Pharmacy Compounding

Meeting unique physician and patient needs

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Goals

• Define pharmacy compounding
• Describe compounding various service areas
• Provide details of the various dosage forms used in compounding
• Describe some of the equipment used in compounding
• Review the safety and quality steps taken in a pharmacy compounding laboratory

What is Compounding?

• Compounding is the method of preparing customized medications to help meet unique practitioner and patient needs.
Compounding pharmacists focus on providing innovative patient care. This may involve compounding eye drops in a sterile lab, preparing medications for animals, or providing bio-identical hormone replacement therapy.

Also known as a problem-solver, a compounding pharmacist’s ultimate goal in preparing customized medications is to help the practitioner and patient achieve a more positive therapeutic outcome.

**Pharmacy**

- The *art* or profession of preparing and preserving drugs, and of *compounding* and dispensing medication *according to the prescriptions* of physicians.

  – Early 20th Century *Webster’s Dictionary*
Compounding
As defined in the NABP Model State Pharmacy Act:
- The preparation, mixing, assembling, packaging, or labeling of a drug or device (i) as a result of a practitioner’s prescription drug order or initiative based on the Practitioner / Patient / Pharmacist relationship in the course of professional practice, or (ii) for the purpose of or as an incident to research, teaching, or chemical analysis, and not for resale or dispensing.
- Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, observed patterns.

Manufacturing
As defined in the NABP Model State Pharmacy Act:
- The production, preparation, conversion, or processing of a drug or device…and includes any packaging, or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such Drugs or Devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by the pharmacies, practitioners, or other persons.

Compounding vs. Manufacturing
- Manufacturing
  - No specific patient in mind when drug is produced
  - Has prescribers matching patients to the product available
  - Economic considerations limit choices in drug dosages and dosage forms
- Compounding
  - Making the formula match the patient’s needs
  - Administering the drug to the site of action in the most effective dosage form available
Pharmacy Compounding Accreditation Board (PCAB)®

• Voluntary accreditation body formed to establish high quality standards for compounding pharmacies
• Ensures compounded preparations meet standards of quality for patient safety

USP Chapter <795>

• USP guidelines are established to define good compounding practices that enable a compounder to prepare compounds extemporaneously that are of acceptable strength, quality, and purity
• State Boards of Pharmacy regulate pharmacies, and have adopted USP <795>

USP Chapter <795>

• Sets guidelines for compounding non-sterile preparations:
  – Use of graded chemicals
  – Potency of compounded preparations
  – Standard operating procedures (SOPs) outlined
  – Beyond-use date of compounded preparation
  – Record-keeping
  – Quality control
Potency Testing

- Hormone triturates
- Capsule formulations
- Oral solutions
- Hormone creams
- Injections

USP Chapter <797>

- Sets guidelines for compounding sterile preparations:
  - Standard operating procedures (SOPs) outlined
  - Sets guidelines for personnel training in aseptic compounding
  - Outlines quality assurance program needs
  - Sets guidelines for cleanrooms needed for compounding at different levels of sterility

Improve Therapeutic Outcomes...

...by solving the problem:

- Avoidance of unwanted dyes, preservatives, fillers, and active ingredients
- Palatable liquid medications
- Administrable dosage forms
- Potential minimization or avoidance of side effects
Improve Therapeutic Outcomes…
...by solving the problem:

• Dose, dosage form, or medication not commercially available
• Combination or sustained-release therapy to improve compliance
• Cost-effective therapy
• Unique dosage form designed for specific problem

Service Areas

Meeting Unique Needs In:

• Hospice
• Pain Management
• Bio-identical Hormone Replacement Therapy
• Veterinary applications
  - Household pets
  - Equine
  - Zoos
  - Exotics
• Dental
• Cosmeceuticals/ Dermatology
Meeting Unique Needs In:

- Podiatry
- Oncology
- Ophthalmology
- Pediatrics
- Neurology
- Nutrition
- Sports Medicine
- And many more…..

Hospice

- Alternative routes of administration
- Individualized pain management
- Nausea & vomiting
- Inhalation therapy
- Emergency kits
- Mouth ulcers
- Saliva stimulants
- Adjunctive therapies

Bio-identical Hormone Replacement Therapy

- Same hormones as exist in the human body
- Natural sources
- Individualized therapy
- Potential minimization or avoidance of side effects
- Clinical benefits
- Patient consultation
- Alternative dosage forms
Compounding is Essential in Veterinary Medicine

- Discontinuation of commercial products by manufacturer
- Weight and species variations
- Compliance problems – Taste, dosage form, volume, smell

Veterinary Compounding

- Concentration of commercial products
- Efficacy of commercial products
- Appropriate product not available (several drugs not combined as vet needs)
- Appropriate vehicle may be irritating
- Animal resistance to available preparations

Pediatric Compounding

- Analgesics
- Antibiotics/antivirals
- Diaper rash treatment
- Head lice treatment
- Topical anesthetics
- Custom-flavored lollipops & troches
Dental Needs

• Hemostatics
• Bleaching gels
• Root canal & dry socket mixtures
• Topical anesthetics
• Pre-procedure sedatives
• Repository antibiotics for abscesses
• Plaque removal rinses
• Adhesives
• Sedatives

Dermatology/Cosmeceuticals

• Acne formulations
• Psoriasis/eczema
• Sun damage
• Skin irritations
• Radiation reactions
• Anti-fungals
• Anti-aging

Pain Management

• Arthritis
• Fibromyalgia
• Headaches
• Nerve pain
• Muscle pain
• Post-surgical pain
Podiatry

- Fungal infections
- Decubitus ulcers
- Diabetic neuropathy
- Circulation problems
- Warts and calluses
- Heel spurs
- Excessive perspiration
- Muscle and joint pain

Exercise and Sports Injuries

- Transdermal gels
  - NSAIDs
  - Muscle relaxants
  - Neuropathic agents
  - Speed gels
- Iontophoresis solutions
- Phonophoresis (ultrasound) gels
- Hank’s balanced salt solution
- Anesthetic sprays and gels
- Antifungals for athlete’s foot and jock itch

Special Needs

- Casein-, gluten-, peanut-free preparations
- Solutions/suspensions for PEG/NG tube administration
- Low-carbohydrate preparations
Dosage Forms

Compounded Dosage Forms

- Oral capsules and liquids
- Transdermals
- Lollipops
- Troches, tablet triturates, and sublingual drops
- Rapid dissolve tablets
- Suppositories, enemas, and rectal rockets
- Effervescent powders

Compounded Dosage Forms

- Nasal and otic preparations
- Topical creams, ointments, gels, powders and sprays
- Oral adhesives, mouthwashes and rinses
- Sterile products
  - inhalation solutions, injections, ophthalmics, TPNs

Compounded Dosage Forms

- Oral capsules and liquids
- Transdermals
- Lollipops
- Troches, tablet triturates, and sublingual drops
- Rapid dissolve tablets
- Suppositories, enemas, and rectal rockets
- Effervescent powders
Compounded Capsules

- Medications formulated in capsules enable the patient to get the exact dosage needed, while avoiding unwanted dyes and fillers.
- Cellulose capsules are available, and are dye-free

Compounded Oral Liquids

Preparing medications in a liquid form allows the patient who can’t swallow pills to get the appropriate medicine in a vast range of flavors, such as tutti-frutti or vanilla butternut.

Compounded Oral Liquids

- Difficulty swallowing
  - Medication not available as liquid
  - Infants, children, geriatrics, hospice
- Avoid unwanted ingredients
  - Free of alcohols, dyes, preservatives and sugars
- Increased compliance
  - Much more palatable preparations with choice of multiple sweeteners and flavors
- Anhydrous formulations
  - May be used if aqueous stability a concern
Effervescent Powders

• Unit-dosed
• Great for large doses of active ingredient, or active unstable in water
• Faster dissolution – add to water and drink immediately
• Better palatability
• Vitamins, minerals, amino acids

Customized Flavors for People and Pets

Compounding pharmacists can provide hundreds of individual flavors and endless combinations to satisfy human and pet patients.

Almond ♦ Apple ♦ Apricot ♦ Banana ♦ Beef ♦ Blueberry
Bubblegum ♦ Butterscotch ♦ Caramel ♦ Cherry ♦ Chicken
Chocolate ♦ Filmcoated ♦ Creme de Menthe ♦ Grape
Lemon ♦ Lime ♦ Mint ♦ Mango ♦ Marshmallow ♦ Orange
Passion Fruit ♦ Peach ♦ Peanut Butter ♦ Peppermint
Piña Colada ♦ Pineapple ♦ Pizza ♦ Pumpkin ♦ Raspberry
Strawberry ♦ Tangerine ♦ Triple Fish ♦ Tutti-Frutti
Vanilla ♦ Watermelon ♦ Wintergreen...and many more!

Medicated Lollipops

Local effects:
Anesthetic ♦ Antifungal ♦ Antiviral ♦ Anti-inflammatory
Saliva stimulant ♦ Healing agents
Medicated Lollipops

Systemic effects:
- Anti-anxiety
- Antipyretic
- Analgesic – Narcotic or Non-narcotic

Medicated Lollipops

Combination effects:
- Smoking deterrent
- Cold preparations
  - Cough suppressant
  - Decongestant
  - Antihistamine
- Sore throat
- Antihistamine

Troches

- Soft gelatin-flavored troches, such as those prepared in the 24- and 30-count molds, provide medication in an easy-to-take and pleasant-tasting form.
Rapid Dissolve Tablets

The Rapid Dissolve Tablet (RDT) is the newest and one of the most unique dosage forms available today. The tablet is placed on the tongue and takes approximately 30 seconds to dissolve.

Medication Baby Bottle

The medication baby bottle or pacifier are effective devices to get accurate doses into an infant.

Compounded Animal Treats

Whether for a dog, cat, or other small animal, this unique dosage form allows for easy administration of medications.
**Compounded Sterile Products**

- Injections – aqueous and oil vehicles
- Ophthalmics – solutions, suspensions, sprays, and ointments
- TPNs and IV admixtures
- Inhalation solutions
  - Combine multiple ingredients to improve compliance
- Irrigating solutions

**Suppositories**

Putting medicine into suppositories allows the patient who can’t swallow to receive the required drug.

**Suppositories and Enemas**

- Rectal, vaginal, or urethral use
- Helpful to patients who have difficulty swallowing, nausea/vomiting
- Injections cause pain, anxiety
- Rapid local affect
  - Hemorrhoids
    - Irritable Bowel Syndrome (Crohn’s disease)
    - Anesthetic, anti-inflammatory, steroid agents
- Reported absorption route for many drugs
  - Prevents 2/3 of first-pass effect
**The Rectal Rocket**

- Designed to get the drug(s) to the *site of action*
- Holds drug(s) at site of action for an *extended period* of time (air vent included)
- Anti-inflammatory agents
- Anesthetic agents
- Steroidal agents

**Nasal and Otic Preparations**

- **Nasal**
  - Rapid absorption of drug
  - Pump metered spray bottle delivers accurate dose of drug
- **Otic**
  - Anhydrous vehicles
    - PEG, Sweet Oil, Propylene Glycol, Glycerin

**Nasal and Otic Preparations**

- **Otic**
  - Combine multiple medications: Anesthetic, anti-inflammatory, antibiotic, antifungal, antiviral, steroid, etc.
  - Powder insufflator available
- **Gels**
  - Carbomer, HEC, HPC, HPMC
Medicated Powders

Any combination of an antifungal, antibiotic, antiviral, steroid or an anesthetic with an oral adhesive could be compounded.

The Polyox Bandage

- Originally designed for oral use
- Superior oral bandage
  - Stays in place for hours, even if “rubbed”
- Many classes of drug used
  - Antihistamine, anesthetic, antiviral, antifungal, anti-inflammatory, etc., or combinations
- Also used for wound care
  - No touching of wound for application
  - No removal of new tissue growth
  - Advantageous in oozing wound

Compounded Inhalation Solutions

- Combination therapies for improved compliance
- Formulations not commercially available
- Veterinary applications
Compounded Topical Formulations

• Creams
  – Water-in-oil emulsions
  – Oil-in-water emulsions
• Ointments
  – Anhydrous vehicles:
    • PEG, Petrolatum
• Gels
  – Carbomer, HEC, HPC, HPMC
• Sprays
• Specialty deodorant stick or lipstick forms
• Penetration agents to enhance effects

Topical Preparations

• Transdermal gels and creams are specially prepared emulsions that penetrate the skin and get medications into the bloodstream quickly
• Effective dosage form for the patient who can’t swallow
• May be used for systemic or local effects
• Other topical dosage forms include lip balms, sprays, foams, and more!

Topical Sticks and Tubes

Dispensing medication in deodorant stick or chapstick-like containers allows the patient to self-administer drugs easily for PRN doses. Tubes provide creams, ointments and gels with increased protection from light and oxidation.
PCCA AccuPen™-15

- Airless metered-dose pump
- Delivers 0.12 mL of most vehicles
- Up to 12 mg active drug per actuation
- Portable
- Locking feature for convenient carrying

Drug Classes Used in Transdermals

NSAIDs ♦ Muscle Relaxants ♦ Anti-nausea Agents
Antiviral Agents ♦ Anti-inflammatory Agents
Anesthetics ♦ Anti-anxiety Agents
Anti-diabetic Agents ♦ Antidepressants
Anti-psychotic Agents ♦ Anti-hypertensive Agents
Thyroid Medication ♦ Antihistamines
Anti-infective Agents

Specialty Bases for Compounding
Exclusive PCCA Bases

- As a member of PCCA, our pharmacy has access to more than 50 high-quality proprietary bases, ranging from hormone replacement therapy to skin rejuvenation to veterinary applications
- Designed to provide our patients and prescribers with the quality they deserve

PCCA VersaBase®

- PCCA VersaBase® is a line of elegant, extremely durable pharmaceutical and cosmetic bases
- Available in a variety of forms, including:
  - Cream
  - Foam
  - Gel
  - Lotion
  - Shampoo

PCCA Lipoderm®

- A Study-Validated Transdermal Vehicle
  - Contains a proprietary liposomal component that may increase the permeation of a variety of actives
  - Stable in cold conditions
  - Aesthetically elegant
PCCA Lipoderm® Studies

• Original Lipoderm Study
  – A Validated Transdermal Vehicle
    With Superior Results Over PLO (with Promethazine)
• Lipoderm with Ketoprofen Study
  – Ketoprofen in PCCA Lipoderm Outperforms PLO in
    Transdermal Testing!
• Feline Vet Study
  – Lipoderm with Tramadol Performs Well in Feline Inner Ear Test

Copies of these studies are available upon request.

PCCA NataCream™

• Composed 100 percent of materials of vegetable origin
• Hypoallergenic and non-comedogenic
• Naturally preserved with PCCA NataPres™
• Mineral oil- and propylene glycol-free
• Ideal for cosmetic or pharmaceutical applications

PCCA Oral Bases

• PCCA-Plus™ Oral Suspending Vehicle
• PCCA-Sweet SF™ Sugar Free Syrup Vehicle
• PCCA Syrup Vehicle™
• PCCA Fixed Oil Suspension Vehicle™
• PCCA Effervescent Powder™
• Rapid Dissolve Tablet Powder™
PCCA Chrysaderm®

- Chrysaderm Day, Night and Eye Complex rejuvenating skin creams reduce the appearance of wrinkles, protecting against harsh external factors for more natural and beautiful skin.

Compounding Equipment

Electronic (Digital) Balance

This device is absolutely necessary for efficient and accurate compounding.
Capsule Machine

• The Jaansun® Capsule Machine provides pharmacists with a more time efficient and accurate method of making capsules. It is designed to avoid labor-intensive hand punching, and accommodates oil-filled capsules, with the capacity to make up to 300 capsules at a time.

Troche Mold

This dosage form provides sublingual or buccal administration in a variety of flavors.

Rapid Dissolve Tablet (RDT) Mold

Active ingredients are mixed with the RDT base, sweetened and flavored, then pressed into the mold and baked.
**Tube Sealer**

The tube sealer provides an efficient way to seal plastic tubes, bags, suppository shells and sleeves.

**Electronic Mortar and Pestle**

- The electronic mortar and pestle provides pharmacists with the modern way to compound creams, gels and ointments.

**Ointment Mill**

- The ointment mill reduces the particle size of powders, crystals, and creams, resulting in a smooth and elegant finished compound.
Lollipop Mold

- The lollipop mold enables pharmacists to prepare medicated lollipops using a variety of bases, such as sorbitol, gelatin, and polyethylene glycol.

Rectal Rocket Suppository Mold

The rectal rocket suppository mold can be used to make six suppositories at a time. The shape of the suppository is designed to keep it in the rectal orifice in direct contact with the hemorrhoid. The mold also features an air vent for each suppository, enabling the dosage form to stay in place for an extended period of time. The air vent is created using a removable metal plate which aids in removing the suppositories from the mold.

Safety in the Compounding Pharmacy

- Safety and quality are of the utmost importance in compounding. Precautions are taken in the pharmacy to offer maximum protection for both the compounder and the patients who will receive the compounds.
Quality & Safety Steps in the Compounding Laboratory

• Formulas are thoroughly read and discussed prior to compounding.
• Calculations are double-checked when preparing a formula.
• An electronic balance with a printer attachment is used to confirm proper weighing of chemicals.

A powder containment enclosure is used to provide maximum protection when compounding. These countertop enclosures are designed for manipulating potent powders, such as hormones; mortar and pestle compounding; and encapsulating powders.

Quality & Safety Steps in the Compounding Laboratory

• All chemicals used in a formula are triple-checked throughout the compounding process.
• The finished compound is labeled immediately in order to confirm the identity of the compound prior to dispensing.
• Compounds are worked on one at a time to avoid confusion and possible mislabeling of a product.
质量和安全步骤

在配药实验室中

• 保持一致性，通过添加有用的注释到配方中，帮助药剂师和员工在未来。
• 为配制产品定制日志表。清晰识别最终产品和接收它们的患者在召回或投诉情况下非常重要。

培训程序

• 建立了关于危险代码和处理散装化学品所需安全设备的培训计划。
• 所有制药团队成员都知道清洁化学泄漏的程序。
• 穿戴适当的防护服，包括口罩、手套、实验服和发网，用于配药。

PCCA 成员

• 我们的药房是 Professional Compounding Centers of America (PCCA) 的成员。
• 通过 PCCA，我们获得了 Pharmacy Consulting Department (PCD) 的访问，该部门拥有 20 多位药剂师的团队和超过 12,000 个配药配方的数据库。
PCCA Member

- PCCA provides accredited compounding courses and continuing education seminars and symposiums, which provide pharmacists and prescribers with ongoing opportunities to earn continuing education credit and practice compounding techniques according to USP Chapter <795> and <797> standards.

PCCA Quality

- PCCA is devoted to assuring the quality of the chemicals sold to its members.

- As a distributor and repackager of both Active and Non-Active Pharmaceutical Ingredients for pharmacy compounding, PCCA is registered and inspected by the FDA and DEA.

PCCA Quality

- PCCA’s Quality Control and Quality Assurance personnel perform as many as nine qualitative analyses on each chemical lot, in addition to reviewing the results and specifications of the Certificate of Analysis.

- Inspection of incoming packaging components and raw materials is paramount to the quality system and compliance with current Good Manufacturing Practices and Regulations.

- If a product is compromised in any way, it fails and is rejected.
Summary

• In this presentation, the following topics were discussed:
  – The definition of pharmacy compounding
  – Compounding’s various service areas
  – The various dosage forms used in compounding
  – Some of the equipment used in compounding
  – The safety and quality steps taken in a pharmacy compounding laboratory

Questions?

• For more information, please contact
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