ACDH
Alberta College of Dental Hygienists

Guidelines for Dental Hygienists in Alberta

Drugs and Natural Health Products

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Guidelines for Drugs and Natural Health Products

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The Alberta College of Dental Hygienists (the College) provides guidelines to support dental hygienists in understanding and meeting their legislated requirements, standards of practice, and code of ethics. Guidelines establish professionally accepted means by which dental hygienists can achieve compliance with the College's standards.

Failing to comply with a guideline may be considered unprofessional conduct if the dental hygienist did not achieve compliance with the standard, or if the departure from the guideline compromises the quality of client care or the integrity and/or credibility of the dental hygiene profession.

A dental hygienist may only depart from a guideline if they can demonstrate their chosen conduct:

- Achieves compliance with the applicable standard;
- Maintains the safety, effectiveness, or appropriateness of client care required by the standard; and
- Upholds the integrity of the dental hygiene profession.

While these guidelines reflect the requirements for dental hygienists at the time of development, these requirements may change from time to time. Dental hygienists remain responsible for ensuring their practice meets current legislative requirements, Standards of Practice, and Code of Ethics.

Dental Hygienists' Responsibilities

Drugs: General Standards of Practice

- The dental hygienist uses an evidence-informed approach to administer, recommend, prescribe (if permitted), sell, provide, and compound drugs safely and appropriately.

Drugs: Prescribing Schedule 1 Drugs Standards of Practice

- The authorized dental hygienist prescribes safely and appropriately within their practice of dental hygiene, competencies, practice setting, and in compliance with legislation.

Documentation Standard of Practice

- The dental hygienist documents clear, accurate, and comprehensive patient records in a timely manner.

Clinical Therapy Standard of Practice

- The dental hygienist applies professional knowledge, training, and experience to competently provide patient-centred clinical therapy safely and effectively.

Informed Consent Standard of Practice

- The dental hygienist must obtain the patient's ongoing informed consent for the initiation and delivery of dental hygiene services.

Evidence-Informed Practice Standard of Practice

- The dental hygienist seeks, promotes, supports, and incorporates an evidence-informed approach in their practice.

Collaboration Standard of Practice

- The dental hygienist collaborates with patients, oral health professionals, and others in a cooperative, constructive, and respectful manner for the benefit of the patient.

Safety and Risk Management Standard of Practice

- The dental hygienist protects their patients, themselves, and others from illness and injury by ensuring a safe practice environment and complying with applicable provincial occupational health and safety legislation.

Code of Ethics (Beneficence and Non-Maleficence)

- Beneficence is the ethical principle of doing good while non-maleficence means to do no harm. Together these principles guide the dental hygienist to provide dental hygiene services that benefit the patient and minimize harm.

It is your responsibility to monitor and comply with any changes to the legislation and/or the College's documents regarding drugs and natural health products.

Dental hygienists who are authorized prescribers should also refer to the Guidelines for Prescribing Schedule 1 Drugs.

Legislation and Regulation

Drugs and natural health products (NHPs) are controlled federally by the *Food and Drug Act*, the *Controlled Drugs and Substances Act* and the regulations made under those Acts, including the Natural Health Products Regulations.

Drugs

The National Association of Pharmacy Regulatory Authorities (NAPRA) maintains schedules of drugs based on the *Controlled Drugs and Substances Act*:

- Schedule 1 drugs require a prescription as a condition of sale.
    - The Health Professions Restricted Activities Regulation section 8(e) allows dental hygienists to compound, provide for selling or sell, incidentally to the practice of dental hygiene, a Schedule 1 drug.
    - College-authorized dental hygienists may prescribe certain Schedule 1 drugs listed in the Health Professions Restricted Activities Regulation section 8(d).
- Schedule 2 drugs require professional intervention prior to sale. Although they are available without a prescription, there is no opportunity for an individual to self-select the drug.
    - The Health Professions Restricted Activities Regulation section 8(e) allows dental hygienists to compound, provide for selling or sell, incidentally to the practice of dental hygiene, a Schedule 2 drug.
    - There is no additional College authorization required to compound, provide for selling or sell Schedule 2 drugs.
- Schedule 3 drugs are available without a prescription from the self-selection area of a pharmacy.
    - There is no authorization required for dental hygienists to recommend or sell Schedule 3 drugs, but these drugs may present risks to certain populations in self-selection. Schedule 3 drugs are sold from the self-selection area of a pharmacy under the direct supervision of a pharmacist who is available, accessible and approachable to assist the patient in making an appropriate self-medication selection.
- Unscheduled drugs are those that are not listed in Schedule 1, 2, or 3 that may be sold from any retail outlet.

Alberta's drug schedules are mostly consistent with NAPRA's national scheduling model. The Alberta College of Pharmacy website provides directions and links that can be used to determine the schedule of drugs in Alberta.

Health Canada assigns drug products an eight-digit Drug Identification Number (DIN) prior to being marketed in Canada. A DIN uniquely identifies the following product characteristics: manufacturer, product name, active ingredient(s), strength(s) of active ingredient(s), pharmaceutical form, and route of administration.

Natural Health Products

NHPs are included in the *Food and Drugs Act's* definition of "therapeutic product." NHP is a term used in Canada to refer to a group of health products including:

- Vitamin and mineral supplements;
- Herbal remedies and other plant-based health products;
- Traditional medicines (e.g., traditional Chinese medicines and Ayurvedic medicines);
- Homeopathic medicines;
- Fatty acids (e.g., omega 3, 6 and 9);
- Probiotics; and
- Some personal care products (e.g., toothpastes, mouthwashes).

NHPs that have been issued a product licence bear an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the label.

- A NPN or DIN-HM on a label means that the product has been authorized for sale in Canada by Health Canada and has been found to be safe and effective when used in accordance with the instructions on the label.

Up-to-date information on licensed NHPs can be found in the Licensed Natural Health Products Database (LNHPD). The MedEffect™ Database provides known safety information associated with NHPs.

Drugs and Natural Health Products in the Practice of Dental Hygiene

All dental hygienists may administer, recommend, sell, or provide drugs and NHPs for patients in accordance with the College's Standards of Practice. Only dental hygienists who are authorized by the College may prescribe certain Schedule 1 drugs listed in the Health Professions Restricted Activities Regulation section 8(d).

Administering, recommending, selling, or providing drugs or NHPs must be done within the legislated practice of dental hygiene, that is, as part of a therapeutic, educational or preventive dental hygiene procedure or strategy and for the purpose of assessing, diagnosing, or treating oral health conditions. Drugs may also be used to manage medical emergencies.

- It is your responsibility to continuously self-assess your own competency to utilize a particular drug or NHP. Take steps to become competent or maintain your competency by seeking out opportunities to learn reliable information (e.g., through completion of coursework, mentorship, or continuing education).

Dental hygienists should administer, recommend, sell, or provide drugs and NHPs in a manner that is consistent with either:

- Indications approved by Health Canada;
- Best practices or accepted clinical practice in peer-reviewed literature; or
- An approved research protocol.

Preparing to Use a Drug or NHP in Your Practice of Dental Hygiene

Before using a drug or NHP, you need to identify:

1. Whether it is appropriate to utilize the strategy for your patient;
2. What Standards of Practice are applicable to you in those circumstances; and
3. Whether you need to collaborate with an authorized prescriber to access the drug for your patient.

You can prepare by asking yourself the following questions:

- Are there any possible contraindications or adverse effects that may occur if this patient receives this drug or NHP?
    - This includes reviewing the patient's medical history for contraindications (e.g., allergies), including the patient's medication history to determine if there are any potential drug interactions (e.g., drug-drug, drug-food).
        - The medication history identifies all prescription, non-prescription and NHPs a patient is taking.
        - Depending on the patient's circumstances, you may take the best possible medication history approach where a complete and accurate list of all the medications a patient is taking is created by consulting at least two sources of information including a patient and/or family interview.
- Is this a prescription drug, non-prescription drug, or NHP?
- Am I:
    - Administering the drug or NHP?
    - Recommending the drug or NHP?
    - Selling or providing the drug or NHP?
    - Compounding a Schedule 1 or 2 drug?
    - Prescribing a Schedule 1 drug?
- If administering a prescription drug, has the patient been issued a prescription from an authorized prescriber (e.g., authorized dental hygienist, dentist, authorized pharmacist, physician or nurse practitioner)?
- Do I have a clinical therapy relationship with this patient and have I personally assessed them to determine if the drug or NHP is appropriate?
- Does the drug or NHP treat an oral health condition?
- Does the drug or NHP assist the patient in reaching their oral health goals?
- Is this an emergency situation that needs to be managed by administering a drug?

Refer to the decision-making tool in Appendix A to assist you in deciding whether to use a drug or NHP for your patient.

Evidence-Informed Approach

Dental hygienists may incorporate drugs and NHPs into their patient's care plan by taking an evidence-informed approach that is safe and appropriate for that patient. This involves:

- Assessing your patient appropriately, including medical history, medication history, and clinical assessments;
- Researching information about the drug or NHP you wish to utilize, including possible drug interactions, contraindications, risks, and benefits of the expected treatment outcomes;
- Basing your decision to utilize drugs and NHPs on current evidence from reliable sources (e.g., scholarly peer-reviewed journals, systematic reviews, clinical and best practice guidelines, data from Health Canada);
- Using your professional judgment to evaluate the appropriateness of the drug or NHP for the patient and their oral health goals while respecting the patient's right to choose their therapy without judgment or bias.
    - Consider the patient's individual needs, values, life circumstances, culture, and inherent dignity.

Informed Consent

Obtain informed consent from your patient by sharing relevant information about:

- The recommended drug or NHP;
- The rationale for selecting a particular drug or NHP;
- The exact nature and anticipated benefits of the proposed drug or NHP;
- The risks (e.g., actual or potential adverse reactions, allergies, or sensitivities), side effects, and costs associated with the drug or NHP;
    - You should inform your patient that there will be a cost for the drug or NHP at a pharmacy or store.
    - Unless you are selling the drug or NHP yourself, you do not have to provide your patient with the exact cost.
- The implications the drug or NHP will have on the patient (e.g., cautions regarding activities, food, or other drugs that may affect the therapeutic effect or pose a risk to the patient while they take the drug or NHP);
- The diagnosis or prognosis, if applicable;
- The reasonable alternative procedures or strategies available and their associated risks; and
- The potential consequences of refusing recommendations.

Drugs in the Practice of Dental Hygiene

Drugs include prescription (Schedule 1) and non-prescription (Schedule 2, 3 and unscheduled) drugs. If a drug is approved by Health Canada, it may be utilized in the practice of dental hygiene if appropriate.

Administering a Drug

Administering a drug means supplying a dose of a drug to a person for the purpose of immediate ingestion, application, inhalation, insertion, instillation, or injection.

- Dental hygienists can administer prescription and non-prescription drugs in their practice of dental hygiene.
- To ensure patient safety, it is your responsibility to know about the drug you are planning to administer and whether it is appropriate for the patient.

Administering drugs is not typically a restricted activity unless the *Health Professions Act* specifies that authorization is required.

- Certain drugs can only be administered if you are authorized by regulations to do so (e.g., vaccines, parenteral nutrition, blood or blood products, diagnostic imaging contrast agents, anaesthetic gases, radiopharmaceuticals).
    - For example, dental hygienists may administer nitrous oxide oxygen sedation by inhalation if they have completed advanced training and are authorized by the College.
- Administering drugs by an invasive procedure on body tissue below the dermis or the mucus membrane, or in or below the surface of the teeth is a restricted activity.
    - The Health Professions Restricted Activity Regulation section 8(a) authorizes dental hygienists to administer drugs by invasive procedures.
    - For example:
        - Dental hygienists may administer an antimicrobial agent by subgingival placement.
        - Dental hygienists who have completed advanced training and are authorized by the College may administer local anaesthetic by injection.

Administering drugs is more than just the physical task of giving a drug to a patient. It also includes a cognitive and interactive aspect of care involving assessing the patient, making clinical decisions, and planning care based on this assessment. Drug administration requires the knowledge and skills of a competent health care professional.

Before administering a drug, consider the rights of medication administration that prevent drug incidents:

- Right patient
- Right drug
- Right dose
- Right route

- Right time
- Right documentation
- Right reason
- Right response

You should only administer those drugs that you are competent to administer.

- Consider the route of administration (e.g., oral, injection, topical) and whether you have the knowledge, skills, and judgment to administer the drug.
- If you self-assess your competency and determine you require additional training, address your learning needs before administering the drug.

Administering Prescription Drugs

Administering a Schedule 1 prescription drug can only be done if the patient has a prescription from an authorized prescriber (e.g., authorized dental hygienist, dentist, authorized pharmacist, physician or nurse practitioner).

- Ensure that there are no contraindications to administering the Schedule 1 drug.
    - This requires a comprehensive medical history review, including reviewing the patient's medication history.
- The patient must provide informed consent for the administration of the Schedule 1 drug.

If you did not prescribe the Schedule 1 drug yourself, then base your decision to administer the drug on collaborative discussion and decision-making between the patient, the prescriber and you.

- The prescriber is responsible for following any legislation, regulations, or standards that apply to them when prescribing (e.g., the Drugs: Prescribing Schedule 1 Drugs Standard of Practice for authorized dental hygienist prescribers).
- You are responsible for knowing the reason for administering the drug and having the knowledge, skills, and judgement to assess the appropriateness of the drug for the patient.
    - Use your professional judgment to identify whether the drug is appropriate to administer (e.g., the patient presents with the condition the drug is intended to treat).
    - If you have questions or concerns regarding the appropriateness of the drug, the prescriber should be consulted prior to administering the drug.
- You should be competent to identify and treat the oral health condition(s) the drug is intended to treat as part of your practice of dental hygiene.

Clarify with the authorized prescriber if a prescription is unclear, inappropriate, illegible, or incomplete. Clear communication of the prescriber's intent is important for the patient's safety.

- As a best practice, obtain a written prescription from the prescriber indicating the Schedule 1 drug to be administered.

- Drug incidents (i.e., preventable events that may cause or lead to inappropriate drug use or patient harm) can occur with verbal instructions when spoken language is misunderstood due to mispronunciation, sound-alike medication names or patient names, or background noises or disruptions.

Documenting an Administered Prescription Drug

Document the name of the authorized prescriber who prescribed the drug for the patient and any relevant discussions you had with the prescriber. You must also document:

- The name, strength, dose, and dosage form of the drug;
  - For local anaesthetic with epinephrine, this information can be conveyed either by calculating the dosage or indicating the concentration and volume administered.
- The route of administration;
- The reason for administering the drug and patient's response to the procedure and drug;
- The date and time the drug was administered;
- Details about the informed consent process; and
- The individual who administered the drug.

Administering Non-Prescription Drugs

The decision to administer non-prescription drugs for a dental hygiene purpose can be initiated by a dental hygienist. If administering a non-prescription drug, you must first recommend the drug (see section below).

Documenting an Administered Non-Prescription Drug

Document the following in the patient's record after administering a non-prescription drug:

- The name, strength, dose and dosage form of the drug;
  - For local anaesthetic without epinephrine, this information can be conveyed either by calculating the dosage or indicating the concentration and volume administered.
- The route of administration;
- The reason for administering the drug and patient's response to the procedure and drug;
- The date and time the drug was administered;
- Details about the informed consent process;
- The individual who administered the drug.

Recommending a Drug

Recommending a drug is not a restricted activity identified by the *Health Professions Act*. While dental hygienists may recommend both prescription and non-prescription drugs, prescription drugs should only be recommended in collaboration with an authorized prescriber.

Dental hygienists may recommend a non-prescription drug after assessing a patient and considering their medical history and medication history.

- Before recommending a drug, use an evidence-informed approach to determine the best strategy for your patient based on their needs, values, and interests.
    - Strategies could include recommending the non-prescription drug, recommending another treatment (or no treatment), or referring your patient to another appropriate health professional to address their concern(s).

Include your patient in the decision-making process by providing them with relevant information for informed consent, including:

- The rationale for selecting a particular drug;
- The implications for using drug therapy (including post-care instructions that may impact their decision to receive the drug);
- Possible side effects and when they should report them; and
- Instructions for administration, including possible drug or food interactions.

You must also document:

- The date the drug was recommended;
- Who recommended the drug;
- The reason for recommending the drug;
- The information you have provided your patient about the drug, (e.g., name, strength, dose, and dosage form of the drug).

Providing or Selling a Drug

The Health Professions Restricted Activity Regulation section 8(e) authorizes dental hygienists to sell or provide Schedule 1 or Schedule 2 drugs that are incidental to the practice of dental hygiene. You may also sell or provide Schedule 3 drugs and unscheduled drugs because these activities are not restricted. Regardless of the drug's schedule or whether the drug is sold or provided at no charge, the Drugs: General Standard of Practice's performance expectations regarding providing or selling a drug apply.

Restrictions on Selling or Providing Drugs

Dental hygienists cannot sell drugs in the same manner as pharmacists. The authorization to provide or sell is intended to provide flexibility to meet patient needs where a pharmacy is not readily accessible, or patient compliance is an issue.

- You can sell or provide drugs to your patient that are incidental to the practice of dental hygiene (i.e., drugs that are used for oral health conditions).

- You must complete an appropriate assessment for your patient before selling or providing a drug (e.g., consider allergies, drug-drug interactions, drug-food interactions, patient's oral health condition, patient's oral health goals).
- All drugs, scheduled and unscheduled, must be stored in a location that does not allow patients to self-select for purchase.

Dental hygienists should not sell or provide products labelled "for professional use" to their patients for at-home use.

- Products used by dental hygienists that are considered "for professional use" by Health Canada are not intended to be distributed to the general public for their at-home use.
- Dental products designated to be "for professional use" may be different formulations than over-the-counter dental products and are subject to different requirements for labelling.

Packaging

Prescription and non-prescription drugs provided or sold by dental hygienists must be given to the patient in the manufacturer's original package or container unless it is not reasonably possible to do so.

Manufacturers are required to ensure that adequate information regarding the drug, including directions for use, are included on the label.

If the product needs to be removed from the manufacturer's package, you must ensure that the package is appropriate for the drug (i.e., the drug will not react with the container) and that the container protects the drug (e.g., from light, humidity, temperature, etc.). A child resistant container should be used unless it is not suitable for the drug or the patient.

In the rare event that you cannot reasonably provide or sell a drug in the manufacturer's packaging, drugs may be repackaged for provision or sale to patients with a label that has the following information:

- For non-prescription drugs:
    - A description of the drug in English including the generic name, strength, and manufacturer of the drug, or the brand name and manufacturer for a combination drug product;
    - The quantity of drug in the package;
    - A lot number for the drug;
    - The expiry date for the drug; and
    - Directions for use.
- For prescription drugs:
    - The name of the client for whom the drug is provided;
    - The name, business address, and business telephone number of the dental hygienist who provided the drug;
    - The name of the prescriber of the drug;

- A description of the drug in English including the generic name, strength, and manufacturer of the drug, or the brand name and manufacturer for a combination drug product;
- The quantity of the drug provided.
- The expiry date for the drug;
- Instructions for the use of the drug; and
- The date the drug was provided;

Additional resources for labelling include:

- Guidance Document: Labelling of Pharmaceutical Drugs for Human Use - Canada.ca
- Labelling requirements for non-prescription drugs: guidance document - Canada.ca

In addition to the documentation for prescribing or recommending a drug, if you provide or sell a drug, you should document the following in the patient record:

- Any additional information about the informed consent process;
- The lot number of the drug;
  - In case of a drug recall, recording the lot number of the drug can facilitate identifying patients who you have provided the recalled drug to.
- The reason for sale or provision of the drug;
  - This includes the rationale for why the patient could not have accessed the drug at a pharmacy.
- The identification of the dental hygienist who provided or sold the drug.

Compounding a Drug

It is rare that a dental hygienist would need to compound a drug. Compounding involves mixing together two or more ingredients, where at least one ingredient is a drug, for the purpose of dispensing a drug.

- This does not include reconstituting a drug with only water or mixing two or more ingredients together (where at least one ingredient is a drug) for immediate administration because neither activity meets the definition of compounding in the *Health Professions Act*.

While dental hygienists may compound Schedule 1 or 2 drugs, you should only do so if:

- It is not reasonably possible for your patient to attend a compounding pharmacy;
- There is no alternative for your patient; and
- You can demonstrate the competency to do so.

If you are in a situation where these three criteria are met and there is a need to compound a Schedule 1 or 2 drug, refer to Alberta College of Pharmacy resources for information about requirements for compounding, including documenting the compounding record in the patient record.

The labelling requirements discussed in the section for "Providing or Selling a Drug: Packaging" (see above) apply to drugs compounded by dental hygienists.

Managing Medical Emergencies Using Drugs

As part of the Safety and Risk Management Standard of Practice, dental hygienists are expected to:

- Ensure that appropriate, evidence-based emergency protocols exist in their workplace.
    - This includes protocols that involve utilizing drugs to manage medical emergencies.
- Follow these established workplace protocols when an emergency situation occurs.
- Ensure that emergency drugs are appropriate for your practice setting, readily accessible and appropriately stored.
- Recognize and respond to adverse events and competently apply appropriate emergency response skills, including administering drugs when indicated.

If your employer does not have emergency protocols appropriate to the practice setting or up-to-date drugs required to appropriately manage emergencies, you are responsible for taking reasonable steps (e.g., collaborating with your employer) to ensure that this is in place for your patients.

Non-Prescription Drugs for Medical Emergencies

If managing a medical emergency for your patient includes administering a non-prescription drug (e.g., diphenhydramine liquid, nitroglycerin sublingual tablets, acetylsalicylic acid) you must follow your Standards of Practice and the guidelines for "Administering Non-Prescription Drugs" (see above) to ensure that your selection and administration of the drug is safe, evidence-informed, and documented in the patient record.

Prescription Drugs for Medical Emergencies

Dental hygienists who are authorized may prescribe and administer epinephrine and/or a bronchodilator to treat a medical emergency. Both of these Schedule 1 drugs are listed in section 8(d) of the Health Professions Restricted Activity Regulation.

If you are not an authorized prescriber, you should adhere to the following:

- If an authorized prescriber (e.g., authorized dental hygienist, authorized pharmacist, dentist, physician, or nurse practitioner) is onsite, a dental hygienist who is not a prescriber should attempt to obtain an immediate, verbal prescription for administering a Schedule 1 drug from them, unless doing so would delay care and place a patient at risk of serious harm.
- In an emergent life and death situation a dental hygienist may prescribe a Schedule 1 drug without being an authorized prescriber if an appropriate, evidence-based workplace protocol is in place.

- You must be appropriately trained in the emergency response skills required to manage the emergency. This includes having the knowledge, skills and judgment to critically assess and appropriately intervene in practice situations where a Schedule 1 drug is required, prescribed, and administered.
- For example:
  - Epinephrine can be administered for anaphylaxis emergencies
  - Bronchodilators (e.g., salbutamol) can be administered for asthma-related emergencies.

Natural Health Products in the Practice of Dental Hygiene

Dental hygienists may recommend, administer, provide, or sell an NHP if it is related to their practice of dental hygiene and has been approved by Health Canada. This includes utilizing NHPs for therapeutic or preventative purposes to promote wellness related to a patient's oral health condition. You must consider the indications and contraindications for the NHP to determine if it is appropriate for your patient.

- Identify contraindications by following an evidence-informed approach and completing a medical history, including a medication history, to determine which prescription drugs, non-prescription drugs and NHPs, if any, the patient is currently taking.

In the patient record, document the NHP you have recommended, administered, provided, or sold to your patient, including:

- The NHP's name and strength;
- Date the NHP was recommended, administered, provided, or sold;
- The purpose for which the NHP was recommended, administered, provided, or sold;
- Route and method of administration;
- The dosage (if applicable based on risk);
  - Dosage is necessary for continuity of care and to prevent:
    - drug-drug interactions,
    - drug-food interactions, or
    - exceeding tolerable upper intake levels.
  - For example, if you sell fluoride supplements, it would be necessary to document the dosage you provided or recommended to your client.
  - There may be limited instances where dosage is unnecessary to document if you have determined there is minimal risk (e.g., topical fluoride gel - this can be documented with the strength of the fluoride gel).
- Any adverse reactions the patient experiences.

Unlike drugs, you may allow patients to self-select NHPs (e.g., fluoridated toothpaste).

Drug Errors, Drug Incidents and Adverse Drug Events

	Preventable Events		Unexpected and Undesired Incidents
Event	**Drug Incidents**	**Drug Errors**	**Adverse Drug Events**
Definition	Drug incidents are any preventable event that may cause or lead to inappropriate drug use or patient harm.	Drug errors are drug incidents where the drug has been released or administered to the patient.	Adverse drug events are unexpected and undesired incidents related to drug therapy that results in an adverse outcome for a patient, including injury or complication.
Event may be related to:	• Professional practice • Drug products • Workplace procedures and systems • Prescribing • Order communication • Product labelling/ packaging/ nomenclature • Compounding • Dispensing • Distribution • Administration (e.g., inappropriate frequency or dosage) • Education • Monitoring • Use • Known drug-drug or food-drug interactions • Documentation		• Allergic reaction • Unintended drug effects • Unknown drug-drug or food-drug interactions

Preventing Drug Errors

Dental hygienists who administer, recommend, prescribe, provide, or sell drugs must participate in a quality assurance program designed to prevent, report, investigate, and evaluate drug errors.

Minimize the risk of errors and ensure the integrity, quality, and safety of drugs in your practice by participating in the process to acquire, store, and dispose of drugs. Review your workplace procedures to ensure you are knowledgeable about the proper storage and disposal of drugs used for dental hygiene purposes.

Acquiring Drugs

Drugs must be approved for use in Canada by Health Canada and acquired through legitimate means (i.e., through a pharmacy or a pharmaceutical company).

- It is inappropriate for a health professional to use drugs that have not been approved for use in Canada (i.e., lack a DIN).

- Acquiring drugs by illegitimate means carries risk that the drug may not be the correct substance, may be beyond the expiry date, may have been stored inappropriately or may be otherwise unsafe.

Storing Drugs

Organize and store drugs in a manner that:

- Minimizes the possibility of errors (e.g., selecting the wrong drug);
    - Unusable, outdated, mislabelled, or deteriorated drugs and those subject to recall can be removed and stored in a separate area until they are safely disposed.
- Secures against theft or loss;
- Maintains the drug's integrity, quality and safety (e.g., follows manufacturer's instructions for temperature, humidity, exposure to light, etc.) to avoid altering the drug's composition, safety, and efficacy;
    - Consider how you will manage a situation where a drug has been exposed to conditions outside the manufacturer specifications (e.g., a refrigerator loses power while storing a drug that requires refrigeration). You should have policies in your workplace to address these situations.
- Prevents patients from self-selecting drugs (prescription and non-prescription) for purchase.

Workplace procedures to store and handle drugs (e.g., returning drugs to storage after use) can reduce risk of error.

Disposing Drugs

Dispose drugs when they expire to prevent drug errors from occurring.

Refer to manufacturer's instructions and municipality requirements for disposing drugs appropriately. You may be able to dispose drugs at a pharmacy, but you should confirm in advance whether the pharmacy will accept drugs for disposal.

You may need to dispose drugs that are recalled.

- Ensure you have a system to locate drugs that you have in your practice in the event of a recall.
- You should also be able to identify patients to whom you have provided or sold the recalled drug to ensure you are able to inform them of the recall.

Responding to and Reporting Drug Incidents, Drug Errors, and Adverse Drug Events

<table>
<tr><th></th><th>Drug Incident</th><th>Drug Error</th><th>Adverse Drug Events</th></tr>
<tr><td rowspan="2">Dental Hygienist's Response</td><td colspan="2">If the drug has been released to the patient, but <u>not yet been administered</u> your response should include:
Notifying the patient of the error; and
Correcting the error if possible.
If the drug <u>has been administered</u> to the patient, your response should include:
Determining whether emergency measures are required to protect the health and safety of the patient;
Monitoring the patient's response to the drug to ensure that an adverse drug event does not occur; and
Referring the patient to another health professional if necessary.</td><td>If <u>emergency measures are required</u> to protect the health and safety of the patient, they should be implemented immediately.
If <u>emergency measures are not required</u>, determine whether to monitor the patient to observe whether the adverse outcome will resolve, and/or refer the patient to another health professional if necessary.</td></tr>
<tr><td colspan="3">When a drug incident, drug error, or adverse drug event occurs or you have reasonable suspicion that a drug incident or drug error will occur, perform an incident analysis.
An incident analysis is a structured process that aims to identify:
What happened;
How and why it happened;
What can be done to reduce the risk of recurrence and make care safer; and
What was learned.</td></tr>
<tr><td>Reporting</td><td colspan="2">Canadian Medication Incident Reporting and Prevention System (CMIRPS)</td><td>Canada Vigilance Program</td></tr>
</table>

Reporting Drug Incidents, Drug Errors, and Adverse Drug Events

Reporting of drug incidents, drug errors, and adverse drug events within your practice setting is a key part of a drug quality assurance program.

- Identifying potential drug errors and adverse drug events before they occur while considering their root causes and contributing factors will assist you in identifying and implementing procedures to prevent errors from occurring.

All drug incidents, drug errors and adverse drug events must be documented within 24 hours of discovery.

- Your documentation should gather the information required to investigate the incident and be easy to audit and review.
- See the Alberta College of Pharmacy's Incident Reporting Form as an example.

Incident Analysis

Incident Analysis is a structured process that aims to identify what happened, how and why it happened, what can be done to reduce the risk of recurrence and make care safer, and what was learned.

- The investigation and analysis process begins with the report which should be completed thoughtfully and thoroughly.
- Following completion of the report, investigate root causes and contributing factors to decide whether any changes or corrective actions should be taken to prevent recurrence.
- See Alberta College of Pharmacy's Incident Analysis Process: Summary and Quick Reference Guide for how to complete this process.

In addition to the analysis of individual incident reports, a regularly scheduled review of all incident reports should be completed to identify commonalities.

- This review may assist in identifying corrective actions that were not or could not be identified based on individual incidents.
- The review may also assist in the analysis of whether corrective actions implemented previously have been successful.
- Appropriate scheduling of this review will depend on the size of the practice and the number of incident reports completed.

Reporting Adverse Drug Events: Canada Vigilance Program

Dental hygienists are required to participate in the Canada Vigilance Program and report adverse drug events.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada.

- This program enables Health Canada to monitor the safety profile of health products after they are marketed to ensure that the benefits of the products continue to outweigh the risks.
- The program collects information regarding health products marketed in Canada including:
    - Prescription and non-prescription drugs;
    - NHPs;
    - Disinfectants and sanitizers with disinfectant claims.
- The information collected by the program can be accessed through the Canada Vigilance Online Database.

The program provides a variety of tools for health professionals and consumers to report suspected adverse reactions.

- Reporting can be done online, by phone or by submitting the "Side Effect Reporting Form" by fax or mail.

- Forms and more information are available on the Canada Vigilance Program website.

Adverse reactions include side effects.

- Health Canada defines a side effect as a harmful and unintended response to a health product, including prescription and non-prescription drugs and NHPs.
- An unintended effect, health product abuse, overdose, interaction (including drug-drug and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable side effects.
- A serious side effect is one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.
    - Side effects that result in significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

All suspected side effects should be reported, especially those that are:

- Unexpected, regardless of their severity (i.e., not consistent with product information or labelling);
- Serious, whether expected or not; or
- Reactions to recently marketed health products (on the market less than five years), regardless of their nature or severity.

Reporting Drug Incidents and Errors

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information, the Institute for Safe Medication Practices Canada (ISMP Canada), Healthcare Excellence Canada and Patients for Patient Safety Canada. The goal of CMIRPS is to reduce and prevent harmful medication incidents and errors in Canada.

Part of CMIRPS program is ISMP Canada's collection of individual practitioner reports of medication incidents.

- These are voluntary reports which help to reduce drug error reoccurrence and to achieve a safer healthcare system.

CMIRPS does not collect or analyze reports of adverse drug reactions or side effects.

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Appendix A: Decision-Making Tool

Utilizing Drugs and Natural Health Products (NHP) in the Practice of Dental Hygiene