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A Compounding Overview

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Learning objectives

After successful completion of this continuing education program, pharmacy technicians will be able to:

1. Recognize patient populations who may benefit from compounded medications.
2. Discuss the benefits and challenges associated with compounding.
3. List different dosage forms that can be compounded.
4. Review how to ensure patient safety when compounding.

Introduction

The art and science of pharmaceutical compounding is a long-practiced and integral part of pharmacy. Long before commercially manufactured medications were available, pharmacists were preparing compounded medications for patients. While the advent of manufactured medications saw a decline in compounding practice, there is a clear and present need for qualified pharmacy staff to prepare compounded medications to meet the unique needs of individual patients and situations.

It is important that pharmacy technicians involved in compounding have the technical knowledge, skills, and abilities to safely prepare a compound. They must also:

• recognize patient populations who would benefit from compounding,

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TABLE 1 - Definitions of Compounding[2-5]

Term	Entity	Definition
Compound	NAPRA	Material that has been prepared (e.g., chemical or pharmaceutical preparation)
Compounding	NAPRA	Act of preparing a pharmaceutical preparation, through preliminary work, to put into a usable state
Nonsterile Compounding	USP <795>	Combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labelling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation
Sterile Compounding	USP <797>	Combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication; This does not include preparation of a sterile product as per the manufacturer's approved labelling for administration to a patient
Anteroom	NAPRA	Fully enclosed room between the clean room & the non-controlled pharmacy area; Transitional room with a visible demarcation line to separate the "dirty"area at the entrance of the anteroom from the "clean" area adjacent to the entrance to the clean room; Space used for garbing & hand hygiene;
Clean Room	NAPRA	Room with controlled atmospheric properties (temperature, air pressure, airflow, content of particles & microorganisms) that is physically separated from rest of pharmacy & other non-controlled areas to decrease the risk of introducing contaminants; Used only for compounding of sterile products; Designed to minimize the introduction, generation & retention of particles;

NAPRA–National Association of Pharmacy Regulatory Authorities; USP–United States Pharmacopeia.

- understand the benefits, as well as the challenges of compounding,
- appreciate the different dosage forms that can be compounded, and
- know how to ensure safety in compounding.

Compounding – Who, what, where, when and why

Health Canada defines compounding as "the combining or mixing of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing," using either raw materials or commercially available products.[1] Table 1 reviews definitions related to compounding from the National Association of Pharmacy Regulatory Authorities (NAPRA) and the United States Pharmacopeia (USP).

Who can compound?

Pharmacists and pharmacy technicians can prepare compounds they have been trained to prepare. Pharmacy assistants who have undergone appropriate training may also compound after receiving formal delegation from a pharmacist.[2,3,6] All compounding personnel must undergo proper orientation and training, and a skills assessment program at their place of practice, with regular evaluations.[2,3,6] Due the complex nature and inherent risks associated with sterile compounding, training of compounding personnel must include an initial training and assessment program consisting of theoretical assessment of policies and procedures, as well as aseptic compounding processes, and practical training and assessment in the clean room and on aseptic technique, using gloved fingertip sampling and media fill tests. As per NAPRA standards, regular competency assessments must re-occur every six months (for high risk) to 12 months (for low to medium risk).[2,3]

What can we compound?

A wide variety of compounded dosage forms can be prepared, in a unique dose/strength for an individual patient. Dosage forms are discussed below.

Where can compounding occur?

Both sterile and nonsterile compounding can be performed in community, hospital and long-term care pharmacies, as well as in specialty pharmacies that focus only on compounding and those that only provide care to veterinary patients. Different locations will compound different dosage forms and use different active pharmaceutical ingredients (APIs) depending on the facility.

Sterile compounding requires an anteroom and a clean room, as well as additional specialized equipment, such as a laminar airflow hood (LAFH).[2,3] Compounding with hazardous ingredients, including nonsterile compounding, requires a separate, ventilated room with additional containment engineering controls, such as external venting and negative pressure to surrounding areas.[2,4]

When do we compound?

Medications can be compounded when there is a therapeutic need that cannot be met through commercially manufactured medications or when a commercial drug product is not available due to a manufacturer shortage, within the triad relationship of the prescriber-pharmacist-patient.[1-3,6]

Why do we compound?

Commercially manufactured medications are not always suitable or available for all patients and do not always meet the needs of all patients. In some instances, a product that a patient has used in the past is no longer available but was the best therapy for that patient. Compounding customized medications can fill these gaps.

Patients Who May Benefit from Compounded Medications

While any patient can require and benefit from a compounded medication, pediatric, geriatric and veterinary patients, patients receiving hospice care, and individuals with allergies, intolerances or sensitivities to specific excipients may benefit the most from compounding.

Pediatric Patients

Most medications are not manufactured in doses or dosage forms suitable for pediatric patients. According to one study, only 60% of new medications marketed for use in children six years of age and younger that were approved by Health Canada between

January 1, 2007 and December 31, 2016 were "available in a child-friendly oral dosage form," leaving a need for compounded medications in this age group.[7] While most children aged 6 – 11 can be trained to swallow a small oral tablet, approximately 9% of children will not be able to, facing barriers such as fear, anxiety, intolerance to unpleasant flavours, and their individual developmental stage.[8]

Additional challenges to administering medications to pediatric patients can include negative responses to taste, texture and smell, especially in children with sensory processing disorders, such as attention-deficit hyperactivity disorder (ADHD), autism and fragile X syndrome.[9,10]

Compounding "serves an important unmet need" in the pediatric population, allowing medications to be customized to each individual need, thereby potentially resulting in better adherence and more optimal therapeutic outcomes.[9-11] Medications can be compounded into suspensions, suppositories, lozenges, lollipops and transdermal dosage forms for pediatric patients and can be flavoured and coloured to suit the patient's preferences.[9] For those who have an intolerance to texture, compounding professionals can reduce particle size of the ingredients to remove any grittiness using either a mortar and pestle or an ointment mill.[9] Oral liquids can also be compounded in more concentrated strengths, ensuring a smaller volume per dose is administered.[10]

Geriatric Patients

Geriatric patients tend to have multiple health conditions. Each requires particular medications for management, leading to polypharmacy, and often, decreased adherence due to a complex medication regime and increased risk of adverse effects.[10,12] Compounding professionals can compound several medications into a single dosage form, thereby decreasing the number of doses that need to be used. Medications, especially those for pain, can be compounded into transdermal dosage forms, which are applied topically, but deliver the medication into the bloodstream for a systemic effect. This not only decreases the need for multiple oral medications, but increases bioavailability, requiring a lower dose to achieve the desired therapeutic outcome, by by-passing hepatic first-pass metabolism.[10] Common adverse effects, such as stomach upset often associated with the oral administration of nonsteroidal anti-inflammatory drugs (NSAIDs), can also be avoided when administering a compounded transdermal medication.

Dysphagia (physical or psychological swallowing difficulties) affects up to 35% of seniors living in community and approximately 50% of seniors in hospital, particularly those who have suffered a stroke or head/neck injury, those with an oropharyngeal tumour, and those with a degenerative neurological or muscular disorder, such as Alzheimer's disease or Parkinson's disease.[13] Compounding professionals can prepare more suitable dosage forms for these individuals, such as orally disintegrating tablets, suspensions (altering thickness according to each individual), suppositories and transdermals.[13]

Patients Receiving Hospice Care

Hospice care provides end-of-life comfort and care for those with a life-limiting illness, and aims to relieve pain and increase quality of life.[14] Many patients receiving hospice care experience pain, constipation (often caused by opioids for pain relief), nausea and vomiting, wounds such as bed sores, anxiety, terminal restlessness or agitated delirium, as well as thrush and mouth sores.[14,15] Compounding professionals can prepare a variety of dosage forms using a variety of medications to help relieve some of these symptoms, including topical and transdermal medications, irrigation solutions, suppositories, lollipops, mouth rinses, and parenteral solutions for infections, pain and nutrition.[15]

Individuals with Allergies, Intolerances or Sensitivities, and Personal Preferences

Individuals with allergies, intolerances or sensitivities to food products, colouring agents, sweeteners and preservatives can present challenges to prescribers and pharmacy staff, since many commercially manufactured medications contain these products. Compounding professionals can prepare medications that are allergen-free, dye-free and preservative-free for an individual.

Many individuals may have personal preferences regarding products they consume. Some may need to avoid animal products due to personal preferences and/or religious beliefs.[9,10] Compounding professionals can prepare medications using plant-based products instead of animal-based products. For example, lactose, a commonly used filler in many commercially manufactured medications, is an animal-based product to which many individuals have an intolerance. Compounding professionals can prepare medications substituting a plant-based filler, such as methylcellulose or microcrystalline cellulose, for lactose.[10] Vegetable-based capsules can also be substituted for animal-based gelatin capsules in compounding.[10]

Veterinary Patients

"The spectrum of therapeutic need in veterinary medicine is large, and the availability of approved drug products for all veterinary species and indications is relatively small."[16] Similar to medications manufactured for humans, medications manufactured for animals are not one-size fits all and not every medication is available in a suitable dose and dosage form for every veterinary patient. Compounding professionals can help with the treatment of veterinary patients by compounding alternate dosage forms and doses.

While some medications manufactured for humans may be suitable for administration to some veterinary patients, they can contain excipients that are not suitable for some veterinary patients. Xylitol, for example, is an excipient that cannot be administered to dogs and administering oral tablets to cats can be very challenging.

A variety of dosage forms can be compounded for veterinary patients in suitable doses and flavours for the patient to help ease administration. Compounded medications can also contain multiple medications, requiring the owner to administer fewer medications. Examples include flavoured capsules or chewable treats for dogs, transdermal dosage forms for cats, liquids or oral pastes for horses, and injections.

TABLE 2 - Dispensing Fees Reimbursed by NIHB[19]

Mixture Category	Eligible NIHB Dispensing Fee
Mixtures Prepared by Dispensing Pharmacy	
External cream, ointment, lotion or powder	Up to 1.5 times the dispensing fee
Internal liquid or powder	Up to 1.75 times the dispensing fee
Sterile injection, eye/ear mixture or suppositories	Up to 2 times the dispensing fee
Mixtures Purchased from another Pharmacy	
All mixture categories	Up to 1 times the dispensing fee

NIHB–Non-Insured Health Benefit

TABLE 3 - NAPRA Guidelines for Beyond-Use-Dates of Nonsterile and some Sterile Compounds[3,6]

Type of Compound	Beyond-Use-Date (BUD) Assigned in the Absence of Data
Water-containing oral formulations	Up to 14 days at a controlled cold temperature
Water-containing topical/dermal, mucosal liquid & semi-solid formulations	Up to 30 days
Nonaqueous formulations	Up to 6 months
Sterile preparations with low risk of microbial contamination (without sterility testing)	48 hours at controlled room temperature; 14 days stored in the refrigerator; 45 days stored in a freezer
Sterile preparations with medium risk of microbial contamination (without sterility testing)	30 hours at controlled room temperature; 9 days stored in the refrigerator; 45 days stored in a freezer
Sterile preparations with high risk of microbial contamination (without sterility testing)	24 hours at controlled room temperature; 3 days stored in the refrigerator; 45 days stored in a freezer

NAPRA–National Association of Pharmacy Regulatory Authorities

Benefits and Challenges of Compounding

Compounding has many benefits and challenges to both the patient and the pharmacy staff.

Benefits of Compounding

Compounded medications can help increase medication adherence, treatment acceptance and therapeutic needs not met by commercially manufactured medications.

As discussed above, compounding professionals can prepare medications tailored to each individual, considering the required dose to administer, suitable and preferred dosage forms, as well as additional individual preferences, such as flavour and texture. Administering a medication in an easy-to-administer dose and form that suits the patient's individual preferences helps increase adherence, while combining multiple medications into a single dosage form reduces polypharmacy.[10,16] Patients who are more involved in decision-making around their treatments tend to have better adherence to the regimen.[10] When patients are receiving a compounded medication, it must be done so within the triad relationship between the prescriber, pharmacist and patient, providing increased opportunity for the patient to be involved in medication decisions.

Compounding professionals can also prepare medications that are no longer available, whether temporarily due to a shortage or permanently when a medication has been discontinued by manufacturers.

Challenges of Compounding

Compounding requires extra resources,

such as time, money and specially trained personnel.

While compounded medications can help increase adherence, the cost of compounding in community pharmacy can be a barrier for some patients. Preparing compounds can be time consuming, and mixing fees are charged in addition to the regular dispensing fees. In addition to the time required to prepare the compound, time is often needed to perform in-depth literature reviews to access written formulas from reputable sources.[17] Specialized equipment, such as suppository molds or capsule machines, may be required, as well as many consumable products, such as weigh boats, to prepare compounds. Active pharmaceutical ingredients can be expensive and difficult to obtain when commercially available medications cannot be used to prepare the compound.

Coverage of compounded medications by provincial/territorial drug plans is limited and coverage through private insurance plans varies. Community pharmacies can call insurance plans for pseudo-DINs when processing prescriptions for compounds, if the active pharmaceutical ingredients are covered. A call should be may each time the compound is processed and documented in case of audits by insurance plans. Community pharmacies can also have the patient pay for the compound out-of-pocket and provide documentation to the patient which the patient can then submit to their insurance plan for re-imbursement.

Eligible First Nations and Inuit people who are covered under the Non-Insured Health Benefit (NIHB) Program may receive coverage for compounds. Appendix E of the NIHB drug benefit list identifies several sterile and nonsterile compounds that are eligible for coverage with associated pseudo-DINs.[18] Additional criteria for coverage without prior approval can be found in section 3.4 of the Guide for Pharmacy Benefits for First Nations and Inuit: Non-Insured Health Benefits. Generally, active ingredients must either be listed as open benefits on the NIHB Benefits List or have a listed pseudo-DIN.[19] If a medication needs to be compounded because the commercially manufactured medication is unavailable, the pharmacy must document the drug shortage and can compound the medication using either the corresponding pseudo-DIN or miscellaneous pseudo-DIN for the corresponding category.[19]

NIHB will reimburse the pharmacy the actual acquisition cost of covered benefits and an increased dispensing fee (see Table 2).[19] NIHB will not reimburse pharmacies for the mixing time or the cost of materials required to prepare or dispense the compound.[19]

In addition to the increased costs associated with preparing a compound, many compounds have short beyond-use-dates (BUDs). This may require the medication to be compounded more frequently, which can further increase cost to the patient. Table 3 reviews NAPRA guidelines for BUDs for nonsterile and sterile compounds. Additional information regarding BUDs for sterile preparations can be found in NAPRA's Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations and may depend on when the medication will be used and the compounding environment.[3]

Compounding requires specialized knowledge about medications, such as pH, drug stability and chemical compatibility to ensure compounds prepared will achieve the desired therapeutic outcome and are stable and safe.[9] For example, if a patient needs a medication compounded into a liquid dosage form, but it is unstable in an aqueous environment, it will need to be compounded in an anhydrous vehicle, such as a fixed oil or almond oil.[9]

Compounding also requires expertise in performing complex calculations and training in compounding techniques.

Due to the wide variety of nonsterile compounds, compounding personnel must be knowledgeable and competent in a wide variety of techniques and in safely operating a variety of equipment.

Sterile compounding is a higher risk activity than nonsterile compounding, and is further divided into low-, medium-, and high-risk compounds due to the risk of microbial contamination (see Table 4). Regardless of the risk level, compounders must ensure the sterility of all sterile compounds, such as injections, eye drops, nasal sprays and some irrigation solutions. Technicians must pay close attention to positioning under a laminar airflow hood or other specialized hood and ensure products used and com-

TABLE 4 - Contamination Risk Levels of Sterile Compounds[2,3]

Low Risk	Medium Risk	High Risk
Final product compounded using up to 3 "sterile units"*; No more than 2 septum punctures at the injection site for each sterile unit*; Simple aseptic transfer technique; Drug prepared for one patient (patient-specific dose)	Final product compounded using 4 or more "sterile units"*; Complex manipulations; Prolonged preparation time; Batch preparations (preparing more than one unit of the same composition during one compounding session)	Nonsterile ingredients or equipment used before terminal sterilization; Nonsterile preparations, containing water, stored for more than 6 hours before terminal sterilization; Improper garbing or gloving by compounding personnel

*A sterile unit is a vial, ampoule or bag of drug or diluent.

BOX 1 - ISMP Resources

The following resources can be found on the ISMP website: https://www.ismp-canada.org/mssa.htm

- Medication Safety Self-Assessment for Community Pharmacy – Canadian version II
- Medication Safety Self-Assessment: Focus on "Never Events" in Community Pharmacy.
- Medication Safety Self-Assessment: Focus on "Never Events" in Hospital and Ambulatory Care Centres
- Hospital Medication Self-Assessment
- Canadian Society of Hospital Pharmacists Assessment Tool for Aseptic Compounding

The following resource can be accessed at https://www.ismp.org/resources/guidelines-sterile-compounding-and-safe-use-sterile-compounding-technology

- Guidelines for sterile compounding and the safe use of sterile compounding technology

ISMP–Institute for Safe Medication Practices

pleted compounds are free from particulates. They must also perform proper hand washing, gloving and garbing procedures.

Dosage Forms

Numerous dosage forms can be compounded to meet the unique needs of each individual patient. Table 5 gives examples of some dosage forms. All dosage forms should be dispensed in a child-resistant container whenever possible. Oral liquids can be dispensed with a child-resistant lid, as well as a press-in adapter that fits in the neck of an oral amber bottle. Suppositories that are wrapped in foil rather than compounded in a sealed suppository shell should be dispensed in child-resistant lids, and lollipops can be dispensed in child-resistant vials by drilling a small hole in the lid of the vial.

Safety While Compounding

All compounding can be high risk for both the patient and the compounder. Compounding personnel must ensure they are reviewing established risk assessments and following established safety protocols to ensure safety for themselves and the rest of the pharmacy team, as well as ensuring they are only preparing compounds in which they have been properly trained and assessed.

"Precise formulations are imperative to provide safe compounds to our patients;" thus it is imperative for compounding personnel to ensure they are following established formulas and using established master formula sheets, which should be independently checked by a second pharmacist before first use.[9,20] This not only helps keep staff safe, but helps to ensure a safe, reproducible compounded preparation for patients.

Compounding personnel must also ensure the quality of all products used in compounding, as well as the final preparation. Processes must be in place to help ensure that each compound is prepared to produce the same therapeutic effects regardless of who prepared the compound. This is important in ensuring therapeutic effect of the medication can be properly assessed in patients who are receiving the same compound long-term.

TABLE 5 - Examples of Compounded Dosage Forms[3,9]

Compounded Dosage Form	Good For:	Additional Information:
Topical creams/ ointments/ gels/lotions	Local treatment of skin conditions; Can be used for bioidentical hormone restoration therapy	Patients can work with the pharmacist to select their preferred dosage form (depending on drug properties)
Transdermal	Treatment of pain; Administering medications to cats (applying medication to inside of outer ear flap)	Anhydrous & hydrous bases available; Can often hold many pain medications in a transdermal cream
Capsules	Manufactured medications that are unavailable; Preparing medications that are allergy-free, dye-free or free from animal products	Multiple medications may be compounded into a single capsule, decreasing polypharmacy & increasing adherence; Capsules are available in many sizes. The patient & pharmacy team can work together to choose the best capsule size for the patient; Flavoured capsules are available to help improve taste & adherence; Calculations must be completed with each new Lot number of any powders, considering packing statistics & assays.
Suppositories	Hemorrhoids, inflammatory bowel disease (e.g., budesonide for ulcerative colitis), and fertility (e.g., progesterone suppositories)	Hot plates should be regularly calibrated every 6 months to ensure the suppository base is heated at the correct temperature to ensure the suppository melts correctly when inserted; Complex calculations are required to calculate the quantity of API & base required depending on the mold used; Should be stored in the fridge to avoid melting
Troches	Pain & inflammation, hormone restoration therapy, nausea	Troches can be compounded using a gelatin, polyglycol, or fatty acid base; Multiple medications can be compounded into a single dose; Flavour can be customized to patient's preference; Faster onset of action
Lollipops	Nausea, local anesthetic (e.g., lidocaine), oral fungal infections	Flavour can be customized to patient's preference
Solutions & Suspensions	Patients who cannot swallow oral solid dosage forms	Volume per dose, thickness, and flavour can be customized for patient; Use commercially manufactured oral solids to compound, especially for medications measured in micrograms (mcg) to prevent dosing errors
Injections	Systemic treatments that cannot be administered enterally and parenteral nutrition,	Must be compounded in a sterile environment in accordance with NAPRA guidelines; Can compound multiple medications in a single dose; BUDs vary depending on the risk of microbial contamination, products used & compounding environment.

API–active pharmaceutical ingredient; BUD–beyond-use-date; NAPRA–National Association of Pharmacy Regulatory Authorities

Reducing Risk for Errors

Numerous errors in compounding have been reported, affecting both sterile and nonsterile preparations. Errors include incorrect calculations, incorrect products used during the compounding process, contaminated products and more. In addition to following the NAPRA guidelines on compound-

TABLE 6 - Examples of when technicians need to collaborate with and/or refer to a pharmacist

Identifying patients who may benefit from or require a compounded medication	Technicians should refer to the pharmacist when they identify an individual who may benefit from a compounded medication; The pharmacist can assess if the medication can be compounded and the intra-professional team can then work with the prescriber & the patient to determine if medication will be compounded.
Patient or caregiver or prescriber inquires about compounded medication	Pharmacy technicians can indicate that their pharmacy has the capability to prepare compounds that have been successfully prepared in the past, however, specific inquiries about compounding for a patient and inquiries about compounds the pharmacy has not compounded in the past must be referred to the pharmacist for assessment.
Patient experiences an adverse reaction	Pharmacy technicians can gather specific information about an adverse reaction & then should refer to the pharmacist for assessment.
Compounded medication is stored improperly	Pharmacists must assess if a medication stored improperly is still stable and can continue to be administered. Pharmacy technicians can gather information, such as how the medication was stored and for how long.
Unsuccessful medication administration	If a patient has not been successful in administering a compounded medication, pharmacy technicians should collaborate with the pharmacist to determine if any other options are available. Examples include changing the flavour of an oral liquid, or further reducing particle size of powders in a topical product.
Problem with dosage form	Issues with dosage forms, such as the medication changing colour, must be referred to the pharmacist for assessment. Pharmacy technicians can gather information such as asking about the storage of the medication.

ing, compounding personnel should review the recommendations for compounding from the Institute for Safe Medications Practice (ISMP) (See Box 1)

To improve patient safety ISMP recommends using technology when possible. This includes the use of bar-code scanning technology for both sterile and nonsterile compounding, automated compounding devices, robots, and intravenous (IV) workflow management systems.[17,20,21] Additional recommendations and guidelines can be found in the resources listed in Box 1.

Bar-code scanning is used to ensure personnel select the correct ingredient for a compound. When used with IV workflow management systems, close-call events (such as scanning an incorrect product during the compounding process) will be documented and captured in a report.[21] When compounding with ingredients that do not have a DIN, ISMP recommends using the chemical abstract service (CAS) number to identify the product.[20]

All new master formulas must be independently double checked by a second pharmacist prior to first use.[20] IV workflow management systems can be programmed to create an alert for such an independent double check when a new master formula record is added.[21] It can also document any changes made, which are time stamped with the name of the individual creating the changes, and automatically perform conversions and calculations.[21]

Automated compounding devices are recommended for compounding parenteral nutrition and robots can be used for hazardous sterile compounds, such as chemotherapy.[21]

Additional recommendations include the use of scales with the capability to use bar-code scanning and record the weight measured for each ingredient.[17] This can reduce the amount of time a pharmacist or pharmacy technician spends performing measurement verifications and provides a hard-copy of measurements.

Issues that should be referred to a pharmacist

Pharmacy technicians must recognize situations that require collaboration with or referral to a pharmacist. Table 6 provides some examples. It is important to keep in mind that even when referring to a pharmacist, a technician should gather as much information as possible.

Conclusion

Despite the numerous commercially manufactured medications available, there are still therapeutic gaps that can be addressed through sterile and nonsterile compounding. Pharmacy professionals currently involved in compounding, or who are working towards becoming involved in compounding, must have specialized knowledge and training in compounding. These specific knowledge, skills and abilities are essential to protect both the compounder and the patient in such a high-risk practice.

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QUESTIONS

Find and answer the questions for this CE lesson online at eCortex.ca. Search using all or part of the course title.

1. Aubrey is a pharmacy technician who has been trained in compounding suppositories. Aubrey is getting ready to compound suppositories using a hazardous active pharmaceutical ingredient (API). Which of the following is TRUE?

a) A separate room is required for hazardous nonsterile compounding, but it does not have to be negative pressure to the surrounding rooms.
b) Aubrey needs to prepare this compound in a separate room with negative pressure to the surrounding rooms.
c) Only the preparation of hazardous sterile compounds requires a separate room with negative pressure.

2. Arden is a patient with severe lactose intolerance, but the medication they require is manufactured with lactose as a filler. Arden tried the commercially available medication and suffered a reaction to the lactose. Which of the following is TRUE?

a) A compounding pharmacy can compound capsules substituting a plant-based filler, such as microcrystalline cellulose in place of lactose.
b) Because this medication is available as a commercially manufactured product, a compounding pharmacy cannot compound this medication.
c) The only option for the compounding pharmacy is to determine if this medication can be compounded into a dosage form that does not need to be taken orally.

3. Morgan is a strict vegan for both personal and religious reasons and requires a medication that is only available in a gelatin capsule. Which of the following is the best course of action for the compounding pharmacy?

a) Offer to compound the capsules using a vegetable-derived capsule, such as cellulose capsules.
b) Nothing. Since the medication is commercially manufactured, it cannot be compounded.
c) The compounding pharmacy will have to find an alternative dosage form for this patient, such as an oral liquid or a transdermal product.

4. Quinn is a First Nations person with coverage under NIHB and requires a topical cream compounded. All components of the compound are listed as open benefits on the NIHB drug benefits list, and a pseudo-DIN is available. Which of the following is TRUE?

a) The pharmacy must call NIHB for prior approval.
b) NIHB will only cover the compound if the active pharmaceutical ingredients are listed on the provincial/territorial drug benefits list.
c) NIHB will cover the cost of the ingredients plus a mixing fee of up to 10 minutes.
d) NIHB will cover the cost of the ingredients plus 1.5 times the pharmacy's usual dispensing fee.

5. Aubrey, a pharmacy technician, has just compounded budesonide suppositories using a fatty acid base, made from a combination of oils. What beyond-use-date (BUD) can Aubrey assign to this compound according to NAPRA?

a) 14 days stored in the fridge
b) 30 days in the fridge
c) 6 months in the fridge
d) Beyond-use-date for this compound cannot be determined

6. When compounding with an ingredient that does not have a DIN, compounding personnel should use which of the following to ensure correct product selection?

a) Certificate of Analysis Number
b) Chemical Abstract Service Number
c) Supplier's Lot Number
d) Supplier's Product Number

7. Which of the following is a benefit of using an IV workflow management system for sterile compounding?

a) Creates an alert for an independent double check on newly created master formulas.
b) Creates an alert requiring two individuals to perform all conversions and calculations.
c) Creates an alert notifying staff of incorrectly scanned products, requiring staff to document in a report.

8. Rowan is a regular patient at a community pharmacy and is picking up a new prescription for a topical ointment to help heal scratches from their cat. Rowan shares that their cat requires medication and that it has been difficult to administer oral tablets to the cat, causing distress in the animal and subsequent scratching of Rowan. How can a compounding pharmacy best help Rowan?

a) The pharmacy can investigate the feasibility of preparing a transdermal dosage form.
b) The pharmacy must refer Rowan to a veterinary-only compounding pharmacy.
c) The pharmacy can fill the largest tube of ointment possible for Rowan, so they do not need to come back as often for refills.

9. Remy is a small child with congenital hypothyroidism who is unable to swallow tablets but requires treatment with levothyroxine. When compounding a levothyroxine suspension which of the following should the compounder ensure?

a) To use raw active pharmaceutical ingredients to reduce the use of fillers and other excipients in the suspension.
b) To use commercially available tablets in the compound to help prevent dosing errors.
c) That a pharmacist has trained the patient on swallowing, but the child has been unsuccessful, before being able to compound a medication that is commercially available.

10. Kai's prescriber has indicated that Kai requires daily oral acetylsalicylic acid (ASA). Kai is unable to swallow tablets due to dysphagia. The chewable tablets are not available and Kai doesn't like the taste of crushed tablets, even when mixed with applesauce. The pharmacy has offered to compound an oral liquid for Kai; however, ASA is not stable in an aqueous formulation. Which of the following is TRUE?

a) The pharmacy will not be able to compound this medication as an oral liquid.
b) The pharmacy could compound this medication in an anhydrous oil base.
c) The pharmacy will have to suggest compounding this medication as a suppository.
d) The pharmacy will have to contact the prescriber for an alternate medication.

11. Frankie is a patient taking multiple medications for chronic neuropathic pain. Frankie finds it difficult to manage taking all their medications and to remember what they have already taken. Also, some of the tablets are quite large and have a bad taste. Frankie has been complaining of side effects including stomach pain and upset, nausea and drowsiness. How can the compounding pharmacy best help Frankie?

a) Determine if their pain medications can be compounded into a single oral capsule.
b) Determine if their pain medications can be compounded into a single transdermal dosage form.
c) Determine if the patient medications can be compounded into an oral liquid.
d) Since all of their medications are commercially available, the pharmacy cannot compound anything for the patient, but can offer compliance packaging to help with adherence.

12. Upon completing a sterile compound, a co-worker of Blake's noticed that their gloves were tucked into the cuffs of their gown sleeves instead of over the cuffs which is part of correct garbing for sterile compounding. What does this mean for the product Blake has just compounded?

a) The compound must be discarded, and another technician must prepare a new one.
b) The beyond-use-date will be reduced to 24-hours at controlled room temperature or 3 days stored in the fridge.
c) The beyond-use-date will be reduced to 30-hours at controlled room temperature or 9 days stored in the fridge.

TECH talk CE

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A Compounding Overview

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