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7 **Characteristics and incidence of opioid analgesic initiations to opioid naïve patients in a**
8 **Canadian primary care setting**
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ABSTRACT

Objective: To examine characteristics and incidence of opioid analgesic initiations to opioid naïve patients in a Canadian primary care setting.

Methods: This is a population-based cross-sectional study, outlining an analysis of health administrative data recorded in a centralized medication monitoring database (PharmaNet) covering 96% of population in British Columbia (BC), Canada. From the PharmaNet database, 5,657 doctors (87% of all practicing family physicians) were selected on the bases of (1) having been currently treating patients (defined as having written at least 25 prescriptions, for any drug, in preceding 12 months); and (2) having prescribed at least one opioid during study period. The primary outcome measure is incidence of new starts for opioid analgesics in opioid naïve people, stratified by several important prescriber and regional characteristics (e.g., graduation year, geographical location).

Results: Between December 1st, 2018 and November 30th, 2019, there were 139,145 opioid initiations to opioid naïve patients. The mean monthly initiation rate was 2.05 prescriptions per physician. Most initiations were in Lower Mainland regions of BC, also where the population is most concentrated (46,456, 33% in the Fraser region), by prescribers who graduated between 1986-1995 (39,601, 28%), and had less than 10 patient visits per day (72,506, 52%).

Conclusions: From data presented in this study, it appears that the rate of opioid analgesic initiations in primary care remains unchanged. Individualized prescribing interventions targeted at physicians are urgently needed considering the current opioid epidemic and known links with opioid analgesics that raise concerns about the potential to cause harm.

Word Count: 249

Key words: opioid, quality improvement, health administrative data;

BACKGROUND

Opioid related morbidity, mortality, and its public health burden continue to increase across Canada.^{1 2} Primary care may have an important role in addressing these harms since opioids are commonly used by family physicians to treat acute or chronic pain.³ As many as 26% of all patients initiated on opioids for the treatment of non-cancer pain may develop a prescription opioid use disorder (OUD) which suggests a substantial proportion of opioid-treated patients at high risk for developing a prescription OUD.⁴ But despite this risk, and the overall prescription opioid epidemic, physicians continue to prescribe opioids for acute and chronic pain in patterns that are inconsistent with best evidence.⁵ This is likely due to a combination of factors including inadequate training for physicians in evidence-based pain treatment,⁶ lack of pain management programs and alternative services for individuals with pain, as well opioid marketing and downplaying of side effects by pharmaceutical companies.⁷ Moreover, the promotion of opioid products to physicians has been associated with increased opioid prescribing.⁸

Research suggests that physicians are the source of opioid prescriptions for up to 37% of individuals who have OUD.⁹ There is also evidence to suggest that the diversion of opioid analgesics is associated with opioid-related harms, including the development of OUD and opioid-related deaths.¹⁰ However, earlier meta-analyses examining the development of prescription OUD following initiation of opioid analgesics have shown heterogenous results.^{11 12} The substantial heterogeneity of findings pertaining to prescription OUD risk among opioid naïve patients may in part be attributed to varied definitions of opioid analgesic initiation as well as prescription OUD.¹³

¹⁴ Some studies determine prescription OUD incidence using the presence of aberrant, drug-related behaviours, such as “failed pill counts, repeated reports of lost drugs, failed urine drug tests, and attempts to get opioids from multiple clinicians,”¹⁵⁻¹⁹ which are overly broad definitions of

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4 prescription OUD. Others use diagnostic criteria such as the Diagnostic and Statistical Manual that
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6 defines OUD in relation to problems experienced as a result of opioid use that do not always apply
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8 to patients who are prescribed opioids for chronic pain.²⁰ It appears that measures of opioid
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10 prescribing based on health administrative data are more useful than opioid use measures alone or
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12 diagnostic criteria to assess the incidence and opioid-related harms.²¹
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16 In addition to problematic measures, there is a dearth of reliable ways to identify at-risk
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18 patients, and the importance opioid sparing approaches to pain management as a means of
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20 preventing development of OUD has been emphasized.⁴ This highlights an opportunity for
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22 information programs, feedback and education for physicians to ensure opioid analgesics are only
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24 used when appropriate. Therefore, it is imperative to employ strategies that reduce harms
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26 associated with prescription OUD.
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31 Recent feedback and education programs have decreased inappropriate prescribing of a
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33 range of medications (e.g., statins or antipsychotics);^{22 23} however, their impact on initiation of
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35 opioid analgesics has not been tested in primary care and there remains a pressing need for research
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37 on safer opioid practices and prescriber-focused interventions to promote such practices.¹² The
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39 objective of this descriptive cross-sectional study, therefore, was to determine the characteristics
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41 and incidence of opioid analgesic initiations to opioid naïve patients in a Canadian primary care
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43 setting.
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48 49 **METHODS**

50 51 *Study design and data sources*

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53 We used a cross-sectional study design to examine the characteristics and incidence of
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55 initiation of opioid analgesics to opioid naïve patients in primary care. We accessed patient-level,
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57 de-identified, linked data from the British Columbia (BC) Ministry of Health's centralized
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4 medication database (PharmaNet) to determine the incidence of opioid analgesics initiation by
5 family physicians in BC. The data includes medications dispensed from BC community
6 pharmacies and cover most of the BC population but exclude approximately four percent of the
7 population covered by federally insured drug plans for Indigenous populations, members of the
8 military, members of the Royal Canadian Mounted Police and persons in federal penitentiaries.
9 Reversed prescription claims, out-of-province prescriptions, and medications dispensed in hospital
10 were not included. We also accessed BC's public health insurance registration database, the
11 Medical Services Plan (MSP), to assess patient enrolment and health insurance coverage.
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24 The 12-month study period was from December 2018 to November 2019. The primary
25 outcome of interest was number of opioid initiations in opioid naïve patients during the study
26 period. For each opioid record in PharmaNet during the study period, we calculated the most recent
27 opioid consumption date as the last opioid dispensing date plus the number of days' supply
28 dispensed. If this date was not in the last six months (i.e., washout period), or the patient never had
29 an opioid dispensed previously, we defined them to be "opioid naïve". We assessed three different
30 durations of the washout period, three, six, and nine months, and focused our paper on the six-
31 month period in concordance with the Primary Care Report by Health Quality Ontario.²⁴ The study
32 was approved by the University of British Columbia Clinical Research Ethics Board (March 6th,
33 2020, Ref # H20-00656). We obtained a waiver of any requirement for consent from the Research
34 Ethics Board at the University of British Columbia because this is an impact evaluation of a
35 government prescribing education program using de-identified prescribing data.
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52 *Study population*

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54 The source population for this study consisted of residents of BC who had been continuously
55 registered with the MSP for the 12-month study period. We first restricted the population to all
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4 prescriptions by family physicians and then looked at the first use of opioids. The study cohort
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6 consisted of members from the source population who received opioid analgesic therapy
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8 (morphine, buprenorphine patch, codeine, fentanyl, hydromorphone, meperidine, oxycodone,
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10 tapentadol, or tramadol) and who did not meet our exclusion criteria: (1) have been dispensed any
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12 opioids or opioid agonist therapies (methadone, buprenorphine sublingual or naltrexone) in the last
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14 six months (i.e., during the washout period); (2) were dispensed opioids on MSP plan B (long-
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16 term care) or plan P (palliative care) during the study period (as a proxy for non-cancer causes);
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18 and (3) have been without continuous MSP enrolment during the washout or study period.
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23 Prescribing data were accessed from all active family physicians who met the inclusion
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25 criteria: (1) have been currently treating patients (defined as having written at least 25
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27 prescriptions, for any drug, in the preceding 12 months); and (2) have prescribed at least one opioid
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29 during the study period.
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32 33 *Data analyses*

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35 Descriptive statistics (i.e., means, counts and proportions) were calculated for the primary
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37 outcome (number of opioid initiations) for each of the three washout periods. We considered a
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39 number of pre-planned variables that could be linked with different patterns of inappropriate
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41 prescribing based on previous literature.²⁵⁻²⁷ The following socio-demographic variables were
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43 used to stratify the prescribing data: year of graduation (1975 or earlier, 1976-1985, 1986-1995,
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45 1996-2005, 2006-2015, 2016 or after), and geographical region (Interior, Fraser, Vancouver
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47 Coastal, Vancouver Island, or Northern Health Authorities). Organizational and practice-related
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49 factors used to describe the sample included: number of visits to the physician (<=10, 11-20, 21-
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51 30, 31-40, >40), number of unique patients seen per year (<=500, 501-1000, 1001-1500, >1500),
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53 and when the prescriber was a majority source of care (MSOC per percentile: 0-25, 25-50, 50-75,
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4 75-100). The MSOC score approximates a practice pattern that is associated more or less
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6 continuity of care, where a higher score indicates a prescriber provides continuous care to more
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8 patients. Intraclass correlation coefficient (ICC - is an indicator of the extent to which patients
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10 who received prescriptions within the same geographical cluster will have similar care processes
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12 or care outcomes^{28,29}) was calculated according to the formula by Fleiss,³⁰ with mean square values
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14 from a one-way ANOVA. The clusters were chosen to be the forward sort areas (first three digits
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16 of postal code) of the prescribers. The average size of the clusters was computed using the method
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18 derived by Armitage.³¹ The R statistical software (version 4.0.3) was used to analyse the data.³²
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24 **RESULTS**

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28 Our analyses included 139,145 initiations of opioid analgesics from 5,657 family
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30 physicians over a period of 12 months from December 2018 to November 2019 (Table 1). Among
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32 patients who did not have a PharmaNet record of being dispensed opioids in the last six months or
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34 who have never had such a record on PharmaNet (i.e. opioid naïve), there were on average 2.05
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36 new prescriptions per physician per month (Figure 1).
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40 *Prescriber characteristics*

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43 The majority of initiations per 1,000 inhabitants were in the Interior (37.62) and Northern
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45 regions (38.79). Prescribers (1,470) who graduated between 1986 - 1995 (39,601 or
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47 28%), initiated the largest number of all opioid analgesic prescriptions, even in comparison to the
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49 second most populated age group (1,577) who graduated between 2006 – 2015 and initiated 30,875
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51 (22%) prescriptions. More than half (72,506, or 52%) of all prescriptions were initiated by
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53 physicians who had less than 10 patient visits per day. Over two-thirds (97,164 or 70%) of all
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55 prescriptions were initiated by physicians who had seen more than 1,500 unique patients per year.
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4 Sixty per cent (83,048) of all prescriptions were initiated by physicians identified as the majority
5 source of care for less than 19 patients (75th percentile). Geographically, prescribers were
6 distributed in 249 clusters, i.e., 87 large urban centres with >175 physicians and 162 small cities/
7 towns with <175 physicians. Among these clusters, the ICC was 0.081, 0.065, and 0.056 for the
8 three-, six- and nine-month washout period respectively (higher values indicate higher degree of
9 similarity among prescribers within the same geographical cluster).
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21 DISCUSSION

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23 We examined characteristics and incidence of opioid analgesic initiations to opioid naïve patients
24 in BC. Consistent with previous studies on this topic,^{9 33-35} the monthly initiation incidence remains
25 relatively stable, despite recent efforts to address the broader opioid overdose epidemic and new
26 guidelines on opioid therapy and chronic non-cancer pain.^{36 37} While Fraser region has the most
27 opioid analgesic initiations, their relative prescriptions per inhabitants appear less than those for
28 Interior BC, Northern BC, and even Vancouver Island. Such geographic imbalance could be
29 attributed, in part, to the various patterns of physicians' retirement and pre-retirement activity in
30 BC's rural areas with earlier retirement age (by approx. 2.3 years),^{38 39} as well as to access to
31 education on safer prescribing and to alternative opioid-sparing approaches to pain management.
32
33 Coupled with the large construction, oil and gas industries dominating these regions, which
34 represent 29% of young male overdose decedents with employment in B.C.,⁴⁰ such factors situate
35 these high-prescribing, high-risk areas to the forefront for future prescriber-focused initiatives to
36 reduce prescription opioid-related harms.⁴¹ The current study adds to the literature by documenting
37 that prescribers who served higher *unique* patient volumes and those who were not providing the
38 majority of care (MSOC) might be initiating more opioid analgesics (60% of all initiations).
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4 Concerns about the effects of fragmented or episodic care have been studied and can be associated
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6 with poorer patient outcomes including increased mortality, hospitalizations and inappropriate
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8 prescribing.²⁵⁻²⁷
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12 A 2007 study linked primary care physicians who spent greater time in practice to increased
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14 inappropriate antibiotic prescribing.⁴² We found that the specific period of prescribers' training, as
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16 determined by year of graduation (1986-1995), might have influenced prescribing behaviours,
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18 which could be attributed, in part, to the lasting effects of pharmaceutical industry marketing of
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20 opioid products to previous cohorts of physicians.⁸ While newer opioid products were introduced
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22 to BC in the mid-nineties, the shifting physician attitudes towards pain control with opioids during
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24 the preceding decades gave advertisers significant leverage in marketing campaigns.⁴³ Our data
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26 also suggest that if the physician had 10 or less patient visits per day, they initiated more opioids.
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28 This finding seems contrary to the data regarding higher *unique* patient volumes, as well as the
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30 literature on prescribing patterns of other medications, such as benzodiazepines⁴⁴ or antibiotics,⁴⁵
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32 ⁴⁶ and, therefore, warrants further investigation. Such investigations should focus on time pressure
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34 and lack of continuity as potential contributors to the physicians' incongruent prescribing patterns,
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36 especially for opioids and other types of psychotropic drugs.^{47 48} This data will inform a
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38 randomized clinical trial to examine the effectiveness and acceptability of individualized
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40 prescribing portraits and educational supports for reducing initiation of opioid analgesics among
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42 opioid naïve patients attending primary care.^{49 50} The trial draws upon a growing body of research
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44 which has established the importance of opioid-sparing approaches to evidence-based pain
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46 management⁵¹ and the significant beneficial effects of audit and feedback (individualized
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48 prescribing portraits) on new prescribing for both acute and chronic conditions.²³ It is hoped that
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50 data from the future clinical trial will help us better understand and model the physician and patient
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4 (e.g., patient age, socio-economic status - SES, comorbidity, preceding surgical procedures)
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6 predictors of higher rates of initiation, as well as differing patterns for specific opioid analgesics.
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10 This analysis is subject to the usual limitations of studies of this nature, as opioid
11 prescriptions may not always be accurately identified in administrative data. The non-cancer
12 eligibility criteria were simplified to exclude palliative care and long-term care patients, which
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14 might miss some patients with cancer diagnoses. Our operational definition of “opioid naïve”
15 status included individuals who may have used opioids in the past. However, the use of opioids
16 even once affects the brain, and therefore is a limitation because the person is no longer opioid
17 naïve. We were unable to match the corresponding region to approximately 200 – 300 (depending
18 on the washout duration) opioid analgesic initiations. We presented findings without adjusting for
19 other potential confounders, e.g., reasons for prescriptions (acute vs. chronic) or duration of
20 prescriptions. Future study can examine this with more sophisticated models and assess the
21 potential impacts on broader health outcomes will also be necessary for understanding the
22 implications of the future individualized prescribing portraits and for examining the willingness to
23 first try non-opioid medications before resorting to opioid analgesics.⁵¹
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42 From data presented in this descriptive cross-sectional study, it appears that the rate of
43 opioid analgesic initiations in primary care remains unchanged. The initiation rates were elevated
44 in certain prescriber groups, such as those who graduated from medical school between 1986-
45 1995, and regions (Interior BC, Northern BC), suggesting provincial disparities in pain
46 management with opioids. In light of the ongoing opioid epidemic and the substantial body of
47 research on links with prescription opioids, evidence-based interventions to reduce initiation of
48 opioid analgesics among opioid naïve patients are a priority.
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Competing interests

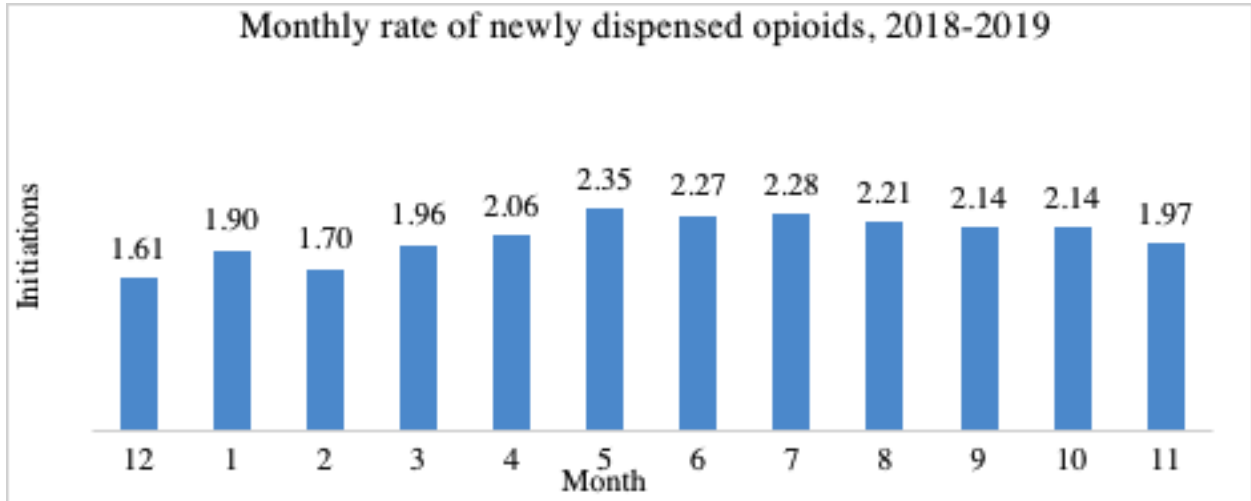
The authors declare that they have no competing interests.

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5 **Figure 1.** Average monthly initiation rates by physicians (n = 5,657) over the course of 12 months
6 (2018 – 2019).
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27 *Figure 1 legend:* Average monthly initiation rates (prescriptions per physician) were determined
28 for a period of 6 months opioid free. Months of the year assigned numbers (1 = January, 12 =
29 December).
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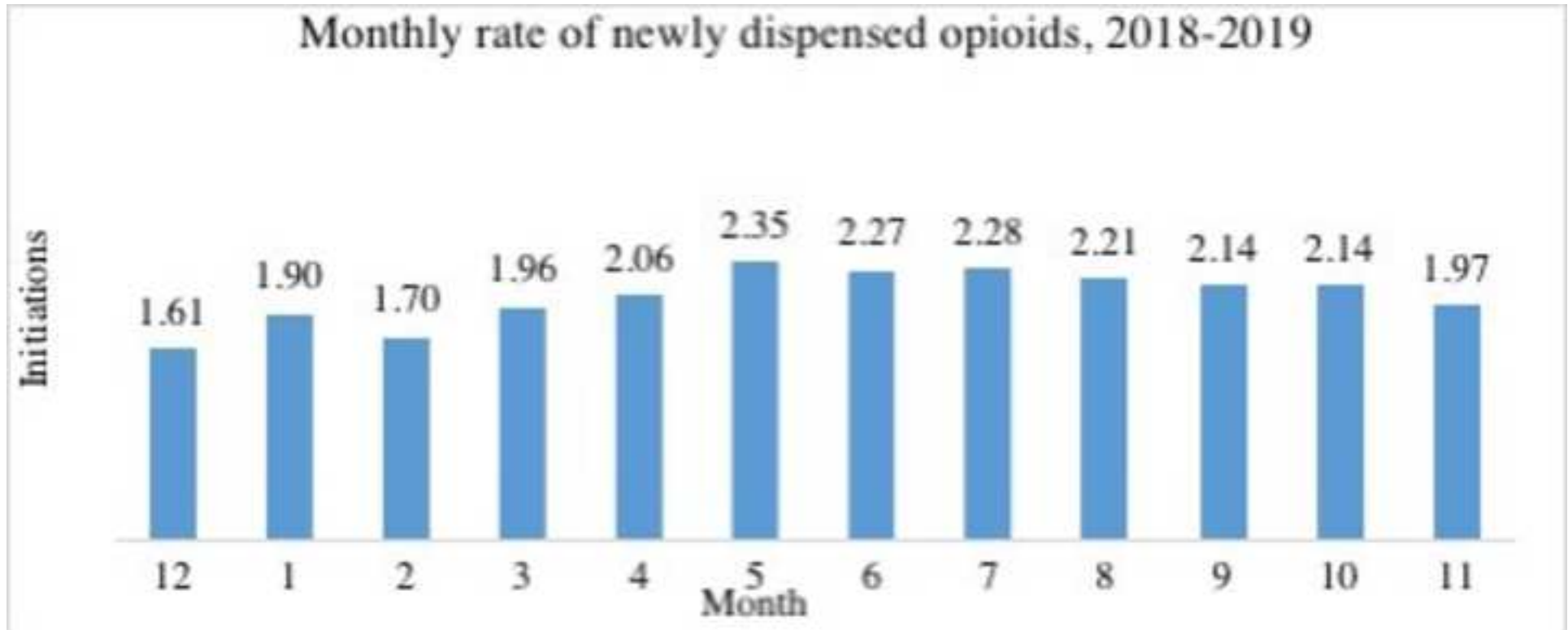


Table 1. Characteristics and incidence of opioid analgesic initiations per month by prescribers who prescribed an opioid to opioid-naïve patients in primary care in British Columbia, in 2018-2019.

Variable	3-month washout N = 174,085	6-month washout N = 139,145	9-month washout N = 109,942
All opioid initiations (Average per month, SD)	14,507 (1,932.33)	11,595 (1,299.38)	9,162 (1,542.44)
Number of prescribers who initiate an opioid naïve patient on opioids (Average per month, SD)	3,593 (122.90)	3,593 (122.90)	3,256 (204.53)
Monthly rate per prescriber (Average, SD)	2.52 (3.03)	2.05 (2.53)	1.65 (2.07)
Yearly rate per prescriber (Average, SD)	30.25 (36.38)	24.60 (30.41)	19.78 (24.78)
Initiations by geographical region, n (%)*			
Interior	35,678 (20.49)	28,673 (20.61)	22,629 (20.58)
Fraser	57,990 (33.31)	46,456 (33.39)	36,946 (33.60)
Vancouver Coastal	32,925 (18.91)	26,514 (19.05)	21,183 (19.27)
Vancouver Island	33,588 (19.29)	26,343 (18.93)	20,378 (18.54)
Northern	13,581 (7.80)	10,902 (7.83)	8,610 (7.83)
Not available	323 (0.19)	257 (0.18)	196 (0.18)
Initiations by region per 1,000 inhabitants, n*			
Interior (762,124 inhabitants)	46.81	37.62	29.69
Fraser (1,829,828 inhabitants)	31.69	25.39	20.19
Vancouver Coastal (1,192,792 inhabitants)	27.60	22.23	17.76
Vancouver Island (800,132 inhabitants)	41.98	32.92	25.47
Northern (281,031 inhabitants)	48.33	38.79	30.64
Not available	-	-	-
Initiations by prescriber year of graduation, n (%)			
1975 or earlier	9,102 (5.23)	7,101 (5.10)	5,500 (5.00)
1976-1985	33,211 (19.08)	26,237 (18.86)	20,694 (18.82)
1986-1995	49,941 (28.69)	39,601 (28.46)	31,257 (28.43)
1996-2005	41,601 (23.90)	33,611 (24.15)	26,647 (24.24)
2006-2015	38,041 (21.85)	30,875 (22.19)	24,507 (22.29)
2016 or after	2,167 (1.24)	1,706 (1.23)	1,326 (1.21)
Unknown	24 (0.01)	17 (0.01)	13 (0.01)
Number of prescribers, n (%)			
Total N per washout period	5,749	5,657	5,558
1975 or earlier	340 (5.91)	332 (5.87)	326 (5.87)
1976-1985	957 (16.65)	943 (16.67)	918 (16.52)
1986-1995	1,493 (25.97)	1,470 (25.99)	1,447 (26.03)
1996-2005	1,224 (21.29)	1,214 (21.46)	1,198 (21.55)
2006-2015	1,613 (28.06)	1,577 (27.88)	1,550 (27.89)
2016 or after	121 (2.10)	120 (2.12)	118 (2.12)
Unknown	1 (0.02)	1 (0.02)	1 (0.02)
Initiations by number of visits per day, n (%)			
<=10	88,689 (50.95)	72,506 (52.11)	57,893 (52.66)
11-20	56,611 (32.52)	43,824 (31.50)	34,052 (30.97)
21-30	20,994 (12.06)	16,633 (11.95)	13,140 (11.95)
31-40	5,778 (3.32)	4,568 (3.28)	3,584 (3.26)
>40	1,489 (0.86)	1,191 (0.86)	930 (0.85)
Not available	524 (0.30)	423 (0.30)	343 (0.31)
Initiations by unique patients seen per year, n (%)			
<=500	3,488 (2.00)	2,778 (2.00)	2,171 (1.97)
501-1000	15,564 (8.94)	12,099 (8.70)	9,447 (8.59)

1001-1500	34,367 (19.74)	26,681 (19.17)	20,759 (18.88)
>1500	120,142 (69.01)	97,164 (69.83)	77,222 (70.24)
Not available	524 (0.30)	423 (0.30)	343 (0.31)
Initiations by unique patients for whom prescriber is a Majority Source of Care, n (%)[§]			
<= 6.1 [percentile (p) 25]	13,713 (7.88)	11,246 (8.08)	8,992 (8.18)
6.1-12 [p25-50]	38,683 (22.22)	31,639 (22.74)	25,422 (23.12)
12-19.2 [p50-75]	50,980 (29.28)	40,163 (28.86)	31,547 (28.69)
>19.2 [p75]	70,185 (40.32)	55,674 (40.01)	43,638 (39.69)
Not available	524 (0.30)	423 (0.30)	343 (0.31)

* In each of the washout cohorts, <3 patients had multiple initiations. Geographic regions are health authorities.³⁰

³¹ Federally covered citizens in British Columbia were not included in the tally. SD = standard deviation. §Majority Source of Care (MSOC) patients are those who, during the calendar year, received three or more services of the General Practice Type (e.g., office visits, complete examinations) and more than 50% of those services from a specific provider.¹²