Drug losses and thefts cost health care facilities in investigations, care for patients with inadequately treated pain or harmed by drug substitution or tampering, and reputation-related damages. Furthermore, losses from health care facilities have the potential to increase illegal supply of opioids via trafficking. In the United States, the Drug Enforcement Agency reports annually on opioid losses from health care institutions (e.g., community pharmacies, hospitals). The Canadian authority that captures data on opioid losses from health care facilities, Health Canada, does not publish an equivalent report. Dating back to at least 1961, any individuals or organizations in Canada licensed to produce, package, assemble, sell or transport opioids are mandated to report losses to Health Canada by fax or email within 10 days (see reporting form in Appendix 1, section 9, available at www.cmajopen.ca/content/8/1/E113/suppl/DC1). This group includes, but is not limited to, a wide variety of facilities such as hospitals, community pharmacies, all companies (e.g., drug manufacturers), long-term care homes and veterinary hospitals.

Health Canada conducts random, targeted inspections of community pharmacies to assess compliance with the mandate, but data on hospital inspections are scarce. Local regulatory

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Research

dispensed opioids in Canada 20 but is not yet classified as a morphine and oxycodone. Tramadol is among the 6 most controlled substance,21 so no loss reports were captured for this drug.

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Opioid losses have been reported in “dosage units” and “incidents of loss,” both of which have important limitations that may not be widely understood. Dosage units indiscriminately count loss quantities (e.g., the loss of 1 tablet is counted as the same as the loss of 1 bottle containing 500 tablets). Incidents of loss ignores the quantity of loss completely and may also be affected by reporting frequency (e.g., hospital A may submit a single report for multiple losses of a drug within a 10-d window, whereas hospital B may submit separate reports after each occurrence).

To broaden the understanding of opioid losses in Canada, we analyzed Health Canada data to estimate milligram losses for 5 common opioids; estimate the wholesale and street value of lost opioids; compare milligrams lost and reason for loss by facility type; and compare opioid loss trends as measured by incidents of loss, dosage units and milligrams.

Methods

Data source
In June 2018, the CBC published Health Canada data from an Access to Information request for all controlled drug losses between Jan. 1, 2012, and Sept. 30, 2017.18,19 This is the largest published data set identified and is therefore valuable for assessing trends in Canadian health care sources. The CBC confirmed that the data were uploaded without alteration as they were received from Health Canada (Tara Carman: personal communication, 2019); the data are consistent in format with previous Access to Information requests.

Inclusion criteria and constraints
We limited our analysis to the most commonly dispensed opioids in Canada based on data from the Canadian Institute for Health Information: codeine, fentanyl, hydromorphone, morphine and oxycodone. Tramadol is among the 6 most dispensed opioids in Canada but is not yet classified as a controlled substance, so no loss reports were captured for this drug.

Outcomes
The Health Canada data state a numeric quantity lost for each incident of loss, but the unit code (e.g., millilitres, tablets, patches) for each report varies. Two authors (M.F. and D.T.), with the support of pharmacy students, used this information to calculate manually the milligrams lost for every reported drug loss (they updated a single file repeatedly and reviewed it continuously in a collaborative manner). For anomalous reports, M.F., D.T. and M.H. came to consensus on how to proceed. We then used the calculated milligrams lost to determine oral morphine equivalents and daily defined doses (see Appendix 1, section 3, for conversion factors). Daily defined doses are defined by the World Health Organization as the “assumed average maintenance dose per day for a drug used for its main indication in adults” and is used to facilitate international comparisons.

We used the lowest estimate of loss for ambiguous or anomalous reports. For example, 1 report listed the loss of 728 packages of hydromorphone hydrochloride, 50 mg/mL. From the data set, it was unclear whether these containers were 1 mL, 5 mL, 10 mL or 50 mL. In this case, the smallest available package according to the drug product monographs found on Health Canada’s Drug Product Database is a box of ten 1-mL vials. To estimate the impact of a nonconservative approach, we recalculated the losses for the top 40% of anomalous reports most affected by the conservative approach for each of the 5 opioids (additional details are provided in Appendix 1, section 2).

For 2017, the data set contains data only for January to September. We therefore provide a prorated estimate for a full year of 2017 only when data are presented by year. We averaged the milligram losses in the first 3 quarters of 2017 and added this value as the loss for the final quarter (October to December).

The definitions from Health Canada for the various loss categories (e.g., unexplained loss, pilferage) in the data set are included in Appendix 1, Supplemental Table S1. Not all loss categories in the data set are captured in Health Canada’s guidance document, but we left these reports in the analysis for comprehensiveness. We assumed the loss description was accurate in the absence of an alternative strategy.

Wholesale and street drug costing
We calculated approximate wholesale costs from the Ontario Drug Benefit database (2019 data) for the entire data set because most oral morphine equivalent losses came from Ontario. If the cost was not available from the Ontario Drug Benefit database, we searched other provincial formularies (see our analytical dataset, available at https://github.com/HumanEra/Health-Canada-Drug-Loss-and-Theft-Data-Analysis, for wholesale pricing information). Although street value fluctuates depending on cycles of supply and demand, geography and drug strength, we used a single point-in-time street value based on information from the Ontario Provincial Police and the literature (Appendix 1, section 4).

Statistical analysis
We conducted descriptive analyses of the opioid losses by calculating milligrams of drug lost, oral morphine equivalents, daily defined doses, approximate wholesale value and approximate street value. We used Microsoft Excel for analyses.

Ethics approval
No personal health information or human participants were involved in the study. No specific institutions are identified, and the data are publicly accessible from Health Canada on request. As a result, ethics board approval was not required.
Results

Restricting our analysis to codeine, fentanyl, hydromorphone, morphine and oxycodone resulted in 64,963 reports, which is 45.6% of the reports in the original data set (142,420). An analysis of the 64,963 reports using a conservative approach when imputing anomalous records showed that the cumulative loss of the 5 opioids between January 2012 and September 2017 was over 112 kg (Table 1). This equates to about $8.7 million in wholesale costs and $136 million if all lost drugs were resold on the street. When we used a more liberal approach on a sample of anomalous reports, milligram losses increased by 7.5 kg, the wholesale value increased by $886,670, and the street value of the losses increased by $9,695,290 (Appendix 1, Supplemental Table S5).

Community pharmacies, companies and hospitals were responsible for nearly all losses, accounting for 76.8%, 17.1% and 6.0% of lost oral morphine equivalents, respectively (Table 2). As a result, all subsequent analyses were focused on these 3 facility types.

The dominant reasons for loss (in milligrams) varied by facility type (Table 3). Community pharmacy losses were primarily from armed robberies (31.1%), break and entry (28.1%), unexplained losses (17.6%) and pilferage (15.5%). Company losses were primarily from unexplained losses (55.8%) and losses in transit (30.7%). Hospitals were affected primarily by pilferage (57.4%) and unexplained losses (33.4%).

More detailed breakdowns of loss trends by province or territory for community pharmacies and hospitals showed that there were substantial reductions in community pharmacy losses in British Columbia over the study period, whereas Ontario hospitals reported an increasing amount of pilferage losses in the more recent years of the study period (Appendix 1, sections 5 and 6).

| Table 1: Opioid losses reported to Health Canada by facilities such as hospitals, community pharmacies, companies, long-term care homes and veterinary hospitals, January 2012 to September 2017 |
|---|
| **Drug; route** | Milligrams lost (per 1000)† | Oral morphine milligram equivalent (per 1000)† | Daily defined dose | Estimated wholesale value, $ | Estimated street value, $ |
| **Codeine** | | | | | |
| Oral | 47,072.3 | 7,060.8 | 196,135 | 1,313,140 | 52,956,369 |
| Injection | 3.7 | 0.9 | 58 | 514 | 4185 |
| Indeterminate | 228.7 | 34.3 | 953 | 6369 | 257,306 |
| **Fentanyl‡** | | | | | |
| Oral | 66.8 | 8,687.6 | 111,379 | 3,212,163 | 26,731 |
| Injection | 10.6 | 1,065.5 | 66,336 | 302,036 | 4257 |
| Transdermal | 184.0 | 18,403.2 | 153,360 | 199,936 | 511,997 |
| Indeterminate | 2.7 | 349.8 | 4484 | 129,346 | 1077 |
| **Hydromorphone** | | | | | |
| Oral | 12,160.0 | 60,799.4 | 607,994 | 1,447,179 | 18,239,833 |
| Injection | 544.4 | 9,526.8 | 136,097 | 199,890 | 816,581 |
| Rectal | 0.5 | 2.8 | 117 | 593 | 702 |
| Indeterminate | 19.2 | 96.0 | 960 | 2288 | 28,803 |
| **Morphine** | | | | | |
| Oral | 15,154.6 | 15,154.6 | 151,546 | 353,846 | 12,578,317 |
| Injection | 325.6 | 976.7 | 10,852 | 205,417 | 270,224 |
| Rectal | 73.0 | 87.7 | 2435 | 11,318 | 60,627 |
| Indeterminate | 134.7 | 134.7 | 1347 | 3151 | 111,794 |
| **Oxycodone** | | | | | |
| Oral | 36,537.3 | 54,805.9 | 487,164 | 1,312,734 | 45,671,623 |
| Rectal | 9.6 | 172 | 319 | 3229 | 11,975 |
| Total | 112,527.7 | 177,204.1 | 1,931,538 | 8,703,149 | 136,152,401 |

*“Oral” refers to tablets, capsules, and sublingual and oral solutions (e.g., syrups); “injection” includes intravenous and subcutaneous formats; “indeterminate” refers to line items in the data set for which the route or format of the drug was ambiguous.
†Column and row totals may not match the sum of numbers in the table because the table shows only rounded numbers.
‡Fentanyl is typically dosed in micrograms, but for consistency with other drugs we report in milligrams.
We observed different trends when reporting milligrams of lost opioids than when reporting dosage units or number of incidents of loss (Table 4). Specifically, the incidents of loss and dosage units lost from community pharmacies increased steadily from 2012, but milligram losses did not. Conversely, hospitals showed increased milligram losses in the more recent years of the study period, whereas the same trend was not seen for incidents of loss and dosage units. Companies did not show discernible trends in any of these metrics. A visual depiction of trends is presented in Appendix 1, section 7.
Interpretation

Our analysis suggests that the lower bound for the average annual loss of 5 common opioids in Canada between January 2012 and September 2017 is 19.6 kg, with a street value of $23.7 million. Community pharmacies were the largest contributor to the losses, followed by companies and hospitals, which suggests that improving security and accounting of opioids in community pharmacies should be prioritized. However, unexplained losses were a major category of loss in all 3 facility types, which suggests that Canadian facilities as a whole lack adequate capacity to track and secure opioids. Furthermore, each type of facility may benefit from targeted research to address unique vulnerabilities: community pharmacies were most susceptible to armed robbery and break and enter, hospitals faced a high rate of pilferage, and company losses often occurred during drug transit.

The analysis also showed that opioid loss reporting should include the quantity of milligrams lost. Community pharmacy losses remained stable over time when measured in milligrams, but loss rates increased when loss was measured by dosage units or incidents of loss. Hospital losses increased over time when measured in milligrams but not when measured by dosage units or incidents of loss. These findings show that dosage units or incidents of loss alone do not tell the full story; reporting losses in milligrams provides an important complementary means of assessing loss trends over time within and between facility types or provinces.

According to the International Narcotics Control Board, Canada consumed 7747 kg (legally acquired) of the 5 opioids analyzed for 2017. The average annual loss in our data set therefore represents 0.25% of Canada’s consumption. However, the true quantities of loss are likely higher than what our analysis estimates and suggest that an annual loss of 19.6 kg of opioid from Canadian facilities is not trivial.

Table 4: Incidents of loss, dosage units lost and milligrams (per thousand) lost by facility type

| Facility type; variable | 2012  | 2013  | 2014  | 2015  | 2016  | 2017 (up to September only) | 2017 (data prorated to full year) |
|-------------------------|-------|-------|-------|-------|-------|-----------------------------|----------------------------------|
| Community pharmacy      |       |       |       |       |       |                             |                                  |
| Incidents of loss       | 4587  | 3948  | 5879  | 7768  | 13 743| 22 517                      | 30 023                           |
| Dosage units lost       | 736 886| 596 185| 947 010| 978 053| 1 152 808| 1 425 626                   | 1 900 835                       |
| Milligrams lost (per 1000) | 17 091.0| 10 904.4| 16 870.6| 18 286.1| 17 425.6| 18 871.1                     | 25 161.5                        |
| Company                 |       |       |       |       |       |                             |                                  |
| Incidents of loss       | 338   | 412   | 524   | 568   | 407   | 252                         | 336                              |
| Dosage units lost       | 90 562| 136 032| 173 273| 111 022| 53 296| 24 053                      | 32 070                           |
| Milligrams lost (per 1000) | 1355.7  | 1974.8 | 2144.4 | 1585.6 | 3682.7 | 780.8                      | 1041.0                          |
| Hospital                |       |       |       |       |       |                             |                                  |
| Incidents of loss       | 650   | 673   | 649   | 625   | 707   | 576                         | 768                              |
| Dosage units lost       | 29 692| 17 820| 47 679| 18 379| 45 929| 16 441                      | 21 921                           |
| Milligrams lost (per 1000) | 128.6  | 155.6 | 88.3  | 213.1 | 318.8 | 518.9                      | 691.8                            |

Previous literature highlights challenges with detecting or reporting losses; hospitals have been fined for insufficient record-keeping and failing to report drug losses. One endoscopy clinic found that more than $10 000’s worth of propofol was unaccounted for in a single 4-week period. These examples suggest that poor traceability obscures detection and reporting of drug losses. Inclusion of nonopioids in future studies would increase the total milligrams lost and the subsequent costs of drug lost.

The 2018 US Drug Enforcement Agency report described an annual average loss of 12.2 million opioid dosage units, compared to 1.1 million dosage units in our data. This discrepancy is similar to the population difference between the US and Canada, which suggests that rates of opioid loss and theft are similar in the 2 countries.

Our findings suggest 4 areas of work that may help better understand and potentially mitigate opioid losses and thefts. First, Health Canada and provincial and territorial regulatory bodies may want to assess the impact of their inspection practices against opioid losses moving forward. In 2015, Health Canada began a community pharmacy inspection program. Data show an upward trend in the incidents and dosage units of opioid lost after this program began but no substantial increase in milligrams lost (Table 4). In contrast, in 2016, the Ontario College of Pharmacists started to inspect and accredit Ontario hospital pharmacies; since then, there has been an increase in milligrams lost to pilferage (Appendix 1, section 6). Further research into the differences between these inspection programs might reveal why such differences were observed and support optimal inspection practices that can be used for all Canadian facilities responsible for opioids. Inspection practices for companies could also be reviewed to ensure they are similarly effective, given that they contribute larger opioid milligram losses than hospitals.

Second, analysis of regional differences may provide insight into best practices that could be adopted nationally.
British Columbia showed a notable reduction in community pharmacy losses from armed robberies and break and enter incidents (Appendix 1, Supplemental Table S9), possibly owing to the implementation of time-delay safes.11,13,14 Caution in drawing strong conclusions is warranted given that there were increases in other loss categories (e.g., unexplained losses) in BC. However, armed robbery and break and enter are one of the primary reasons for loss in community pharmacies, and regional differences of this nature may provide regulators and facility managers some indication of potentially helpful practices that may be worth adopting.

Third, the prominence of “unexplained losses” in all facilities suggests that further research is needed to understand why Canadian facilities are unable to track the reasons for loss. The high rate of unexplained losses also raises questions about the misclassification of drug losses. For example, reports of accidental breakage or spillage of a controlled drug may actually be false reports made by hospital staff to obscure diversion, particularly if there are not robust processes in place to verify these losses.

Finally, to support these areas of work, we suggest that Canadian stakeholders would benefit from an annual summary of controlled substance losses reported to Health Canada, similar to that published by the US Drug Enforcement Agency.11 This report would facilitate regular assessment of diversion, particularly if there are not robust processes in place to verify these losses.


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