

Opioids: Risk Evaluation/Mitigation Strategies in Veterinary Medicine

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Introduction: Risk Assessment and Strategic Management of Opioid Class Medications

Opioid-class medications have been used in veterinary medicine for many years and remain an important part of the arsenal that our profession can call upon to fight pain. Opioids function as effective analgesics either alone or in combination with other classes of analgesics. They are important for management of significant pain occurring in chronic conditions such as cancer or for perioperative and postoperative patients, producing patient comfort.

This document is not intended to be a policy paper, a position statement nor a standard for legal use, but rather a brief summary of current knowledge and best practices as a potential reference for the veterinary health care team, and as a resource for further discussions.

Recognizing a balance between safe and effective prescription of opioid class medicine for the benefit of the veterinary patient and the societal crisis in opioids in humans is critical to our continuing privilege of prescription. *Most provincial licensing bodies have detailed guidelines for the purchase, safe storage, tracking, dispensing and disposal/destruction of scheduled drugs, and it is incumbent for each licensed practitioner to maintain competence in this.* The government of Canada provides the overarching legislative environment for prescribers.

STAFF ORIENTATION/TRAINING

This is a *whole clinic* issue, so the veterinarian must ensure proper training of the entire veterinary health care team, meticulous records, and a well-secured inventory to ensure a tamper-proof chain of custody from purchase, through prescription and into case follow up.

Signs of illegal medication redirection are not always obvious. There are a few so-called "red flags" that may assist a clinic to be alert to possible diversion efforts.

Below are a few pointers about red flags to review periodically at staff meetings:

 If a client seeking veterinary care exhibits unusual behaviours this may indicate drug-seeking behaviour, though frequently the client is a source for redistribution to others rather than for own-use. Their role may be inadvertent (by not keeping dispensed medication locked away from family/guests in the home environment), or less commonly it may be a cleverly designed ruse to obtain drugs for illegal redirection, sometimes from multiple practices as part of a gang or other drug-seeking plan. "Doctor shopping" is a known concern in human medicine, whereby the client goes to many practices with the same apparently painful problem.

- In veterinary medicine, the reviewer of a medical record transfer from other clinics finds multiple scripts for opioids;
- A client undertaking long distance travel to a clinic;
- An animal that has repeat unexplained/suspicious injuries requiring narcotic-level pain management;
- Noting that different clients bring in the same patient for "pain";
- Multiple pets from the same address with pain problems;
- Client using cash payment for settling a narcotic prescription invoice;
- Asking for an early refill (e.g., I lost the vial)
- Request for specific opioids even though that knowledge would be unexpected of a typical client;
- Requests for larger amounts or stronger medications than would be prudent.

INTERNAL QUALITY ASSURANCE

Ordering

If a staff member orders the product under direction of the veterinarian, if it is not a veterinarian esigned script sent directly, ensure the original veterinarian-signed version of the prescription is what was sent (as in a signed faxed script). Have another staff member and the veterinarian proof that the amount received back matches the prescription before entering stock into inventory logs. The College of Veterinarians of Ontario (CVO) regulations require both the purchasing veterinarians' signature, and the signature of the person logging the order in the narcotic log.

Inventory

Inventory counts should be delegated to one staff member to help simplify tracking. Inventory must be taken at least weekly, and always be signed off by two people, including the veterinarian in charge of the practice. In Ontario, the CVO advises that audits be carried out by more than one staff member, and that the role of auditor be rotated if staff size in the clinic allows.

Veterinarian proofing of the inventory should occur periodically, with no notice to the staff to confirm log accuracy. Where possible, keep minimal stock, or avoid stocking opioid products. Use pharmacies to fulfill scripts for fentanyl patches and other home products where possible. This streamlines practice narcotic inventory. If left over or damaged hospital inventory needs to be disposed of or destroyed, follow the municipal, provincial and national guidelines to the letter. Staff should be trained to report any discrepancy in inventory immediately. Though rare, a staff member may steal or redirect opioids.

The narcotic log should be updated at the time of hospital use or drug dispensing, and the address and name of the client appear beside the amount dispensed and inventory balance. Records should be kept a minimum of two years. This may be less than the minimum in some jurisdictions. CVO regulations require that medical records be kept for five years after the date of the last entry in the record. Logs are kept as long as any patient documented in the log still has an active medical record.

The log and inventory should be kept locked away at all times when not in use. The practice of keeping the cupboard or box open for the duration of business hours is not encouraged.

Prescription Security

Another goal is to help prevent forged, lost, duplicated scripts, and prevent stolen prescription pads. Pads should be under lock and key and never left in an exam room with a client unattended. In some jurisdictions for example, each prescription is numbered and customized so that missed pad pages are easily noticed, and no other prescriber can use the pad. Tracking of paper script pad pages assumes the prescriber keeps track of the number of the most recent script written. The veterinarian should review the record of the patient prior to signing a refill to assure him/her that the proper amount of time has elapsed, or that another clinic doctor has not already refilled it recently.

In the Patch-for-patch program in Ontario, a first prescription must contain the written note: "**First Prescription**" on the physical or digital prescription. A patch must be returned to the dispenser before another one can be released. Prior to disposal the dispenser must ensure the patches are rendered unusable, and safe disposal practiced, with a recommended minimum two staff signing off on the disposal. Health Canada recommends that another health professional witness and sign (i.e., veterinarian or RVT). Before placing a prescription for a fentanyl patch the prescriber must notify the dispenser (if an external pharmacy) in writing or by phone ahead of the client pick up.

In Alberta, the College of Physicians & Surgeons of Alberta (CPSA) have written guidelines for physicians including the need to reassess the patient to whom the narcotic is prescribed after four weeks on therapy and thereafter every three months, and to check the PIN/Netcare network before prescribing at those times. These guidelines do not yet exist for veterinarian Canadian jurisdictions though in some states, veterinarians must check their state registry network before making certain prescriptions.

Safe Management and Prescription Practices

A helpful checklist to review before a prescription is made is found in section 3-7 of the Saskatchewan Provincial Dispensing Manual). Three questions should be answered:

- 1. Is this my patient?
- 2. Do I have a valid Veterinarian-Client-Patient-Relationship (VCPR)?
- 3. Is the drug required for the condition I am treating?

Fulfilling Dispensing Guidelines (Tips):

1. Is this my patient?

Scan microchips, record tattoos and take a photo of the pet to be inserted into the medical record to ensure there is no misidentification of a patient.

2. Do I have a valid VCPR?

Does the prescriber have recent and sufficient knowledge of health and pain assessments? Normally, this is within a 12-month timeframe, but in many cases much less than 12 months is appropriate.

3. Is this drug required for the condition I am treating?

- Ensure that the minimum effective dose and duration is reflected in the prescription.
- Confirm the patient is suitable for opioids based on their health status.
- Document all assessments and plans in the medical record.
- Confirm and record that the prescription continues to be indicated, and that it is efficacious for pain management of the patient. Professional pain staging is important both before and during treatment.

CLIENT EDUCATION

Client education about proper use, side effects, and secure storage of the patient prescription is incumbent upon the prescribing veterinarian. Ideally, a written treatment plan that outlines narcotic medication risks and benefits, proper handling, administration, storage and disposal should be strongly considered. Information for the caregiver regarding home assessment of comfort/pain signs also should be provided as part of that written plan. Follow up by the veterinarian to confirm the drug is still needed should be done before refills are authorized, and the client should be made aware in the plan instructions that this is an integral part of the plan.

If a patient plan sheet is dispensed, one would plan to keep a copy for the medical record to confirm what was advised at script pick up or discharge. Train staff, or have the veterinarian directly review that plan with the client in person to ensure compliance. Some practices require that the client initial the copy of the plan, and that the signed copy is inserted in the medical record to ensure they signed off on understanding of that full explained plan.

SUMMARY

It is very rare to find a veterinarian out of compliance, but rarely, licensing body or legal proceedings do occur. The burden of proof rests on the practitioner to prove innocence if practitioner drug investigation or prosecution occurs, so it is important to adopt best practices for management of all restricted drugs.

Increased clinic staff awareness, public education, and careful prescription practice can help veterinary professionals reduce possible diversion leading to misuse, while continuing to prescribe these important medications.

Veterinarians are a part of "one health" and thus can play their role in protection of the public health while ensuring the humane management of animal pain. Review of current legislation and guides for handling opioids is both important from a public health perspective, as well as being a requirement of licensure.

APPENDIX 1: PUBLIC HEALTH SITUATION, Backgrounder

Illegal and redirected prescription products have in combination, led to the current North American opioid crisis. The USA declared opioids a public health emergency in October 2017. An emergency task force was struck in Ontario in fall 2017 to deal with the public health fallout of misuse of opioids, while around the provinces as another example; British Columbia declared a public health emergency due to opioids back in April of 2016.

The human cost of the opioid crisis is increasing. Family concerns, hospitalization, addict treatment programs and even user death are some consequences of this unfortunate situation. Though veterinarians are a potential source for some of these illegally redirected opioids, the veterinary profession is considered to play a very minor source role. There are no published statistics confirming veterinarians in Canada have been a part of illegal diversions to date that the writer is aware of, though possibly rare instances may have gone undocumented. In the USA, according to Simpson (2014)³ one case per 30 million people, or 6.5 cases in the US per calendar year were reported redirections from veterinary sources.

Sources for opioids include bona fide prescription of quality products with illegal redirection, or the illegal market. Illegal market-sourced opioids are subject to the whims of the dealers. Opioids are frequently "cut" with other drugs, or placed into another drug product without any advisement of the "doctoring" to the consumer. This is problematic because some of the chemical derivatives of drugs are dangerous even in small doses, and small or unknown doses of even prescription quality opioids are potentially harmful due to their high potency.

Keeping in mind that statistics are fuzzy because most reports do not distinguish illegal-based source outcomes from redirection-based outcomes, below are some human statistics for reference. The CIHI 2016¹ report of human hospitalizations and emergency visits from overdose as follows: "Between 2007–2008 and 2014–2015, the rate of hospitalizations due to opioid poisoning increased more than 30% to almost 14 per 100,000 population. The rate of ED visits increased by 53% in Alberta and 22% in Ontario between 2010–2011 and 2014–2015. Hospitalization rates for people increased across all age groups, although the greatest change occurred among youth aged 15 to 24; the rate for this age group increased by 62% from 6.5 to more than 10 per 100,000." They also reported that "The majority of poisonings among youth were intentional (52%)"^{1.}

In a Health Canada 2013 Canadian Tobacco, Alcohol and Drugs Survey, one in seven Canadians 15+ years of age reported opioid use in the past year.⁴ The reports did not distinguish between bona fide prescription pain therapy and illegal source or redirected use; this is on par with most survey reports. In the 2012 CTADS report opioid use was measured at 12%, versus 15% in 2013. The same survey done in 2015 noted a 13% use and of these they reported, 2% self-reported abusing the opioids.⁵ Overall use did not apparently increase, while complications did.

CIHI also reported "Synthetic opioids (such as fentanyl and tramadol) accounted for 6% of hospitalizations due to opioid poisoning in 2014–2015. However, the rate of hospitalizations due to synthetic opioid poisoning increased from 0.5 to 0.8 per 100,000 population across the study period (from 166 in 2007–2008 to 300 in 2014–2015)."¹

According to the CIHI, "Fentanyl is considerably more potent than other opioids, and even small quantities can result in poisoning The finding that approximately one-third of opioid poisonings were intentional is consistent with trends in the recorded use of opioids in self-harm behaviours in Canada. For example, between 1998 and 2007, opioid analgesics were the most common category of substances implicated in nearly 400 suicides in Toronto, Ontario, accounting for 28% of all cases" ¹ In the US, it was reported that 49 states tracked controlled substances and about one third required veterinarians to report to state databases when they write a controlled substance prescription. (Cima, 2017)⁶

APPENDIX #2 AROUND THE PROVINCES AND TERRITORIES

- In Newfoundland & Labrador, the licensing of physicians now requires a mandatory course be completed on drugs with abuse potential. <u>https://www.med.mun.ca/Medicine/Communications/News-at-Medicine/March-2017/Safeprescribing-Addressing-the-opioid-problem-in.aspx</u>
- In Nova Scotia, mainstream media article warns of possible abuse and veterinarian doctor shopping, published by the CBC, MacIvor, A. (June 23, 2017) "Opioid Abusers Could be "Doctor Shopping" with Pets, Vet Warns. Dr. Frank Richardson of the Nova Scotia VMA was interviewed for this article and pointed out that the veterinarians are not part of the province prescription monitoring system, which leaves a loophole for prescription abuse.

http://www.cbc.ca/news/canada/nova-scotia/pets-veterinarians-opioids-drugs-1.4173607

- Saskatchewan a Dispensing Manual <u>http://svma.sk.ca/uploads/pdf/dispensing manual.pdf</u> Section 3-7 to 3-10 outlines prescribers' responsibilities.
- 4. In Alberta, in 2016 they began registration in the Triple Prescription Monitoring Program (TPP) with the College of Physicians and Surgeons in Alberta (CPSA)—early findings reported were in the Nov_Dec_17 Members Newsletter p. 21 at: http://www.abvma.ca/document/3552/Nov_Dec_17.pdf
- 5. Ontario Fentanyl Patch-for Patch program started Oct 1, 2016, to accord with Bill 33, see Frequently Asked Questions: Implementation of the Safeguarding our Communities Act (Patch for Patch Return Policy), (2015). Ontario Public Drug Programs Division, Ministry of Health and Long-Term Care

http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/fq_exec_office_20160 916.pdf

CVO Factsheet patch-For-Patch Fentanyl Return program.

http://www.cvo.org/Resources/Professional-Practice-Standards-and-College-Policy/Veterinary-Prescribing-and-Dispensing/Patch-For-Patch-**Fentanyl**-Return-Program-Fact-Sheet.aspx

APPENDIX #3: DEFINITIONS

For the purposes of discussion,

Patient: the animal that is assessed and treated by a licensed veterinarian

Prescription drug: those medications only available by professional prescription via an authorization for release and use by the person for the pet named on the prescription.

Client: owner, caregiver, agent with responsibility for the patient's welfare and care that pays the professional for medicine, surgery and preventive care, using a valid VCPR.

VCPR (veterinary client patient relationship); must be active for a prescription to be made, requires current assessment of the patient, usually considered within the year or as needed on a case-by-case basis.

Opioid/Narcotic: Drug class includes both illegal and legal forms of the products; legal forms are set out in the schedules. Representative drugs in this class of interest to veterinary care include fentanyl, tramadol, (both synthetic), hydrocodone, oxycodone, hydromorphone, morphine, buprenorphine, butorphanol and codeine. Only a legally registered dispenser (pharmacist, veterinarian) is allowed to possess these scheduled substances.

Diversion/redirection: the use of the prescribed drug for use other than its intended purpose for pain relief in the patient.

References and Further Reading:

- Canadian Institute for Health Information, Canadian Centre on Substance Abuse. Hospitalizations and Emergency Department Visits Due to Opioid Poisoning in Canada. Ottawa, ON: CIHI; 2016 Cette publication est aussi disponible en français sous le titre "Hospitalisations et visites au service d'urgence liées à une intoxication aux opioïdes au Canada". ISBN 978-1-77109-527-3 (PDF)
- The Colorado Department of Regulatory Agency; Veterinary Policy for Prescribing and Dispensing Opioids, <u>https://drive.google.com/file/d/OBzKoVwvexVATRIBZdWxCdGJwcDQ/view</u> authored by the Colorado State Board of Veterinary Medicine, October 13, 2016.
- 3. Simpson, RJ. (2014) Prescription drug monitoring programs: Applying a one size fits all approach to human and veterinary medical professionals, custom tailoring is needed. *J Anim and Environ* L. 5-2.
- 4. Health Canada 2013 Alcohol, Tobacco and Drug Survey (CTADS). <u>https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-</u> <u>survey/2013-summary.html</u>
- Health Canada 2015 Alcohol, Tobacco and Drug Survey (CTADS). https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugssurvey/2015-summary.html
- 6. AVMA: Cima, G. (Jan 19, 2017) States Track Drug Dispensing to Counter Drug Fraud <u>https://www.avma.org/News/JAVMANews/Pages/170201a.aspx</u>

Additional Resources and Tools

College of Physicians and Surgeons of Alberta Prescribing: Drugs with Potential for Misuse or Diversion <u>http://www.cpsa.ca/standardspractice/prescribing-drugs-misuse-diversion/</u>

College of Pharmacists of British Columbia. Controlled Prescription Program August 2011. <u>http://library.bcpharmacists.org/6 Resources/6-4 Drug Distribution/5015-</u> <u>ControlledPrescriptionProgram.pdf</u>

Progress Report on the Joint Statement of Action to Address the Opioid Crisis in Canada. Canadian Centre on Substance Use and Addiction (May 2017). [For December 2016-February 2017]

<u>http://www.ccsa.ca/Resource%20Library/CCSA-Addressing-Opioid-Crisis-in-Canada-Summary-Appendix-2017-en.pdf</u>

CVO. Who is in Control of your Controlled Substances? <u>http://www.cvo.org/For-Licensed-Members/Who-is-in-control-of-your-controlled-substances.aspx</u>

Controlled Drugs and Substances Act, Canada at <u>http://laws-lois.justice.qc.ca/enq/acts/C-38.8/</u> Subsection of law relevant to veterinarians; Part G, Food and Drugs Regulations (Controlled Drugs Schedules) <u>http://lawslois.justice.qc.ca/enq/regulations/C.R.C., c. 1041/page-10.html#h-7</u>

Health Canada 5-point Action Plan Opioid Misuse— Public health emergency response, prevention, treatment, harm reduction, enforcement in the Infographic (.pdf): <u>https://www.canada.ca/en/health-canada/services/publications/healthy-living/taking-action-canada-opioids-crisis.html</u>

A recent opinion article (CBC, July 26, 2017 "Feverish talk about an opioid crisis ignores the benefits for chronic pain patients" by Downton, DR). <u>http://www.cbc.ca/news/opinion/opioids-chronic-pain-1.4216530</u>). In this article, the author distinguishes between veterinary profession and human profession medical use versus addicts, as she points out sometimes this is lost in the media reports.

AVMA: Delegates tackle timely issues in veterinary medicine (opioid article) July 24, 2017 <u>http://atwork.avma.org/2017/07/24/delegates-tackle-timely-issues-in-veterinary-medicine/</u>

Provincial Veterinary Regulatory Bodies

CVO <u>http://www.cvo.org</u> Nova Scotia <u>http://nbvma-amvnb.ca</u> PEI <u>http://www.peivma.com</u> Manitoba <u>https://www.mvma.ca</u> BC: <u>http://www.cvbc.ca</u> New Brunswick <u>http://nbvma-amvnb.ca</u> NFLN/Labrador: <u>https://sites.google.com/site/nlvetcollege/contact-the-college</u> Québec <u>https://www.omvq.qc.ca</u> NWT <u>www.hss.gov.nt.ca/</u> Nunavut <u>gov.nu.ca</u> Saskatchewan <u>http://www.svma.sk.ca</u> Alberta: <u>http://www.abvma.ca</u>

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