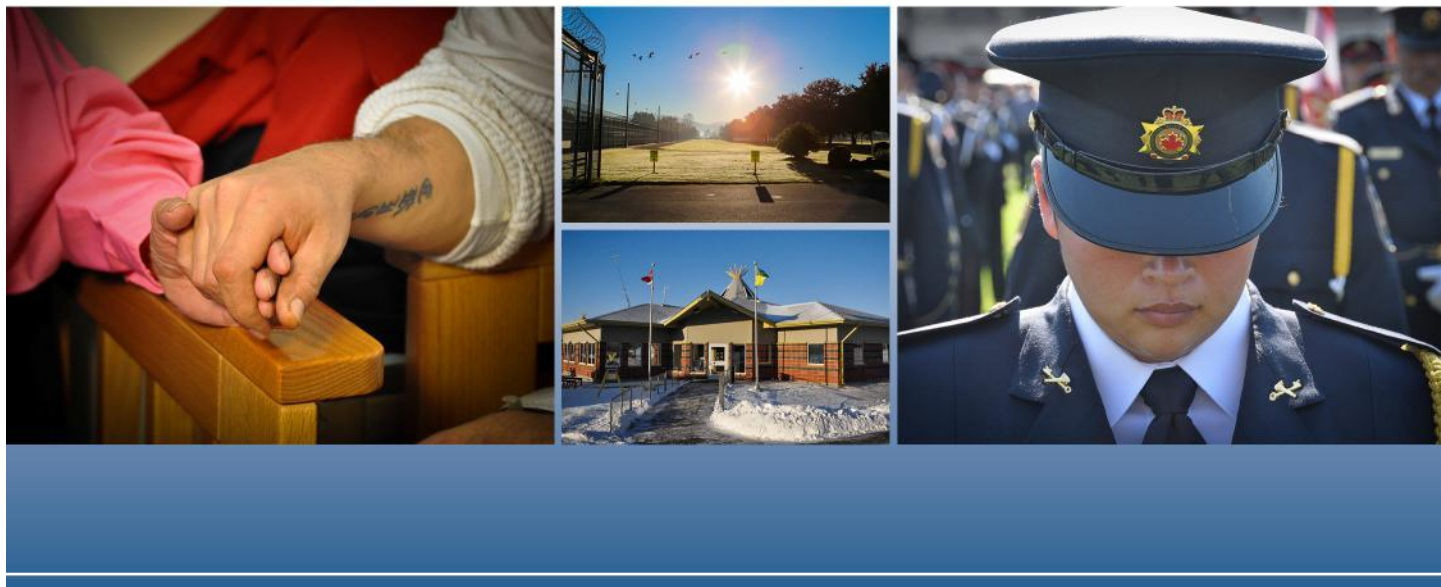


# CORRECTIONAL SERVICE CANADA

CHANGING LIVES. PROTECTING CANADIANS.



## RESEARCH REPORT

### Approved and 'Off-Label' Use of Prescribed Psychotropic Medications Among Federal Offenders

2017 N° R-387

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**Approved and 'Off-Label' Use of Prescribed Psychotropic Medications among Federal Offenders**

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## Executive Summary

**Key words:** *off label prescription practices, psychotropic drugs, prescriptions of medication in prisons, offenders' mental health*

Anecdotal reports about the unapproved, 'off-label' use (i.e., the use of a drug for an indication or at a dosage or method of administration for which it has not been approved, and which is not described by the drug label) of psychotropic medications to control inmates' behaviour are a source of public concern. This issue has recently been raised by the Correctional Investigator.

Research shows that the prevalence of psychotropic medication use is 2 – 6 times greater among incarcerated offenders compared to the general population, and highest among incarcerated women offenders (Lafortune & Vacheret, 2009; Torrey et al., 2010; Varela-Gonzalez et al., 2007). A 2015 study conducted in the Correctional Service of Canada (CSC) on the prevalence of psychotropic medication prescriptions in federal institutions found that about 30% of inmates had active prescriptions for psychotropic medication compared to a rate of about 8% in the general Canadian population (Farrell MacDonald et al. 2015).

We drew a purposive sample of thirteen Canadian federal institutions representing each of the five regions, different security levels, and men's and women's designated facilities. From a sample of  $N = 468$  inmates files, information on the names of all psychotropic medications prescribed, indications for use, dosage, frequency and route of administration was retrieved. Designation of approved or off-label use of medications was determined by consulting three main sources: (1) the Health Canada (2016) Drug Product Database, (2) the Canadian Compendium of Pharmaceuticals and Specialties 2016, and (3) the American Hospital Formulary Service Drug Information 2016. Inter-rater reliability was good at 63% across all prescriptions for psychotropic medication.

Findings indicated that 36.2% of prescriptions for psychotropic medication in CSC are off-label. Of these, the majority (98.6%) are frequently prescribed off-label by clinicians. There were no differences in the prevalence of approved versus off-label prescriptions based on Indigenous ancestry (Indigenous = 34.1%; non-Indigenous 37.2%) or gender (women = 37.7%; men = 35.2%). Among the different types of psychotropic medications, drugs to treat insomnia are most commonly prescribed off-label. Offenders sentenced for the most serious violent offences and those with a high number of institutional charges are most likely to be prescribed psychotropic medications for approved purposes; however, there is no pattern of off-label prescription practices among these groups. Prescription practices were also not related to sentence length.

The rate of off-label prescriptions for psychotropic drugs of 36.2% in CSC is similar to rates cited in other correctional surveys and to a Quebec study that found that psychotropic medications were prescribed off label by physicians in the community between 26% and 67% of the time (Egualle et al., 2012). When analysed by offender, in CSC 44% - 49% of men and women in the sample were prescribed at least one off-label psychotropic medication, a rate in line with a cross sectional review of published reports completed by the Royal College of Psychiatrists (2007). The rate of off-label prescription of psychotropic drugs in the CSC, therefore, is not higher, and may be somewhat lower, than rates in many communities.



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## **Introduction**

In his *Annual Report 2013-2014*, the Correctional Investigator of Canada expressed concern over the high rates of psychotropic medication use in Correctional Service of Canada (CSC) institutional facilities, in particular, among women inmates (Correctional Investigator of Canada, 2014). International research shows that the prevalence of psychotropic medication use is 2 – 6 times greater among incarcerated offenders compared to the general population, and highest among incarcerated women (Lafortune & Vacheret, 2009; Torrey, Kennard, Eslinger, Lamb, & Pavle, 2010; Varela-Gonzalez et al., 2007). Anecdotal reports about the unapproved, ‘off-label’ use (i.e., the use of a drug for an indication or at a dosage or method of administration for which it has not been approved, and which is not described by the drug label) of psychotropic medications to control offenders’ behaviour have raised public concerns about the well-being of inmates, and the ethical and legal ramifications of the practice (Hassan, Senior, Frisher, Edge, & Shaw, 2014; Kilty, 2012; Reeves, 2012).

### **Prevalence of Psychotropic Medication Use in Prisons**

A 2015 study conducted in the Correctional Service of Canada on the prevalence of psychotropic medication prescriptions in federal institutions found that about 30% of incarcerated offenders had active prescriptions for psychotropic medication compared to a rate of about 8% in the general Canadian population (Farrell MacDonald, Keown, Boudreau, Gobeil, & Wardrop, 2015). The prevalence of active prescriptions for psychotropic medication was higher among women inmates (45.7%) compared to men (29.6%), and women were also more likely to have more than one active prescription for a psychotropic medication. There were no substantive differences between Indigenous and non-Indigenous inmates in the prevalence of active prescriptions for psychotropic medication.

International research also reports a higher prevalence of psychotropic medication use among prison inmates. A 2014 national report on mental health care in U.S. jails and prisons found that between 25% - 60% of inmates received a psychotropic medication (Torrey et al., 2010), compared to 20% of the general population (Medco Health Solutions, 2011). A study conducted in prisons in the east of England found that 19.6% of male inmates and 44.0% of female inmates had an active prescription for a psychotropic medication, rates 5 – 6 times greater than found in community samples (Hassan et al., 2014). In a Spanish study, 20.5% of inmates

received psychotropic medication, compared to about 8% of the general population (Varela-Gonzalez et al., 2007). A 2012 national census of prisoners in Australia reported that 21% were taking a psychotropic medication, double the rate reported in the general population (Davison et al., 2015).

### **Approved and ‘Off-Label’ Use of Psychotropic Medication**

Health Canada is responsible for authorizing all drugs marketed for sale in Canada. The ‘label’ (a detailed product monograph, as well as product packaging) identifies the population group for which the drug is to be used, the indication(s) the drug is used to treat, the recommended dosages and the route of administration (Health Canada, 2015). Once approved by Health Canada, the drug is officially approved for use only according to its label. ‘Off-label’ is the use of a drug in a population, for an indication or at a dosage or method of administration for which it has not been approved, and which is not described by the drug label (Canadian Senate Report, 2014; Wittich, Burkle, & Lanier, 2012). Nevertheless, off-label prescription practice is common especially in paediatrics, psychiatry, among the elderly, in transplant medicine, HIV/AIDS treatment, and in cancer treatment. International studies report that as many as 30% - 50% of prescriptions for psychotropic medications are for off-label use (Brown, in approvals). For example, in Canada, a Quebec study found that psychotropic medications were prescribed off-label by physicians between 26% and 67% of the time (Egualé et al., 2012). A report published by the Royal College of Psychiatrists based on a review of published research concluded that as many as 50% of adult psychiatric patients are prescribed at least one off-label medication (Royal College of Psychiatrists, 2007). In a French study, 39.8% of prescriptions for psychotropic medications issued in a psychiatric hospital were for off-label uses (Martin-Latry, Ricard, & Verdoux (2007). A study of Medicaid prescriptions in the state of Georgia in the US found that more than two-thirds of psychotropic medication prescriptions were for off-label uses (Chen et al., 2006).

### **Reason for Current Study**

In response to concerns raised by the Correctional Investigator about the high rates of psychotropic medication use by federal inmates, and to investigate concerns about the appropriateness of use of prescribed psychotropic medications by inmates, this study examined prescribing practices for psychotropic medication in a sample of CSC institutions. The study

compares the proportion of medications prescribed by physicians for ‘approved’ uses to treat mental health problems to the proportion of medications prescribed by physicians for ‘off-label’ uses among men and women offenders and based on Aboriginal ancestry. The research includes an analysis of demographic, criminal history, substance abuse and institutional behaviour correlates of approved and off-label psychotropic medication prescriptions, and an assessment of the prevalence of approved and off-label psychotropic medication prescriptions in the sample compared to estimated prevalence rates in the general Canadian population.

## **Method**

### **Participants**

A purposive sample of thirteen federal institutions representing each of the five regions in CSC, different security levels, and men and women offender designated facilities, was drawn, with all five women's institutions included to ensure a sufficient number of cases for comparative analysis. A list of all inmates at each selected institution with one or more active prescriptions for a psychotropic medication was provided by the Regional pharmacies. From this list, systematic selection of every fifth name was used to identify individual inmates' health care files to be reviewed. All information on the name of the psychotropic medication(s) used, indication(s) for use, dosage, frequency and route of administration recorded on a spreadsheet. Where a systematically selected file was not available, or where the number of files selected at an institution was too few based on systematic selection, additional files were randomly selected until a sufficient number of files (between 30 and 40) containing the required information was obtained at each institution.

The data on psychotropic medication prescriptions were provided by CSC to the researcher and were merged with additional data including date of birth, Indigenous ancestry, sentence length, admission date, major admitting offence, substance abuse assessments, and the Dynamic Factors Identification and Analysis-Revised Substance Abuse (DFIA-R) domain ratings, along with the number of institutional misconduct charges. The final data set contains information for 468 individual inmate cases (295 men, 173 women), and a total of 829 prescriptions for a psychotropic medication. Across the thirteen institutions, 144 (30.8%) inmates self-identified as being of Indigenous ancestry (First Nations/Métis/Inuit), and 324 (69.2%) identified as non-Indigenous (White or otherwise).

Table 1

*Profile of Psychotropic Medication Prescriptions Sample N=468, by Region, Institution, Security Level and Gender*

Region	Institution	Security Level	Number	
			Men	Women
Atlantic	Atlantic Institution	Maximum	40	-
	Nova Institution for Women	Multilevel	-	36
Quebec	Donnacona Institution	Maximum	38	-
	Federal Training Centre	Minimum	29	-
	Joliette Institution	Multilevel	-	29
Ontario	Collins Bay Institution	Minimum	28	-
	Grand Valley Institution for Women	Multilevel	-	37
	Warkworth Institution	Medium	40	-
Prairies	Edmonton Institution	Maximum	40	-
	Edmonton Institution for Women	Multilevel	-	38
	Saskatchewan Penitentiary	Medium	40	-
Pacific	Fraser Valley Institution for Women	Multilevel	-	33
	Matsqui Institution	Medium	40	-
Total	13 Institutions		295	173

## Procedure

Approved or off-label use of psychotropic medication prescriptions was determined by consulting and comparing information from three main sources: (1) Health Canada (2016) Drug Product Database ([www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php)) which contains label and other information on all drugs approved for use in Canada; (2) Canadian Compendium of Pharmaceuticals and Specialties 2016 (Canadian Pharmacists Association, 2016) which contains detailed drug product monographs (labels) approved by Health Canada,

along with additional clinical drug information; and (3) the American Hospital Formulary Service Drug Information 2016 (American Society of Health-System Pharmacists, 2016), considered an evidence-based standard for drug information in institutional formulary environments, which also contains up-to-date information on scientifically supported off-label uses of medications. In addition, off-label uses of psychotropic medications were also measured against published research in PubMed 2016 (U.S. National Library of Medicine) and MEDLINE 2016 (EBSCOhost) search engines, and other web-based search engines, including WebMD 2016 (<http://www.webmd.com>). Data were coded (0=approved, 1=off-label) for each individual inmate ( $N = 468$ ) with a psychotropic medication prescription and for each prescription (range = 1 – 6). IBM-SPSS 24<sup>®</sup> (IBM Corporation, 2016) was used to perform the statistical analysis.

Inter-rater reliability was assessed by the authors independently coding (0=approved, 1=off-label) a randomly drawn sample of 40 cases from the final data set. The Kappa ( $\kappa$ ) statistic (Cohen, 1960) was computed for all prescriptions issued to the 40 inmates ( $\kappa (N = 73) = .628, p < .001$ ) demonstrating a ‘substantial’ level of agreement (McHugh, 2012) between the raters.

## Results

The percentage and number of approved and off-label prescriptions for psychotropic medication in the sample analyzed by gender, age group and Indigenous ancestry, is presented in Table 2. Data were missing for 49 prescriptions for which no indication for use was recorded. Slightly more than one-third (36.2%) of psychotropic medication prescriptions were indicated for off-label use, a prevalence rate similar to the findings from the Quebec study by Egualé et al. (2012), and somewhat lower than other international estimates. There were no statistically significant differences in the pattern of distribution of approved versus off-label prescriptions for psychotropic medication by gender, age, or Indigenous ancestry (although for offenders in the oldest age group ( $\geq 55$ ) a greater percentage of prescriptions were for approved use than for those who were younger than 55). Similarly, no statistically significant differences were observed in the distribution of the number of prescriptions for psychotropic medications issued to individual inmates based on gender or Indigenous ancestry (Table 3). Rates of off-label prescriptions by offender are presented in Table A1 in Appendix A. Findings indicate that slightly less than half of men and women and Indigenous and non-Indigenous offenders in the sample were prescribed an off-label psychotropic medication during the period examined in this study, a rate comparable to those cited in a cross sectional review of prescription practices among psychiatrists in the United Kingdom (Royal College of Psychiatrists, 2007).

Table 2

*Approved and 'Off-label' Prescriptions for Psychotropic Medication (N=829)*

Group	Approved % (n)	Off-label % (n)	$\chi^2$ (df)
Total	63.8 (529)	36.2 (300)	
Gender			
Men	64.8 (331)	35.2 (180)	0.10 <sup>ns</sup> (1)
Women	62.3 (198)	37.7 (120)	
Age			
19-24	57.7 (41)	42.3 (30)	7.02 <sup>ns</sup> (4)
25-34	63.6 (211)	36.4 (121)	
35-44	60.3 (105)	39.7 (69)	
45-54	65.1 (114)	34.9 (61)	
55 or older	76.9 (50)	23.1 (15)	
Indigenous Ancestry			
Indigenous	65.9 (174)	34.1 (90)	0.74 <sup>ns</sup> (1)
Non-Indigenous	62.8 (355)	37.2 (210)	

<sup>ns</sup> non-significant, \* p < .05, \*\* p < .01, \*\*\* p < .001.

Table 3

*Prescriptions for Psychotropic Medication, by Number of Prescriptions Issued*

Group	One % (n)	Two % (n)	Three % (n)	Four+ % (n)	$\chi^2$ (df)
Total	49.6 (232)	29.1 (136)	11.8 (55)	9.6 (45)	
Gender					
Men	52.9 (156)	26.4 (78)	9.8 (29)	10.8 (32)	9.55 <sup>ns</sup> (5)
Women	43.9 (76)	33.5 (58)	15.0 (26)	7.5 (13)	
Ancestry					
Indigenous	47.2 (68)	30.6 (44)	11.8 (17)	10.4 (15)	2.21 <sup>ns</sup> (5)
Non-Indigenous	50.6 (164)	28.4 (92)	11.7 (38)	9.3 (30)	

<sup>ns</sup> non-significant, \*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$ .

The distribution of approved and off-label prescriptions for psychotropic medication according to AHFS-defined drug class is shown in Table 4 (see Appendix B for a complete list of CSC National Formulary medications by AHFS category). There is a statistically significant difference ( $\chi^2 (4, N = 827) = 55.49, p < .001$ ) in the distribution of psychotropic medications by AHFS-defined drug class. More than one-half of prescriptions for anti-depressant agents (62.2%) and antipsychotic agents (61.8%) are for approved uses; similarly CNS stimulants prescribed to treat ADHD (90.1%) and antimanic drugs used to treat bi-polar disorder (71.0%) are prescribed predominantly for approved purposes. On the other hand, the majority of prescriptions for anxiety/insomnia are designated as off-label.

As found in other Canadian and international research, the most commonly prescribed psychotropic medications, both in the public and in prisons, are the anti-depressant class of drugs. Consistent with the findings of Farrell-Macdonald et al. (2015), among Canadian federal inmates, prescriptions for anti-depressant medication were most frequent, followed by antipsychotic agents; however, in contrast to the earlier report, in the current study, CNS stimulants were the third most commonly prescribed medications (largely for the indication of

ADHD), rather than anxiety/insomnia agents. Overall, prescriptions for the AHFS-defined categories of psychotropic medications among Canadian federal inmates reflect similar prescribing practices as in prisons in other Western countries (Hassan et al., 2014; Hilliard, Barloon, Farley, Penn, & Koranek, 2013; Varela-Gonzalez et al., 2007)

Table 4

*Rates of Approved and Off-label Prescriptions for Psychotropic Medication, AHFS-Defined Categories*

Group	Approved % (n)	Off-label % (n)	$\chi^2$ (df)
Anti-depressant agents	62.2 (252)	37.8 (153)	55.49*** (4)
Antipsychotic agents	61.8 (123)	38.2 (76)	
Anxiety/insomnia agents	39.5 (32)	60.5 (49)	
CNS stimulants	90.1 (100)	9.9 (11)	
Antimanic agents	71.0 (22)	29.0 (9)	
Total <sup>a</sup>	529	298	

<sup>a</sup> 1 prescription for an analgesic agent and 1 prescription for an anti-hypertensive agent not included in table  
<sup>ns</sup> non-significant, \*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$ .

Approved and off-label prescriptions for psychotropic medication are broken down by indication for use, based on the Diagnostic Statistical Manual (DSM)-5 (American Psychiatric Association, 2013) classification categories in Table 5. Psychotropic medications prescribed for schizophrenia spectrum and other psychotic disorders (87.7%), bipolar and related disorders (79.5%), depressive disorders (78.9%) and disruptive, impulse-control and conduct disorders (69.2) were used largely according to approved prescription guidelines. Sleep-wake disorders

have a very high rate of off-label prescription use (73.7%). Higher rates of off-label prescribing were also found in relation to anxiety disorders (53.9%), trauma and stressor-related disorders (56.7%), substance-related and addictive disorders (54.5%) and other mental disorders (58.9%). The five most common indications for use of a prescribed psychotropic medication are: (1) depressive disorders (2) anxiety disorders, (3) disruptive, impulse control and conduct disorders, (4) sleep-wake disorders and (5) personality disorders. All these diagnoses are found at high prevalence rates among offenders populations in both international (Anderson, 2004; James & Glaze, 2006; Butler, Indig, Allnutt, & Mamoon, 2011; Fazel & Seewald, 2012) and Canadian studies (Beaudette & Stewart, 2016; Derkzen, Booth, McConnell, & Taylor, 2012; Lafortune, 2010).

Table 5

*Approved and Off-label Prescription of Psychotropic Medication, By Indication for Use Based on DSM-V Classification<sup>a,b</sup>*

Group	Approved n (%)	Off-label n (%)
Schizophrenia spectrum and other psychotic disorders	87.7 (64)	12.3 (9)
Bipolar and related disorders	79.5 (58)	20.5 (15)
Depressive disorders	78.9 (209)	21.1 (56)
Anxiety disorders	46.1 (105)	53.9 (123)
Obsessive-compulsive and related disorders	50.0 (6)	50.0 (6)
Sleep-wake disorders (e.g. insomnia)	26.3 (41)	73.7 (115)
Trauma and stressor-related disorders (e.g. PTSD)	43.3 (13)	56.7 (17)
Disruptive, impulse-control and conduct disorders (e.g. ADHD)	69.2 (126)	30.8 (56)
Substance-related and addictive disorders	45.5 (5)	54.5 (6)
Personality disorders	50.0 (44)	50.0 (44)
Other mental disorders	(37) 41.1	58.9 (53)
Total <sup>a</sup>	708	500

<sup>a</sup> Multiple indications for a single prescription

Comparisons of approved and off-label prescriptions for psychotropic medication by most serious offence and time served (March 10, 2016 at completion of data collection) are presented in Table 6. There is a statistically significant relationship ( $\chi^2 (7, N = 814) = 37.39, p < .001$ ) between the type of offence (in the current sentence) and the proportion of prescriptions for coded as approved or off-label with the most serious violent offences (homicide, robbery, assault and sexual offences) being more likely to have a higher rate of psychotropic medication prescribed for approved use, compared to rates among offenders with less serious violent offences (e.g., arson, kidnapping, weapons, & explosives), drug offences, and property offences. There is no statistically significant difference related to the pattern of prescription practices related to length of sentence served; those with longer sentences are not more likely to have prescriptions coded as off-label than approved.

Table 6

*Approved and Off-label Prescription of Psychotropic Medication, by Most Serious Offence on Sentence and Time Served to Date*

	Approved % (n)	Off-label % (n)	$\chi^2$ (df)
Most serious offence on sentence <sup>a</sup>			
Homicide and related	72.8 (158)	27.2 (59)	37.39*** (7)
Robbery	60.2 (97)	39.8 (64)	
Drug offences	53.6 (45)	46.4 (39)	
Assault	67.9 (91)	32.1 (43)	
Sexual offences	79.5 (35)	20.5 (9)	
Property offences	63.5 (54)	36.5 (31)	
Other violent offences <sup>b</sup>	33.3 (12)	66.6 (24)	
Other non-violent <sup>c</sup> offences	49.1 (26)	50.9 (27)	
Sentenced served to date <sup>a</sup>			
0-36 months	61.9 (346)	38.1 (213)	6.04 <sup>ns</sup> (3)
37-72 months	65.4 (83)	34.6 (44)	
73-120 months	60.0 (30)	40.0 (20)	
121 or more months	75.6 (59)	24.4 (19)	

<sup>a</sup> Missing data for 6 cases accounting for a total of 15 missing prescriptions

<sup>ns</sup> non-significant, \*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$

<sup>b</sup> Include<sup>s</sup> Arson, Kidnapping, Weapons, & Explosives

<sup>c</sup> Criminal Code Traffic, Impaired Driving, Other Criminal Code, Public Order Offences

Approved and off-label prescriptions for psychotropic medication, by total number of institutional charges during the sentence and DFIA-Revised Substance Abuse domain ratings are shown in Table 7. There is a statistically significant difference ( $\chi^2$  (3,  $N = 814$ ) = 8.73,  $p < .05$ ) in the distribution of approved versus off-label prescriptions for psychotropic medication based

on the number of institutional charges, with inmates with 1-2 charges or more than 5 charges having the highest rates of prescriptions for psychotropic medication for approved purposes. This finding does not, however, suggest that there is a pattern of off-label prescribing for psychotropic drugs for offenders who evidence problematic behaviour while incarcerated.

There is also a statistically significant, though inconsistent, relationship ( $\chi^2(3, N = 814) = 16.717, p < .001$ ) between inmates' rated need level on the substance abuse domain of the DFIA-R and prescription practices for psychotropic medication; both offenders with no need and those with the highest level of need are among inmates most likely to have their psychotropic prescriptions coded as being for an approved use.

Table 7

*Approved and Off-label Prescription of Psychotropic Medication, By Institutional Charges and DFIA-Revised Substance Abuse Domain Ratings*

	Approved % (n)	Off-label % (n)	$\chi^2(df)$
Institutional Charges <sup>a</sup>			
None	57.6 (136)	42.4 (100)	8.73* (3)
1-2	67.6 (92)	32.4 (44)	
3-5	59.7 (89)	40.3 (60)	
More than 5	68.6 (201)	31.4 (92)	
Substance Abuse Domain Rating <sup>a</sup>			
No need	73.5 (83)	26.5 (30)	16.72*** (3)
Low need	57.7 (41)	42.3 (30)	
Moderate need	51.0 (73)	49.0 (70)	
High need	66.0 (320)	34.0 (165)	

<sup>a</sup> Missing data for 6 cases for which institutional charge data not recorded, accounting for a total of 15 missing prescriptions

<sup>ns</sup> non-significant, \*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$ .

## Discussion

In their 2015 report, Farrell-Macdonald et al. concluded that, although the use of psychotropic medications among incarcerated federal offenders was greater than in the general Canadian population, the prevalence rate was “commensurate with similar correctional populations” (p.11). As found in other correctional studies, they found that incarcerated women were prescribed psychotropic medications more frequently than men, possibly reflecting higher prevalence rates for mental health problems among women in the population and among women inmates (Beaudette & Stewart, 2016; Derkzen et al., 2012; Derkzen, Barker, McMillan, & Stewart (in approvals); Health Canada, 2002; Prins, 2014). The Farrell-MacDonald study found no significant difference in the prevalence of psychotropic medication prescriptions based on Indigenous ancestry.

In the current study, estimates of the prevalence of prescriptions for off-label uses of psychotropic medications are in the same order (36.2%) as were found in the Quebec study of prescription practices in the general population (Egualé et al. , 2012), and somewhat lower than international estimates of off-label prescribing in general populations. This finding may reflect the increased scrutiny of prescribing practices that is usually found in institutional environments (hospitals, institutions with psychiatric staff), compared to clinics and private medical practices (Frank, Conti, & Goldman, 2005). An analysis by offender indicated that slightly less than 50% of men, women, and Aboriginal offenders in our sample had been prescribed an off-label psychotropic drug; this rate is comparable to those cited in a review of published studies compiled by the Royal College of Psychiatrists (2007).

This study found no significant differences by gender, age or Indigenous ancestry in the use of approved versus off-label prescriptions for psychotropic medication. However, a statistically significant difference was found in the distribution of approved versus off-label psychotropic medication prescriptions by AHFS-defined drug class, with anti-depressant and antipsychotic agents and CNS stimulants and antimanic agents more likely to be prescribed for approved purposes only. On the other hand, the majority of prescriptions for anxiety/insomnia agents were for off-label uses, perhaps a reflection of the high prevalence of off-label prescribing observed for the *DSM-5* diagnosis of sleep-wake disorders, echoing findings from other research (Hassan et al., 2013; Kilty, 2012).

There is no evidence that off-label prescription practices are being used to manage offenders involved in institutional misconducts or who had more serious violent offence histories. There was no clear pattern of relationship between DFIA-R substance abuse domain ratings or the number of institutional charges and distribution of approved versus off-label prescriptions for psychotropic medication. Both offenders with high need and no need on the DFIA-R substance abuse domain were more likely to be prescribed psychotropic medication for an approved purpose than those who were moderate need. Likewise, there is no trend to more frequently prescribe psychotropic medications for off-label use to offenders involved in misconducts; those with more than 5 institutional charges and those with 1-2 charges had a similar percentage of their prescriptions coded as for approved use.

## **Conclusion**

The prevalence rate of off-label prescriptions for psychotropic medication in CSC falls within estimates found in studies of prescription practices of these medications in the community and in studies completed in correctional settings. There are no significant differences by gender, age or Indigenous ancestry in the proportion of these prescriptions for approved versus off-label purposes. Neither does there appear to be a pattern associating the offenders' history of substance use with off-label prescription practices. Among the different classes of psychotropic drugs, anxiety/insomnia agents were identified as the most likely class of psychotropic medications to be prescribed off-label. The condition found to have the highest rate of off-label prescriptions was insomnia.

## References

- American Society of Health-System Pharmacists (2016). *AHFS drug information 2016*. Bethesda, MA: American Society of Health-System Pharmacists.
- Andersen, H.S. (2004). Mental health in prison populations: A review – with special emphasis on a study of Danish prisoners on remand. *Acta Psychiatrica Scandinavica*, 110(424), 5-59. doi: 10.1111/j.1600-0447.2004.00436\_2.x
- Beaudette, J.A., & Stewart, L.A. (2016). National prevalence of mental disorders among incoming federally-sentenced men offenders. *Canadian Journal of Psychiatry*, doi: 0706743716639929
- Brown, G. (2016). *Prescription practices for psychotropic medications in the community and in prison populations: Review of current literature*. (Research Report R-373). Ottawa, ON: Correctional Service of Canada.
- Butler, T., Indig, D., Allnutt, S., & Mamoon, H. (2011). Co-occurring mental illness and substance use disorder among Australian prisoners. *Drug and Alcohol Review*, 30, 188-194. doi: 10.1111/j.1465-3362.2010.00216.x
- Canadian Pharmacists Association (2016). *Canadian compendium of pharmaceuticals and specialties 2016*. Toronto, ON: Canadian Pharmacists Association.
- Canadian Senate Report (2014). *Prescription pharmaceuticals in Canada: Off label use*. Ottawa, ON: Standing Senate Committee on Social Affairs, Science and Technology.
- Chen, H., Reeves, J.H., Fincham, J.E., Kennedy, W.K., Dorfman, J.H., & Martin, B.C. (2006). Off-label use of antidepressant, anticonvulsant and antipsychotic medications among Georgia medicaid enrollees in 2001. *Journal of Clinical Psychiatry*, 67(6), 972-982.
- Cohen, J. (1960). A coefficient of agreement for nominal scales. *Education and Psychological Measurement*, 278, 1440-1445.
- Correctional Investigator of Canada (2014). *Annual Report 2013-2014 - Of the Office of the Correctional Investigator of Canada*. Ottawa, ON: Her Majesty the Queen in Right of Canada.
- Davison, S., Fleming, J., Butler, T., Morgan, V., Petch, E., .....Janca, A. (2015). *Mental health and substance use problems in Western Australia prisoners. Report from the health and Emotional Wellbeing Survey of Western Australia Reception Prisoners*. Western Australia Department of Health.
- Del Paggio, D. (2012). Psychotropic medication abuse by inmates in correctional facilities. *Mental Health Clinician*, 1(8), 187-188. doi: 10.9740/mhc.n95631

- Derkzen, D., Barker, J., McMillan, K., & Stewart, L. (in approvals). *Rates of current mental disorders among women offenders in custody in CSC*. (Research in Brief). Ottawa, ON: Correctional Service of Canada.
- Derkzen, D., Booth, L., McConnell, A., & Taylor, K. (2012). *Mental health needs of federal women offenders* (Research report R-267). Ottawa, ON: Correctional Service of Canada.
- Egualé T., Buckeridge, D.L., Winslade, N.E., Benedetti, A., Hanley, J.A., & Tamblyn, R. (2012). Drug, patient, and physician characteristics associated with off-label prescribing in primary care. *Archives of Internal Medicine*, 172(10), 781-788. doi: 10.1001/archinternmed.2012.340
- Farrell Macdonald, S.F., Keown, L.A., Boudreau, H., Gobeil, R., & Wardrop, K. (2015). *Prevalence of psychotropic medication prescription among federal offenders* (R-373). Ottawa, ON: Correctional Service of Canada.
- Fazel, S., & Seewald, K. (2012). Severe mental illness in 33,588 prisoners worldwide: Systematic review and meta-regression analysis. *British Journal of Psychiatry*, 200, 364-373. doi: 10.1192/bjp.bp.111.096370.
- Frank, G., Conti, R.M., & Goldman, H.H. (2005). Mental health policy and psychotropic drugs. *The Milbank Quarterly*, 83(2), 271-298.
- Hassan, L., Edge, D., Senior, J. & Shaw, J. (2013). Staff and patient perspectives on the purpose of psychotropic prescribing in prisons: care or control? *General Hospital Psychiatry*, 35, 433-438. doi: 10.1016/j.genhosppsych.2013.01.012
- Hassan, L., Senior, J., Frisher, M., Edge, D., & Shaw, J. (2014). A comparison of psychotropic medication prescribing patterns in East of England prisons and the general population. *Journal of Psychopharmacology*, 28(4), 357-362. doi: 10.1177/0269881114523863
- Health Canada (2002). *A report on mental illnesses in Canada*. Ottawa, ON: Health Canada.
- Health Canada (2016). *Drug Product Database*. Retrieved from [www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php)
- Health Canada (2015). *Guidance document: Labelling of pharmaceutical drugs for human use*. Ottawa, ON: Health Canada.
- Hilliard, W.T., Barloon, L., Farley, P., Penn, J.V., & Koranek, A. (2013). Bupropion diversion and misuse in the correctional facility. *Journal of Correctional Health Care*, 19(3), 211-217. doi: 10.1177/1078345813486448
- IBM Corporation (2016). SPSS Statistics 24. Somers, NY: IBM Corporation Software Group.

- James, D.J., & Glaze, L.E. (2006). *Mental Health Problems of Prison and Jail Inmates* (Pub no NCJ 213600). Washington DC: Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. Retrieved from <http://www.bjs.gov/index.cfm?ty=pbdetail&iid=789>
- Kamath, J., Temporini, H.D., Quarti, S., Zhang, W., Pagano, K.L., DeMartinis, N., & Trestman, R.L. (2008). Psychiatric use and utility of divalproex sodium in Connecticut prisons. *International Journal of Offender Therapy and Comparative Criminology*, 52(3), 358-370. doi: 10.1177/0306624X07307367
- Kilty, J.M. (2012). 'It's like they don't want you to get better': psy control of women in the carceral context. *Feminism and Psychology*, 22(2), 162-182. doi: 10.1177/0959353512439188
- Lafortune, D., & Vacharet, M. (2009). La prescription de médicaments psychotropes aux personnes incarcérées dans les prisons provinciales du Québec. *Santé mentale au Québec*, 34(2), 147-170. doi: 10.7202/039130ar
- Lafortune, D. (2010). Prevalence and screening of mental disorders in short-term correctional facilities. *International Journal of Law and Psychiatry*, 33, 94-100. doi: 10.1016/j.ijlp.2009.12.004
- Martin-Latry, K., Ricard, C., & Verdoux, H. (2007). A one-day survey of characteristics of off-label prescription of psychotropic drugs. *Pharmacopsychiatry*, 40(3), 116-120.
- Mattes, J.A. (2012). Medications for aggressiveness in prison: Focus on oxcarbazepine. *Journal of the American Academy of Psychiatry and the Law*, 40(2), 234-238.
- McHugh, M.L. (2012). Inter-rater reliability: The kappa statistic. *Biochemica Medica*, 22(3), 276-282.
- Medco Health Solutions (2011). America's State of Mind. Retrieved from <http://apps.who.int/medicinedocs/documents/s19032en/s19032en.pdf>.
- MEDLINE (2016). EBSCOhost. Retrieved from <http://web.b.ebscohost.com/roxy.nipissingu.ca/ehost/search/advanced?sid=230e81cf-7ed5-410a-b923-fe04568cc7cf%40sessionmgr103&vid=0&hid=110>
- PubMed (2016). U.S. National Library of Medicine. Retrieved from <http://www.ncbi.nlm.nih.gov/roxy.nipissingu.ca/gquery/gquery.fcgi>
- Reeves, R. (2012). Guideline, education, and peer comparison to reduce prescriptions of benzodiazepines and low-dose quetiapine in prison. *Journal of Correctional Health Care*, 18(1) 45-52. doi: 0.1177/1078345811421591
- Rezansoff, S.N., Moniruzzaman, A., Gress, C., & Somers, J.M. (2013). Psychiatric diagnoses

- and multiyear recidivism in a Canadian provincial offender population. *Psychology, Public Policy, and Law*, 19(4), 443-453. doi: 10.1037/a0033907
- Royal College of Psychiatrists (2007). CR142. Use of licensed medicines for unlicensed applications in psychiatric practice. Retrieved from <http://www.rcpsych.ac.uk/publications/collegereports/cr/cr142.aspx>
- Torrey, E.F., Kennard, A.D., Eslinger, D., Lamb, R., & Pavle, J. (2010). *More mentally ill persons are in jails and prisons than hospitals: A survey of the States*. Arlington, VA: Treatment Advocacy Centre.
- Varela-González, O., Algora-Donoso, I., Gutiérrez-Blanco, M., Larraz-Pascual, M.E., Barreales-Tolosa, L., & Santamaría-Morales, A. (2007). Use of psychotropic drugs in prison (Madrid III Penitentiary Centre). *Revista española de sanidad penitenciaria*, 9, 38-46.
- WebMD (2016). Retrieved from <http://webMD.com>.
- Wittich, C.M., Burkle, C.M., & Lanier, W.L. (2012). Ten common questions (and their answers) about off-label drug use. *Mayo Clinic Proceedings*, 87(10), 982-990. doi: 10.1016/j.mayocp.2012.04.017
- Zaitlow, B.H. (2010). Psychotropic control of women prisoners: The perpetuation of abuse of imprisoned women. *Justice Policy Journal*, 7(2). Retrieved from [http://www.cjcj.org/uploads/cjcj/documents/Psychotropic\\_Control.pdf](http://www.cjcj.org/uploads/cjcj/documents/Psychotropic_Control.pdf)

## Appendix A

Table 1A

*Approved and 'Off-label' Prescriptions for Psychotropic Medication by Offender (N = 468)*

Group	Approved Only  % (n)	Off-label Only  % (n)	Both On and Off- label  % (n)	Unknown  % (n)	$\chi^2$ (df)
Total	51.3 (240)	25.0 (117)	18.8 (88)	4.9 (23)	
Gender					
Men	51.2 (151)	26.1 (77)	16.3 (48)	6.4 (19)	6.89 <sup>ns</sup> (3)
Women	51.4 (89)	23.1 (40)	23.1 (40)	2.3 (4)	
Age <sup>a</sup>					
19-24	48.5 (16)	21.2 (7)	30.3 (10)	0.0 (0)	19.55 <sup>ns</sup> (12)
25-34	49.1 (85)	26.6 (46)	21.4 (37)	2.9 (5)	
35-44	49.5 (51)	30.1 (31)	16.5 (17)	3.9 (4)	
45-54	51.9 (55)	26.4 (28)	13.2 (14)	8.5 (9)	
55 or more	63.3 (31)	10.2 (5)	16.3 (8)	10.2 (5)	
Indigenous Ancestry					
Indigenous	52.1 (75)	24.3 (35)	20.1 (29)	3.5 (5)	1.14 <sup>ns</sup> (3)
Non-Indigenous	50.9 (165)	25.3 (82)	18.2 (59)	5.6 (18)	

<sup>a</sup> Missing data for 4 cases for which no date of birth or age information was provided

<sup>ns</sup> non-significant, \* p < .05, \*\* p < .01, \*\*\* p < .001.