 people in each prison. Data were not available by age-group or gender. One prison closed  
28 in 2018 but data for that prison were included up to that date (i.e., excluding the last two  
29 time periods).  
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38 We accessed data on OAT use rates and proportions in the community between 2015 and  
39 2018 using publicly available data from the Narcotics Monitoring System (NMS), which  
40 included people ages 15 and older who received methadone or buprenorphine/naloxone  
41 in Ontario between January 1 2015 and December 31 2018. The NMS is administered by  
42 Ontario's Ministry of Health and collects information from dispensers on all prescribed  
43 monitored drugs dispensed to people in the community in Ontario (i.e., not including  
44 people in hospital or in provincial prisons), including buprenorphine/naloxone and  
45 methadone. We accessed these data through the Ontario Prescription Opioid Tool, which  
46 is a publicly available tool that presents data on the number and rates of people  
47 prescribed all opioids, including OAT, in Ontario.<sup>38</sup> These data are available as counts  
48 (absolute number of prescriptions) and a rate per 1000 population on a monthly and  
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3 yearly basis. Yearly data are available by sex, and by age groups. Age groups are 0-14,  
4 15-24, 25-44, 45-64, and 65+ years of age. Data for OAT were presented for ages 15 and  
5 older and so our analyses use data for age 15 and older.  
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### 8 9 10 ***Statistical Analysis***

11 We describe the rates of prescribed OAT as the percent of people in the applicable study  
12 population receiving OAT in the time period of data capture (prevalence rates expressed  
13 as percent or per population size). We also estimated the rate of change in OAT  
14 prescribing prevalence between February 2015 and September 2018 across provincial  
15 prisons and the rate of change in prescribing in the community over the same time period.  
16 Rates of change were expressed as prevalence rate ratios (PRR) per year and were  
17 estimated using Poisson regression with robust standard errors. Prevalence rates of opioid  
18 agonist prescribing for all of Ontario were graphed by time. We performed simple Wald  
19 contrasts to determine if the PRRs for OAT prescribing, using pooled data across prisons,  
20 were significantly different ( $\alpha$  level of .05) from the overall provincial rates of change, in  
21 the 2015 to 2018 time period.  
22

23 Variability in OAT prescribing across prisons and over time, was illustrated using box-  
24 plot graphs. These present the median prescribing rate, across prisons, the 25<sup>th</sup> and 75<sup>th</sup>  
25 percentiles for prescribing rates and markers for prisons with prescribing rates outside  
26 this range. Hypothesis tests assessed if the observed differences in prescribing rates  
27 across prisons were statistically significant as a main effect. These were conducted as  
28 overall significance tests for a main effect in prescribing rate across prison (global test for  
29 all prisons being different from the overall mean rate). Tests for overall differences across  
30 prisons were performed using negative binomial regression controlling for time of  
31 reporting. For tests of statistical significance,  $\alpha$  was set at .05. Analyses were performed  
32 using Stata software, version 16 (StataCorp).  
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### 50 **Results**

51 We examined data for 26 provincial prisons. We had cross-sectional prescribing data for  
52 provincial prisons at two time points in 2015, four time points in 2016, four time points in  
53 2017, and two time points in 2018. During the period under study, the cross-sectional  
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3 population size for the included provincial prisons ranged from 11 people in the smallest  
4 prison to 1,096, and the total population across the 26 provincial prisons ranged between  
5 7,140 and 8,122.  
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8 Over the study period and across provincial prisons, the total percentage of people treated  
9 with methadone ranged between 6.9% and 8.4%, with buprenorphine/naloxone ranged  
10 between 0.8% and 4.8%, and with either treatment ranged between 8.2% and 13.2%  
11 (Figure 1).  
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14 As shown in Table 1, methadone prescribing did not increase significantly in the prison  
15 population between 2015 and 2018, and it decreased by a factor of 0.99 per year in the  
16 whole population. In contrast, buprenorphine/naloxone prescribing increased  
17 significantly in provincial prisons as well as in the whole population: the prevalence rate  
18 increased in provincial prisons by a factor of 1.70 per year, which was significantly  
19 higher than the increase in prescribing for the whole population, where the prevalence  
20 rate increased by 1.20 times per year.  
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23 The percentage of people prescribed OAT was variable across provincial prisons, as  
24 shown in Figure 2. Methadone prescribing across prisons was fairly consistent over the  
25 time period. Buprenorphine/naloxone prescribing across prisons increased over the time  
26 period with the median prevalence, and 25<sup>th</sup> and 75<sup>th</sup> percentiles all increasing over the  
27 period under study. Relative to the overall pattern for methadone,  
28 buprenorphine/naloxone prescribing was more variable across prisons, with several  
29 prisons being outliers with prescribing rates far higher than those seen in the lower 75%  
30 of all prisons.  
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33 The difference in prescribing prevalence between prisons was statistically significant, as  
34 a main effect for prison, and beyond variability by chance. Results for the global tests  
35 contrasting prevalence across all 26 prisons relative to the provincial average in prisons  
36 (testing as a main effect) were statistically significant ( $p < 0.001; 25df$ ) in all cases. Results  
37 from likelihood ratio tests for prisons after controlling for date of data collection were  
38 similarly statistically significant for all three models for methadone,  
39 buprenorphine/naloxone and overall OAT ( $p < 0.001; 25df$ ). The same modeling confirmed  
40 that there was no statistically significant trend over time in for methadone prescribing,  
41 during this time window (there was no trend treating date as a continuous variable or for  
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3 reporting date treated as categorical). All analyses found significant effects for both date  
4 (i.e., trend over time) and across prisons (as a categorical main effect) for  
5 buprenorphine/naloxone prescribing and any OAT prescribing.  
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## 10 **Discussion**

11 This study demonstrates that rates of OAT prescribing increased over the study period in  
12 provincial prisons. This may reflect increased need over time, as opioid-related  
13 emergency department visits and mortality in Ontario increased year-over-year from  
14 2015 to 2018 and hospitalizations increased every year but one from 2015 to 2018.<sup>39</sup> It  
15 may also reflect changes in accessibility or acceptance of OAT in Ontario prisons. We  
16 also found there were highly variable rates of OAT prescribing across provincial prisons  
17 for the same time period, which is unlikely to be solely attributable to variation in patient  
18 eligibility for and interest in treatment. Some of the difference in rates of OAT  
19 prescribing between prisons may reflect regional variability in community prescribing,  
20 which we did not assess in this study.  
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29 This study has several limitations. Information on OAT prescribing was only available as  
30 quarterly point-in-time data. These data do not differentiate between initiation of OAT  
31 and continuation of OAT in provincial prison, and this information would be relevant for  
32 developing interventions to improve OAT access and quality in prisons. In the absence of  
33 individual-level clinical data, we are unable to examine characteristics of individuals  
34 treated over time or assess whether there was continuity of OAT on admission and  
35 release. We are also not able to understand whether people have access to OAT, e.g.,  
36 whether people were offered OAT on admission if indicated, or indicators of high-quality  
37 OAT, such as whether dose was increased in a timely fashion and whether a therapeutic  
38 dose was achieved. Further information from charts and from people in prisons would  
39 provide additional information. Information on OAT receipt and OAT coverage in the  
40 community was available in age groups that did not match the age group of the  
41 incarcerated population; community data was presented for the age group of 15 years of  
42 age and older, while the incarcerated population was ages 18 and up.  
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53 A recent study of Berlin prisons examined similar questions regarding prevalence of  
54 OAT prescribing.<sup>40</sup> They found that 6.8% of the incarcerated population was on OAT.  
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3 We found a substantially higher prevalence rate, which may be due to differing need  
4 between these two contexts. Our study adds to that by including data over a several year  
5 period, for a large population, in North America during opioid overdose crisis, and  
6 compares across institutions and with community. In comparison theirs is very recent and  
7 only examines a single point in time; however, they were able to determine the  
8 prevalence of opioid dependence and thus look at treatment coverage.  
9

10 While it is encouraging to see an upward trend in correctional OAT prescribing in this  
11 population, the degree to which treatment needs are being met in this setting remains  
12 unclear as we lack data on the prevalence of opioid use disorder in people in Ontario  
13 provincial prisons. To support health system and treatment planning, research is needed  
14 to determine the prevalence of opioid use disorder and to describe OAT access, initiation  
15 and continuity for people who experience incarceration. Such work would be facilitated  
16 through the use of clinical data as well as administrative data, and the lack of an  
17 electronic medical record in Ontario provincial prisons is a current barrier to data  
18 collection and analysis. In addition, research should explore differences between prisons  
19 that may prevent or promote access to high quality OAT, and facilitators to OAT access  
20 in other jurisdictions that have successfully improved OAT access.  
21

22 Research and public health interventions should also consider the structural forces that  
23 create an environment where people who use drugs are more likely to experience  
24 incarceration. Criminalization of drug use ipso facto leads to incarceration, and structural  
25 factors such as homelessness and poverty create conditions that further increase the risk  
26 of incarceration. Of particular importance are the ways that racism and colonization  
27 shape drug policy, the policing of Black and Indigenous people, and the over-  
28 incarceration of Black and Indigenous people in Canada. Increasing OAT access may  
29 reduce the likelihood of subsequent incarceration.<sup>41</sup>  
30

31 This study demonstrates that OAT prescribing increased substantially between 2015 and  
32 2018 in provincial prisons in Ontario, Canada. Furthermore, there was significant  
33 variation in prescribing prevalence between different prisons. Future research is needed  
34 on opioid use disorder prevalence in people in prisons and on institutional and systems  
35 level factors that promote or inhibit access to OAT. In the meantime, health and  
36 correctional staff and administration should work to support universal access to high  
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3 quality OAT for people with opioid use disorder in provincial prison and after release.  
4 Supporting treatment for opioid use disorder could prevent the substantial burden and  
5 harms associated with opioid use in this population.  
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### 10 **Author Contributions**

11 F. Kouyoumdjian conceived and supervised the study. S. Bondy completed the analyses.  
12 C. Bodkin contributed to study design and wrote the first draft of the manuscript. All  
13 authors contributed to interpretation of analyses, revised the manuscript, and approved  
14 the final version.  
15

### 16 **Funding Statement**

17 This work was supported by the Canadian Research Initiative in Substance Misuse.  
18

### 19 **Competing Interests**

20 L. Regenstreif received honoraria from Indivior for giving presentations on Sublocade  
21 and for Advisory Board participation on Sublocade and Suboxone film. We have no other  
22 competing interests to disclose.  
23

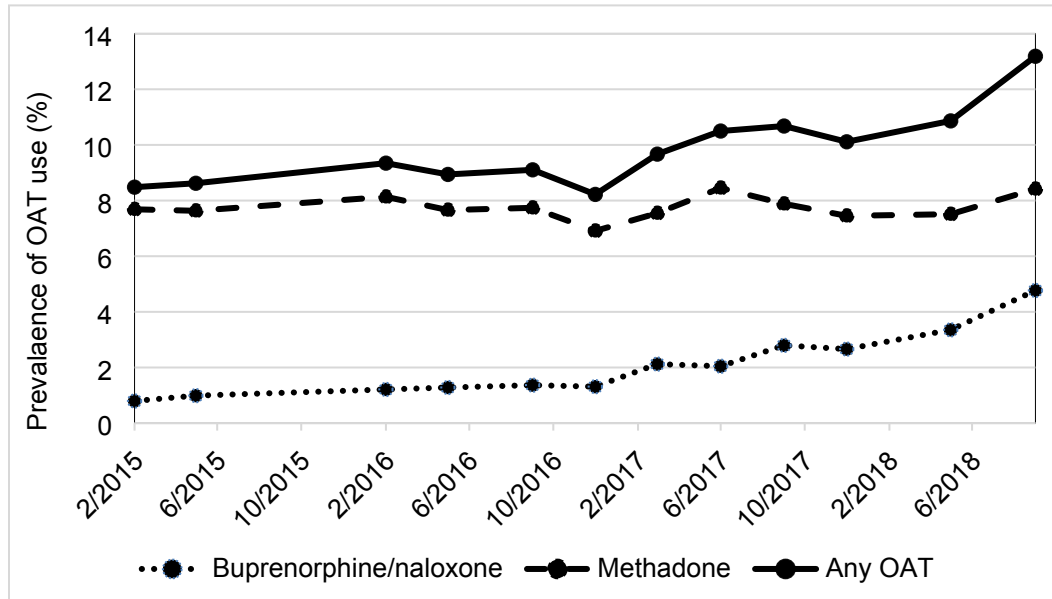
### 24 **Ethics**

25 This study was approved by the Hamilton Integrated Research Ethics Board (#5878).  
26

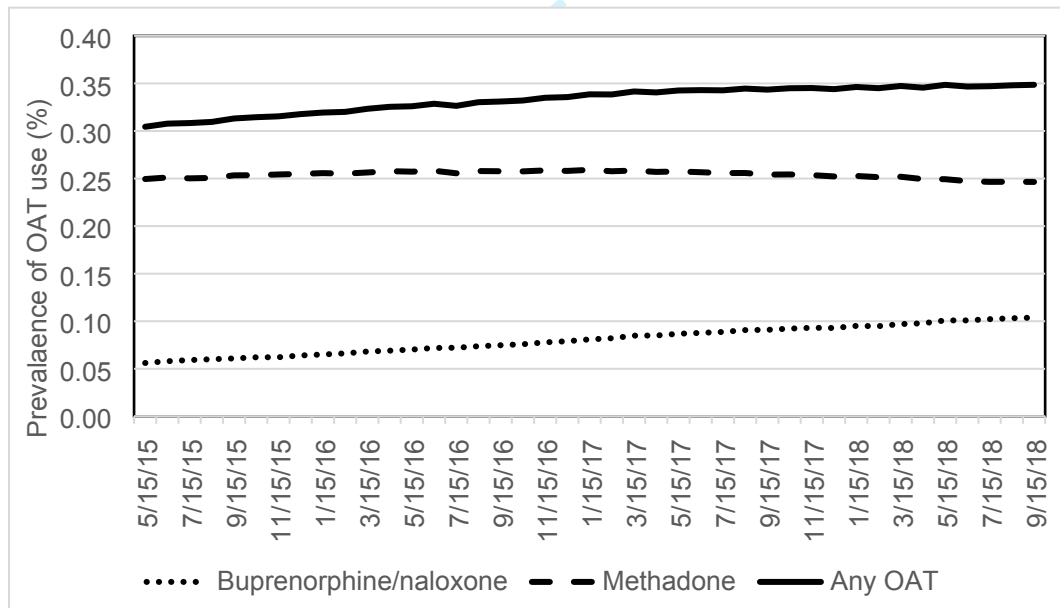
### 27 **Data sharing statement**

28 We are not able to share data because of restrictions specified in our Research Agreement  
29 with the Ministry of the Solicitor General. To request access to data, interested persons  
30 could contact [mescsresearch@ontario.ca](mailto:mescsresearch@ontario.ca).  
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Figure 1. Percentage of people prescribed OAT in provincial prisons and in the whole population in Ontario, 2015 to 2018 by OAT type



Ontario provincial prisons



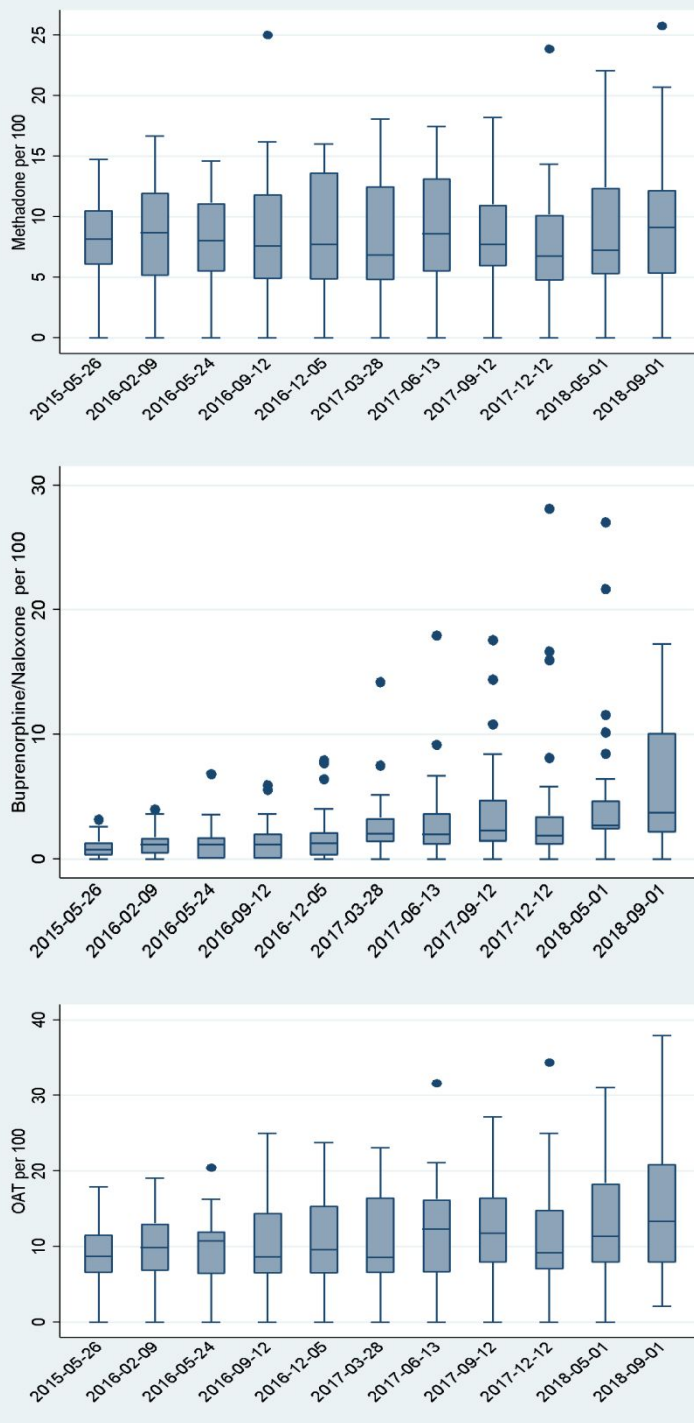
Ontario whole population

**Table 1.** Prevalence rate ratio of trends in prescribed methadone, buprenorphine/naloxone or either in Ontario, Canada, 2015 to 2018

|                        | Provincial prison population* |        |      | Whole population |        |       | Are PRRs different? |                   |         |
|------------------------|-------------------------------|--------|------|------------------|--------|-------|---------------------|-------------------|---------|
|                        | PRR                           | 95% CI |      | PRR              | 95% CI |       |                     | p value for trend |         |
| Methadone              | 1.01                          | 0.94   | 1.09 | 0.77             | 0.99   | 0.999 | 0.034               | p=0.078           |         |
| Buprenorphine/naloxone | 1.70                          | 1.47   | 1.96 | 0.000            | 1.20   | 1.19  | 1.21                | 0.000             | p<0.001 |
| Any OAT                | 1.12                          | 1.04   | 1.21 | 0.003            | 1.04   | 1.04  | 1.04                | 0.000             | p<0.001 |



**Figure 2.** Boxplots\* of percent of people prescribed methadone, buprenorphine/naloxone or either per quarter across provincial prisons in Ontario, 2015 to 2018



\*The centre line indicates the median prevalence of prescribing, and the box shows the range in rates for the 25<sup>th</sup> and 75<sup>th</sup> percentiles for prevalence of prescribing; dots indicate provincial prisons with extreme prevalence rates.

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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

|                              | Item No | Recommendation  | Page No    |
|------------------------------|---------|---|------------|
| <b>Title and abstract</b>    | 1       | (a) Indicate the study's design with a commonly used term in the title or the abstract  | 1          |
|                              |         | (b) Provide in the abstract an informative and balanced summary of what was done and what was found   | 2-3        |
| <b>Introduction</b>          |         |   |            |
| Background/rationale         | 2       | Explain the scientific background and rationale for the investigation being reported  | 4          |
| Objectives                   | 3       | State specific objectives, including any prespecified hypotheses  | 5          |
| <b>Methods</b>               |         |   |            |
| Study design                 | 4       | Present key elements of study design early in the paper   | 6,7        |
| Setting                      | 5       | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection   | 5,6,7      |
| Participants                 | 6       | (a) Give the eligibility criteria, and the sources and methods of selection of participants   | 6,7        |
| Variables                    | 7       | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable  | 4,6        |
| Data sources/<br>measurement | 8*      | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group              | 6,7        |
| Bias                         | 9       | Describe any efforts to address potential sources of bias   | N/A        |
| Study size                   | 10      | Explain how the study size was arrived at   | 6,7        |
| Quantitative variables       | 11      | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why  | 7          |
| Statistical methods          | 12      | (a) Describe all statistical methods, including those used to control for confounding   | 7          |
|                              |         | (b) Describe any methods used to examine subgroups and interactions   | 7          |
|                              |         | (c) Explain how missing data were addressed   | N/A        |
|                              |         | (d) If applicable, describe analytical methods taking account of sampling strategy  | N/A        |
|                              |         | (e) Describe any sensitivity analyses   | N/A        |
| <b>Results</b>               |         |   |            |
| Participants                 | 13*     | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 7,8        |
|                              |         | (b) Give reasons for non-participation at each stage  | N/A        |
|                              |         | (c) Consider use of a flow diagram  | N/A        |
| Descriptive data             | 14*     | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  | 5,6,7      |
|                              |         | (b) Indicate number of participants with missing data for each variable of interest   | N/A        |
| Outcome data                 | 15*     | Report numbers of outcome events or summary measures  | 8,12,13,14 |

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|----------------------------|--------------------------|----|--|------------|
| 1<br>2<br>3<br>4<br>5<br>6 | Main results             | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 8.12.13.14 |
| 7<br>8<br>9                |                          |    | (b) Report category boundaries when continuous variables were categorized  | N/A        |
| 10<br>11                   |                          |    | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period   | N/A        |
| 12<br>13<br>14             | Other analyses           | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses   | 8,9        |
| 15                         | <b>Discussion</b>        |    |  |            |
| 16                         | Key results              | 18 | Summarise key results with reference to study objectives   | 9          |
| 17<br>18<br>19<br>20       | Limitations              | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias   | 9          |
| 21<br>22<br>23<br>24       | Interpretation           | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence                                   | 9,10       |
| 25<br>26                   | Generalisability         | 21 | Discuss the generalisability (external validity) of the study results  | 10         |
| 27                         | <b>Other information</b> |    |  |            |
| 28<br>29<br>30<br>31       | Funding                  | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based  | 11         |

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## Rates of opioid agonist treatment prescribing in provincial prisons in Ontario, Canada, 2015 to 2018: A repeated cross-sectional analysis

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|---------------------------------|--|
| Journal:                        | <i>BMJ Open</i>  |
| Manuscript ID                   | bmjopen-2021-048944.R1   |
| Article Type:                   | Original research  |
| Date Submitted by the Author:   | 12-Sep-2021  |
| Complete List of Authors:       | Bodkin, Claire; Hamilton, Department of Family Medicine<br>Bondy, Susan ; University of Toronto<br>Regenstreif, Leonora; McMaster University Department of Family Medicine<br>Kiefer, Lori; University of Toronto, Dalla Lana School of Public Health;<br>Ontario Ministry of Community Safety and Correctional Services<br>Kouyoumdjian, Fiona; McMaster University Faculty of Health Sciences, Department of Family Medicine |
| <b>Primary Subject Heading</b>: | Addiction  |
| Secondary Subject Heading:      | Evidence based practice, Health policy, Legal and forensic medicine, Mental health, Public health  |
| Keywords:                       | MENTAL HEALTH, PRIMARY CARE, Forensic psychiatry < PSYCHIATRY, Substance misuse < PSYCHIATRY, PUBLIC HEALTH, FORENSIC MEDICINE   |
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3 **Rates of opioid agonist treatment prescribing in provincial prisons in Ontario,**  
4 **Canada, 2015 to 2018: A repeated cross-sectional analysis**  
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33 Manuscript Word Count: 2855  
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**Abstract****Objective:**

To describe opioid agonist treatment prescribing rates in provincial prisons and compare with community prescribing rates.

**Design:**

We used quarterly, cross-sectional data on the number and proportion of people prescribed opioid agonist treatment in prison populations. Trends were compared with Ontario surveillance data from prescribers, reported on a monthly basis.

**Setting:**

Provincial prisons and general population in Ontario, Canada between 2015 and 2018.

**Participants:**

Adults incarcerated in provincial prisons and people ages 15 years and older in Ontario.

**Main Outcomes and Measures:**

Opioid agonist treatment prescribing prevalence, defined as treatment with methadone or buprenorphine/naloxone.

**Results:**

In prison, 6.9% to 8.4% of people were prescribed methadone; 0.8% to 4.8% buprenorphine/naloxone; and 8.2% to 13.2% either treatment over the study period. Between 2015 and 2018, methadone prescribing prevalence did not substantially change in prisons or in the general population. The prevalence rate of buprenorphine/naloxone prescribing increased in prisons by 1.70 times per year (95%CI 1.47-1.96), which was significantly higher than the increase in community prescribing: 1.20 (95%CI 1.19-1.21). Buprenorphine/naloxone prescribing prevalence was significantly different across prisons.

**Conclusions:**

The increase in opioid agonist treatment prescribing between 2015 and 2018 in provincial prisons shows that efforts to scale up access to treatment in the context of the opioid overdose crisis have included people who experience incarceration in Ontario. Further work is needed to understand unmet need for treatment, and treatment impacts.

**Article Summary:**

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3 Strengths of this study  
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- 5 - This is the first study describing the rates of opioid agonist treatment prescribing  
6 in a prison population over time and during the opioid overdose crisis.  
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8 - We used whole population prescribing rates for people in prisons and in the  
9 community.  
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11 Limitations of this study  
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- 13 - We lack data on the prevalence of opioid use disorder to determine opioid agonist  
14 treatment coverage for people with opioid use disorder.  
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17 **Keywords:**

18 Opioid-Related Disorders, Addiction Medicine, Prisons, Prisoners, Opiate Substitution  
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## Background

There is a substantial burden of opioid-related morbidity and mortality in people who experience incarceration in Canada.<sup>1-4</sup> Research consistently identifies high rates of substance use disorders in this population,<sup>5-10</sup> and a majority of people report recent drug use at the time of admission to custody,<sup>7,8,11-14</sup> including use of opioids,<sup>12</sup> and a substantial proportion use drugs in custody.<sup>8,13,15-17</sup> Reliable estimates of opioid use disorder prevalence among incarcerated and non-incarcerated people in Ontario are not available. This represents an important information gap and barrier to planning, delivery, and evaluation of efforts address opioid related harms in this setting. One Ontario study of adult males incarcerated in a provincial prison in 2009 found that 10.4% reported injection non-heroin opioid use in the year prior to incarceration, while 4.4% reported injection heroin use during the same time period.<sup>12</sup> This is an order of magnitude higher than Jacka et al's estimate that 0.63% of the entire Ontario population used any drug intravenously in 2011.<sup>18</sup> People who experience incarceration commonly engage in behaviours such as injecting drugs,<sup>5,11,12,14,16,19-24</sup> sharing needles and other paraphernalia,<sup>5,19,21,24-26</sup> and polysubstance use,<sup>7,11</sup> which increase the risk of harms such as overdose and bloodborne infections. Further, evidence from Ontario reveals that the risk of death from overdose is high in this population compared to the general population, in particular at the time of release.<sup>1,2</sup> Not only do people in prison have higher rates of illicit substance use, but people who use drugs have higher rates of incarceration in the context of the criminalization of drug use.<sup>27</sup>

Opioid agonist treatment (OAT) is the first line treatment for opioid use disorder (OUD), and the standard of care across Canada.<sup>28</sup> OAT provides a long-acting opioid medication that binds to opioid receptors and prevents drug cravings and opioid withdrawal symptoms. OAT reduces both all-cause and overdose mortality.<sup>29</sup> In incarcerated populations, OAT reduces HIV transmission and complications, hepatitis C transmission and complications, and mortality after release, and improves a host of other health, social, and psychological outcomes.<sup>30-33</sup> Implementation of a state-wide correctional OAT program in Rhode Island produced a 60.5% reduction in overdose mortality rates within 1 year of release from prison.<sup>34</sup> OAT may also positively impact recidivism, but available evidence is limited in quantity and quality.<sup>35</sup>

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3 Though challenges to access remain, OAT is widely available in the community and is  
4 being rapidly scaled in response to the current opioid overdose crisis. Canadian and  
5 international law confers an obligation to provide equivalent care in prison. The United  
6 Nations Standard Minimum Rules for the Treatment of Prisoners, also known as the  
7 Nelson Mandela Rules, were adopted by the UN General Assembly in 2015 and call for  
8 prison health care services that are comparable to community services and continuity of  
9 care from the community to prison and back again.<sup>36</sup> Despite the burden of opioid-related  
10 morbidity and mortality, evidence of OAT effectiveness, and the principle of  
11 equivalence, access to OAT in correctional facilities is often limited. A recent qualitative  
12 study of OAT prescribing in provincial correctional facilities in Ontario demonstrated  
13 that many physicians working in this setting do not prescribe OAT, and a minority  
14 initiate OAT for patients in custody.<sup>37</sup> Quantitative data from Vancouver, British  
15 Columbia revealed that among 597 recently incarcerated people with opioid use disorder,  
16 only 35% were prescribed OAT while in custody, and less than 10% of those prescribed  
17 OAT in custody were new initiations.<sup>38</sup>  
18 Information on OAT use in people in prison is important to understand whether this  
19 population has access to this evidence-based treatment, which could mitigate the risk of  
20 harms for people who experience incarceration. We aimed to describe rates of OAT  
21 prescribing in provincial prisons in Ontario, Canada between 2015 and 2018, and  
22 compared these rates with rates of OAT prescribing in the community.  
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## 39 **Methods**

### 40 ***Context***

41 Provincial prisons in Canada hold adults aged 18 years and older who are awaiting trial  
42 or sentencing, or who are sentenced to less than 2 years in prison. In Ontario, provincial  
43 prisons are publicly funded and administered by the Ministry of the Solicitor General. We  
44 use the term “provincial prison” to represent all provincial correctional facilities, and  
45 “people who experience incarceration” to represent the population of those who  
46 experience detention and incarceration in provincial prisons, and “in custody” to refer to  
47 the time while in a provincial prison.  
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3 For Ontario residents, hospitalizations and medically necessary physician services are  
4 paid for through the public health insurance system, the Ontario Health Insurance Plan  
5 (OHIP), including while in provincial prison. In custody, prescribed medications are paid  
6 for by the Ministry of the Solicitor General. In the community, a subset of OHIP-eligible  
7 people are eligible for coverage of prescribed medication costs through the Ontario Drug  
8 Benefit (ODB) program, including people aged 65 years or older, and people who receive  
9 benefits based on financial need and employment status or disability.

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11 Regarding health care in Ontario provincial prisons, people are routinely assessed by a  
12 nurse on admission, which includes a history of prescribed medications and substance  
13 use. They are then seen by a physician or nurse practitioner in the ensuing weeks or  
14 sooner if medically indicated. The physician or nurse practitioner may order prescribed  
15 medications without seeing a patient, e.g., at the time of admission for continuity of  
16 medication, or after assessing the patient. The model of care in Ontario prisons requires  
17 that every facility have at least one OAT prescriber but does not require all primary care  
18 physicians to prescribe OAT, which may represent a barrier to accessing OAT. As this  
19 study was a review of administrative health data, patients and the public were not  
20 consulted in the development of this study.  
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### 34 ***Data Sources***

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36 The Ministry of the Solicitor General provided quarterly snapshot data between 2015 and  
37 2018 on the number and proportion of people in each provincial prison who were  
38 prescribed buprenorphine/naloxone and methadone, which were the two forms of OAT  
39 available during the period under study. These snapshots were aggregate cross-sectional  
40 data of people prescribed these treatments on a single day. These data are routinely  
41 reported by health care staff in each provincial prison to the Ministry of the Solicitor  
42 General. The Ministry of the Solicitor General also provided data on the number of  
43 people in each prison. Data were not available by age-group or gender. One prison closed  
44 in 2018 but data for that prison were included up to that date (i.e., excluding the last two  
45 time periods).  
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53 We accessed data on OAT use rates and proportions in the community between 2015 and  
54 2018 using publicly available data from the Narcotics Monitoring System (NMS), which  
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3 included people ages 15 and older who received methadone or buprenorphine/naloxone  
4 in Ontario between January 1 2015 and December 31 2018. The NMS is administered by  
5 Ontario's Ministry of Health and collects information from dispensers on all prescribed  
6 monitored drugs dispensed to people in the community in Ontario (i.e., not including  
7 people in hospital or in provincial prisons), including buprenorphine/naloxone and  
8 methadone. We accessed these data through the Ontario Prescription Opioid Tool, which  
9 is a publicly available tool that presents data on the number and rates of people  
10 prescribed all opioids, including OAT, in Ontario.<sup>39</sup> These data are available as counts  
11 (absolute number of prescriptions) and a rate per 1000 population on a monthly and  
12 yearly basis. Yearly data are available by sex, and by age groups. Age groups are 0-14,  
13 15-24, 25-44, 45-64, and 65+ years of age. Data for OAT were presented for ages 15 and  
14 older and so our analyses use data for age 15 and older.

15  
16 We obtained study approval from the Hamilton Integrated Research Ethics Board  
17 (#5878). Consistent with the Tri-Council Policy Statement: Ethical Conduct for Research  
18 Involving Humans- TCPS 2 (2018), we did not obtain individual consent for study  
19 participation; we accessed only aggregate data and it would not be feasible to identify or  
20 contact those whose data we used.<sup>40</sup>

### 21 22 23 24 25 26 27 28 29 30 31 32 33 34 ***Statistical Analysis***

35  
36 We describe the rates of prescribed OAT as the percent of people in the applicable study  
37 population prescribed OAT in the time period of data capture (prevalence rates expressed  
38 as percent or per population size). We also estimated the rate of change in OAT  
39 prescribing prevalence between February 2015 and September 2018 across provincial  
40 prisons and the rate of change in prescribing in the community over the same time period.  
41 Rates of change were expressed as prevalence rate ratios (PRR) per year and were  
42 estimated using Poisson regression with robust standard errors. Prevalence rates of opioid  
43 agonist prescribing for all of Ontario were graphed by time. We performed simple Wald  
44 contrasts to determine if the PRRs for OAT prescribing, using pooled data across prisons,  
45 were significantly different ( $\alpha$  level of .05) from the overall provincial rates of change, in  
46 the 2015 to 2018 time period.  
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3 Following prior work on variations in prescribing practices across provincial prisons, we  
4 also explored variability in OAT prescribing across prisons and over time.<sup>37</sup> We used  
5 box-plot graphs, which present the median prescribing rate, the 25<sup>th</sup> and 75<sup>th</sup> percentiles  
6 for prescribing rates and markers for prisons with prescribing rates outside this range.  
7  
8 Hypothesis tests assessed if the observed differences in prescribing rates across prisons  
9 were statistically significant as a main effect. These were conducted as overall  
10 significance tests for a main effect in prescribing rate across prison (global test for all  
11 prisons being different from the overall mean rate). Tests for overall differences across  
12 prisons were performed using negative binomial regression controlling for time of  
13 reporting. For tests of statistical significance,  $\alpha$  was set at .05. Analyses were performed  
14 using Stata software, version 16 (StataCorp).

#### 23 24 *Patient and Public Involvement*

25 Three of the authors have clinical practices caring for people who are currently or  
26 formerly incarcerated. The research question emerged from their patient's experiences of  
27 trying to access OAT while incarcerated. There was no formal patient or public  
28 involvement in the project design, data collection, or analysis.  
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#### 34 **Results**

35 We examined data for 26 provincial prisons. We had cross-sectional prescribing data for  
36 provincial prisons at two time points in 2015, four time points in 2016, four time points in  
37 2017, and two time points in 2018. During the period under study, the cross-sectional  
38 population size for the included provincial prisons ranged from 11 people in the smallest  
39 prison to 1,096, and the total population across the 26 provincial prisons ranged between  
40 7,140 and 8,122.  
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43 Over the study period and across provincial prisons, the total percentage of people treated  
44 with methadone ranged between 6.9% and 8.4%, with buprenorphine/naloxone ranged  
45 between 0.8% and 4.8%, and with either treatment ranged between 8.2% and 13.2%  
46 (Figure 1).  
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52 As shown in Table 1, methadone prescribing did not increase significantly in the prison  
53 population between 2015 and 2018, and decreased by a factor of 0.99 per year in the  
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3 whole population. In contrast, buprenorphine/naloxone prescribing increased  
4 significantly in provincial prisons as well as in the whole population: the prevalence rate  
5 increased in provincial prisons by a factor of 1.70 per year, which was significantly  
6 higher than the increase in prescribing for the whole population, where the prevalence  
7 rate increased by 1.20 times per year.  
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11 The percentage of people prescribed OAT was variable across provincial prisons, as  
12 shown in Figure 2. Methadone prescribing across prisons was fairly consistent over the  
13 time period. Buprenorphine/naloxone prescribing across prisons increased over the time  
14 period with the median prevalence, and 25<sup>th</sup> and 75<sup>th</sup> percentiles all increasing over the  
15 period under study. Relative to the overall pattern for methadone,  
16 buprenorphine/naloxone prescribing was more variable across prisons, with several  
17 prisons being outliers with prescribing rates far higher than those seen in the lower 75%  
18 of all prisons.  
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21 The difference in prescribing prevalence between prisons was statistically significant, as  
22 a main effect for prison, and beyond variability by chance. Results for the global tests  
23 contrasting prevalence across all 26 prisons relative to the provincial average in prisons  
24 (testing as a main effect) were statistically significant ( $p < 0.001; 25df$ ) in all cases. Results  
25 from likelihood ratio tests for prisons after controlling for date of data collection were  
26 similarly statistically significant for all three models for methadone,  
27 buprenorphine/naloxone and overall OAT ( $p < 0.001; 25df$ ). The same modeling confirmed  
28 that there was no statistically significant trend over time in for methadone prescribing,  
29 during this time window (there was no trend treating date as a continuous variable or for  
30 reporting date treated as categorical). All analyses found significant effects for both date  
31 (i.e., trend over time) and across prisons (as a categorical main effect) for  
32 buprenorphine/naloxone prescribing and any OAT prescribing.  
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## 48 **Discussion**

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50 This study demonstrates that rates of OAT prescribing increased over the study period in  
51 provincial prisons. This may reflect increased need over time, as opioid-related  
52 emergency department visits and mortality in Ontario increased year-over-year from  
53 2015 to 2018 and hospitalizations increased every year but one from 2015 to 2018.<sup>41</sup> It  
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3 may also reflect changes in accessibility or acceptance of OAT in Ontario prisons. We  
4 also found there were highly variable rates of OAT prescribing across provincial prisons  
5 for the same time period, which is unlikely to be solely attributable to variation in patient  
6 eligibility for and interest in treatment. Some of the difference in rates of OAT  
7 prescribing between prisons may reflect regional variability in community prescribing,  
8 which we did not assess in this study.  
9

10 This study has several limitations. Information on OAT prescribing was only available as  
11 quarterly point-in-time data. These data do not differentiate between initiation of OAT  
12 and continuation of OAT in provincial prison, and this information would be relevant for  
13 developing interventions to improve OAT access and quality in prisons. In the absence of  
14 individual-level clinical data, we are unable to examine characteristics of individuals  
15 treated over time or assess whether there was continuity of OAT on admission and  
16 release. We are also not able to understand whether people have access to OAT, e.g.,  
17 whether people were offered OAT on admission if indicated, or indicators of high-quality  
18 OAT, such as whether dose was increased in a timely fashion and whether a therapeutic  
19 dose was achieved. Further information from charts and from people in prisons would  
20 provide additional information. Information on OAT receipt and OAT coverage in the  
21 community was available in age groups that did not match the age group of the  
22 incarcerated population; community data was presented for the age group of 15 years of  
23 age and older, while the incarcerated population was ages 18 and up.  
24

25 A recent study of Berlin prisons examined similar questions regarding prevalence of  
26 OAT prescribing.<sup>42</sup> They found that 6.8% of the incarcerated population was on OAT.  
27 We found a substantially higher prevalence rate, which may be due to differing need  
28 between these two contexts. Our study adds to that by including data over a several year  
29 period, for a large population, in North America during opioid overdose crisis, and  
30 compares across institutions and with community. In comparison theirs is very recent and  
31 only examines a single point in time; however, they were able to determine the  
32 prevalence of opioid dependence and thus look at treatment coverage.  
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34 Describing the rates and variability in OAT prescribing in prisons provides stakeholders  
35 with a starting point to understand and address gaps in access to evidence-based first line  
36 treatment for opioid use disorder within the provincial prison system. While it is  
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3 encouraging to see an upward trend in correctional OAT prescribing in this population,  
4 the degree to which treatment needs are being met in this setting remains unclear as we  
5 lack data on the prevalence of opioid use disorder in people in Ontario provincial prisons.  
6 To support health system and treatment planning, research is needed to determine the  
7 prevalence of opioid use disorder and to describe OAT access, initiation and continuity  
8 for people who experience incarceration. Such work would be facilitated through the use  
9 of clinical data as well as administrative data, and the lack of an electronic medical record  
10 in Ontario provincial prisons is a current barrier to data collection and analysis. In  
11 addition, research should explore differences between prisons that may prevent or  
12 promote access to high quality OAT, and facilitators to OAT access in other jurisdictions  
13 that have successfully improved OAT access.  
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15  
16 Research and public health interventions should also consider the structural forces that  
17 create an environment where people who use drugs are more likely to experience  
18 incarceration. Criminalization of drug use ipso facto leads to incarceration, and structural  
19 factors such as homelessness, poverty, racism, and colonization create conditions that  
20 further increase the risk of incarceration. Lack of access to OAT in prison in turn  
21 exacerbates the health effects of structural oppression. Increasing OAT access may also  
22 reduce the likelihood of subsequent incarceration.<sup>43</sup>  
23

24  
25 This study demonstrates that OAT prescribing increased substantially between 2015 and  
26 2018 in provincial prisons in Ontario, Canada. Furthermore, there was significant  
27 variation in prescribing prevalence between different prisons. Future research is needed  
28 on opioid use disorder prevalence in people in prisons and on institutional and systems  
29 level factors that promote or inhibit access to OAT. In the meantime, health and  
30 correctional staff and administration should work to support universal access to high  
31 quality OAT for people with opioid use disorder in provincial prison and after release.  
32 Supporting treatment for opioid use disorder could prevent the substantial burden and  
33 harms associated with opioid use in this population.  
34

### 51 **Author Contributions**

52  
53 FK conceived and supervised the investigation and contributed to study design. SB  
54 directed the statistical analyses and contributed to study design. CB contributed to study  
55

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3 design and wrote the first draft of the manuscript. LK and FK contributed to data  
4 acquisition. FK, SB, CB LK, and LR contributed to interpretation of analyses, critically  
5 reviewed and revised the manuscript, and approved the final version.  
6  
7

### 8 **Funding Statement**

9  
10 Funding support was provided by the Canadian Institutes of Health Research through the  
11 Canadian Research Initiative in Substance Misuse (SMN-139150).  
12

### 13 **Competing Interests**

14  
15 L. Regenstreif received honoraria from Indivior for giving presentations on Sublocade  
16 and for Advisory Board participation on Sublocade and Suboxone film. We have no other  
17 competing interests to disclose.  
18  
19

### 20 **Ethics**

21  
22 This study was approved by the Hamilton Integrated Research Ethics Board (#5878).  
23

### 24 **Data sharing statement**

25 We are not able to share data because of restrictions specified in our Research Agreement  
26 with the Ministry of the Solicitor General. To request access to data, interested persons  
27 could contact [mcscsresearch@ontario.ca](mailto:mcscsresearch@ontario.ca).  
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3 Figure 1. Percentage of people prescribed OAT in provincial prisons and in the whole  
4 population in Ontario, 2015 to 2018 by OAT type  
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For peer review only

**Table 1.** Prevalence rate ratio of trends in prescribed methadone, buprenorphine/naloxone or either in Ontario, Canada, 2015 to 2018

|                        | Provincial prison population* |        |                   | Whole population |        |                   | Are PRRs different? |       |         |
|------------------------|-------------------------------|--------|-------------------|------------------|--------|-------------------|---------------------|-------|---------|
|                        | PRR                           | 95% CI |                   | PRR              | 95% CI |                   |                     |       |         |
|                        |                               |        | p value for trend |                  |        | p value for trend |                     |       |         |
| Methadone              | 1.01                          | 0.94   | 1.09              | 0.77             | 0.99   | 0.99              | 0.999               | 0.034 | p=0.078 |
| Buprenorphine/naloxone | 1.70                          | 1.47   | 1.96              | 0.000            | 1.20   | 1.19              | 1.21                | 0.000 | p<0.001 |
| Any OAT                | 1.12                          | 1.04   | 1.21              | 0.003            | 1.04   | 1.04              | 1.04                | 0.000 | p<0.001 |

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3 **Figure 2.** Boxplots\* of percent of people prescribed methadone, buprenorphine/  
4 naloxone or either per quarter across provincial prisons in Ontario, 2015 to 2018  
5 \*The centre line indicates the median prevalence of prescribing, and the box shows the  
6 range in rates for the 25<sup>th</sup> and 75<sup>th</sup> percentiles for prevalence of prescribing; dots indicate  
7 provincial prisons with extreme prevalence rates.  
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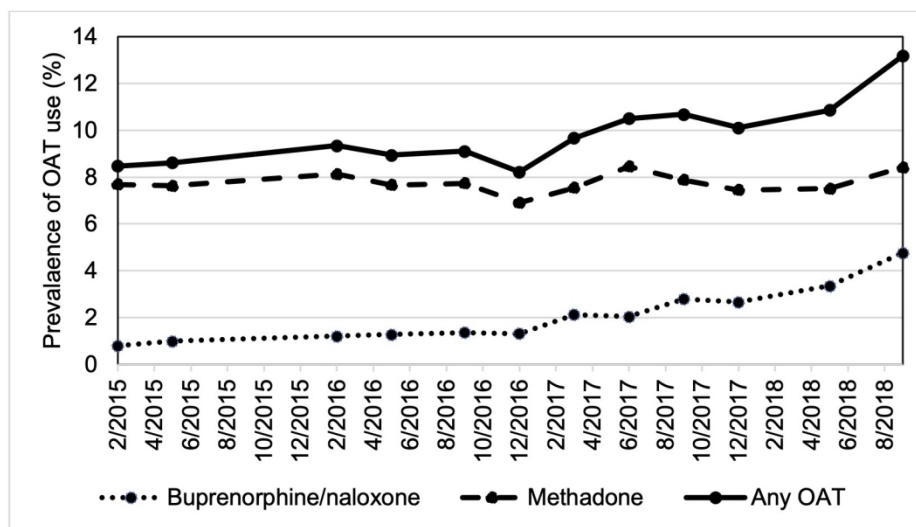
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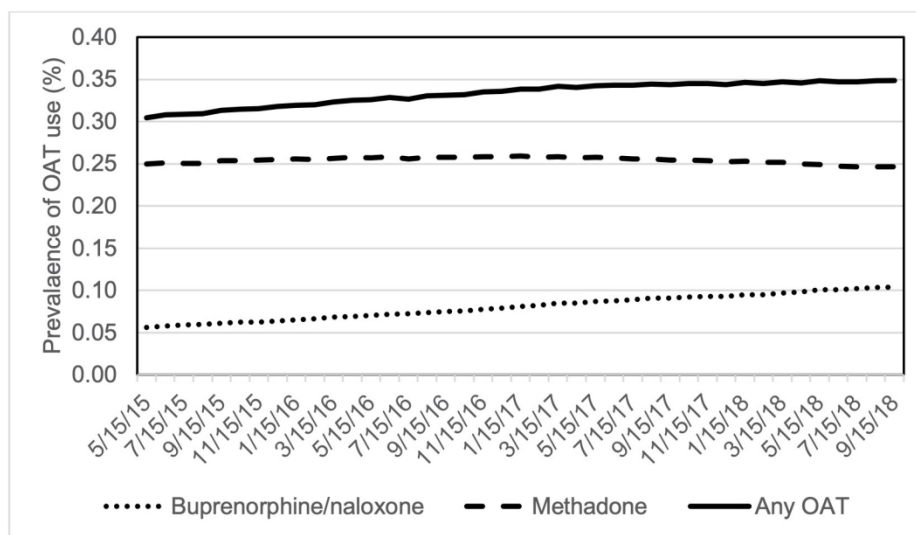


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Ontario provincial prisons



Ontario whole population

Figure 1. Percentage of people prescribed OAT in provincial prisons and in the whole population in Ontario, 2015 to 2018 by OAT type

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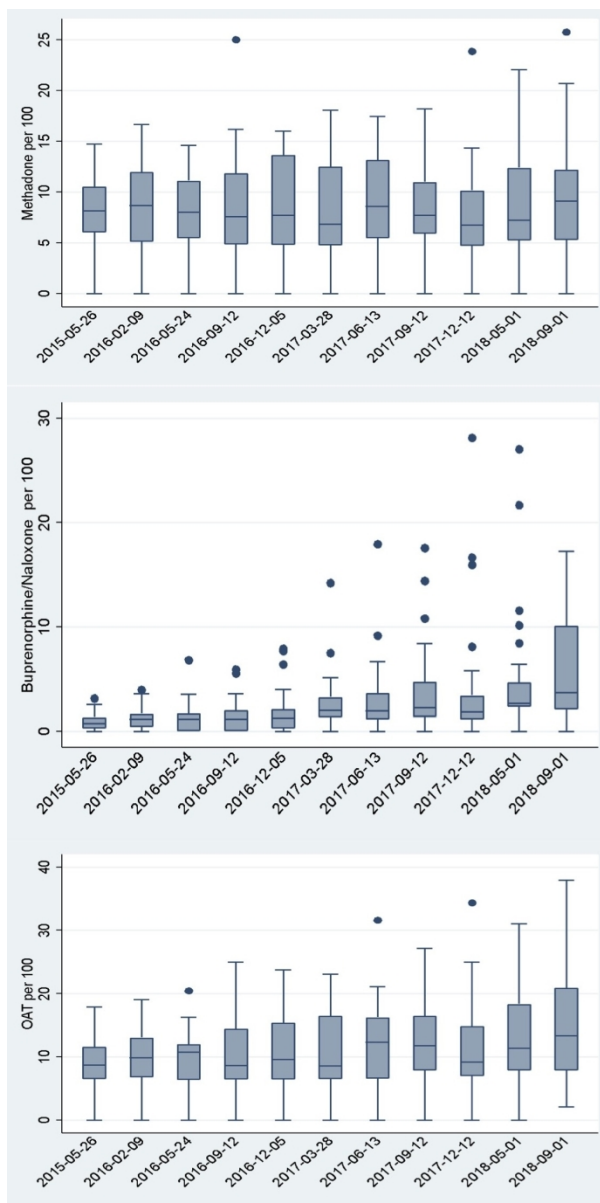


Figure 2. Boxplots\* of percent of people prescribed methadone, buprenorphine/naloxone or either per quarter across provincial prisons in Ontario, 2015 to 2018

\*The centre line indicates the median prevalence of prescribing, and the box shows the range in rates for the 25th and 75th percentiles for prevalence of prescribing; dots indicate provincial prisons with extreme prevalence rates.

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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

|                              | Item No | Recommendation  | Page No    |
|------------------------------|---------|---|------------|
| <b>Title and abstract</b>    | 1       | (a) Indicate the study's design with a commonly used term in the title or the abstract  | 1          |
|                              |         | (b) Provide in the abstract an informative and balanced summary of what was done and what was found   | 2-3        |
| <b>Introduction</b>          |         |   |            |
| Background/rationale         | 2       | Explain the scientific background and rationale for the investigation being reported  | 4          |
| Objectives                   | 3       | State specific objectives, including any prespecified hypotheses  | 5          |
| <b>Methods</b>               |         |   |            |
| Study design                 | 4       | Present key elements of study design early in the paper   | 6,7        |
| Setting                      | 5       | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection   | 5,6,7      |
| Participants                 | 6       | (a) Give the eligibility criteria, and the sources and methods of selection of participants   | 6,7        |
| Variables                    | 7       | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable  | 4,6        |
| Data sources/<br>measurement | 8*      | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group              | 6,7        |
| Bias                         | 9       | Describe any efforts to address potential sources of bias   | N/A        |
| Study size                   | 10      | Explain how the study size was arrived at   | 6,7        |
| Quantitative variables       | 11      | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why  | 7          |
| Statistical methods          | 12      | (a) Describe all statistical methods, including those used to control for confounding   | 7          |
|                              |         | (b) Describe any methods used to examine subgroups and interactions   | 7          |
|                              |         | (c) Explain how missing data were addressed   | N/A        |
|                              |         | (d) If applicable, describe analytical methods taking account of sampling strategy  | N/A        |
|                              |         | (e) Describe any sensitivity analyses   | N/A        |
| <b>Results</b>               |         |   |            |
| Participants                 | 13*     | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 7,8        |
|                              |         | (b) Give reasons for non-participation at each stage  | N/A        |
|                              |         | (c) Consider use of a flow diagram  | N/A        |
| Descriptive data             | 14*     | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  | 5,6,7      |
|                              |         | (b) Indicate number of participants with missing data for each variable of interest   | N/A        |
| Outcome data                 | 15*     | Report numbers of outcome events or summary measures  | 8,12,13,14 |

|    |                          |    |  |
|----|--------------------------|----|--|
| 1  |                          |    |  |
| 2  | Main results             | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included |
| 3  |                          |    | 8,12,13,14   |
| 4  |                          |    |  |
| 5  |                          |    |  |
| 6  |                          |    |  |
| 7  |                          |    |  |
| 8  |                          |    | (b) Report category boundaries when continuous variables were categorized  |
| 9  |                          |    | N/A  |
| 10 |                          |    |  |
| 11 |                          |    | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period   |
| 12 |                          |    | N/A  |
| 13 | Other analyses           | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses   |
| 14 |                          |    | 8,9  |
| 15 | <b>Discussion</b>        |    |  |
| 16 | Key results              | 18 | Summarise key results with reference to study objectives   |
| 17 |                          |    | 9  |
| 18 | Limitations              | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias   |
| 19 |                          |    | 9  |
| 20 |                          |    |  |
| 21 | Interpretation           | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence                                   |
| 22 |                          |    | 9,10   |
| 23 |                          |    |  |
| 24 |                          |    |  |
| 25 | Generalisability         | 21 | Discuss the generalisability (external validity) of the study results  |
| 26 |                          |    | 10   |
| 27 | <b>Other information</b> |    |  |
| 28 | Funding                  | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based  |
| 29 |                          |    | 11   |
| 30 |                          |    |  |
| 31 |                          |    |  |

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).