Pharmaceutical Compounding Errors

Goal: To provide information on the occurrence, causes and prevention of compounding errors.

Objectives: After reading and studying the article, the reader will be able to:

1. Discuss the overall issue of errors that occur in compounding.
2. List at least 5 general reasons for compounding errors.
3. Describe the effects of compounding errors on patients.
4. Differentiate between different types of errors that can occur.
5. Describe different adverse events that have resulted from compounding errors in the past ten years.

INTRODUCTION

Pharmacies that compound specific drugs for individual patients are an essential part of our health care system. Compounding pharmacies formulate therapeutic and diagnostic products for physicians in practice and those engaged in research. They make individualized chemotherapeutic agents, diagnostic agents, noncommercial formulations (e.g., a liquid rather than a tablet), doses that are flavored, preservative-free, dye-free, without specific allergens, and other customized or combination products. A compounding pharmacy can fall under a range of categories such as: hospital, neighborhood, chain, nuclear, specialty and others.

Sterile and non-sterile compounding continues to grow at a rapid rate throughout health systems in the U.S. To get a perspective on scope, the Cleveland Clinic Health System (CCHS) consists of 10 hospitals and 15 outpatient pharmacies. In 2012 at CCHS, approximately 870,000 sterile doses were compounded, with 56% of doses prepared in response to patient-specific orders and 44 percent of doses prepared in anticipation of patient need based on historical data.1

As compounding pharmacies continue to grow, so does the risk that a compound is incorrect or contaminated by microorganisms. This issue of Secundum Artem will focus on the compounding of preparations that do not meet the required standard of quality and how they occur. Some errors are minimal with no adverse effects; however, some errors are serious and lead to patient harm and even death. Table 1 has a summary of some illnesses and deaths associated with compounding errors (2001-2012).

DEFINITIONS

Compounding - The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.

Error - An act, assertion, or belief that unintentionally deviates from what is correct, right, or true.

Medication error - Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

Note: The term “prescription” will be used to include “prescription”, “medication order” and “formulation” in this paper.
Compounders are responsible for the preparation of medications that are not commercially available. These medications are often compounded for specific patients who may have allergies or other unique medical needs. However, compounding errors can occur and lead to serious consequences, including patient harm or death. This section discusses various classification, description, and prevention of compounding errors and their causes. The aim is to provide a comprehensive overview and strategies to minimize these errors.

### ERRORS: CLASSIFICATION, DESCRIPTION AND PREVENTION


### General

**Receipt of the prescription** - Incomplete and incorrect information present on the prescription.

**Avoiding the Error:** Upon receipt of the prescription from either the patient or the healthcare provider, it must be confirmed to include complete information on the patient and the medication, etc.

**Interpretation of the prescription** - The prescription can be misinterpreted for a number of reasons including legibility, misspellings, etc.

**Avoiding the Error:** The prescription interpretation should be confirmed by a second individual.

**Transcription errors** - Following initial receipt and interpretation of the prescription, errors can occur when transferring the information into the computer. These errors can involve the names of the ingredients, the quantities, the units of weight/ measurement, instructions for the patient, etc.

**Avoiding the Error:** The information should be checked by a separate individual after computer entry.

**Calculations incorrect** - This is possibly the number one cause in compounding errors. Misplaced decimals, incorrect calculations, lack of understanding of what needs to be done, etc. Incorrect calculations can result in errors throughout the entire compounding process and have resulted in patient deaths.

**Avoiding the Error:** Routine practice in calculations and continuing education is important. Also, it is vital that the person checking the calculations do so without even looking at the other persons work as it tends to influence the “checker” and the same mistake can be made. It must be done totally separately and then the answers compared and checked. It is generally good to use “exact equivalents” during the calculation process and “round off” at the end.

**Labelling errors** (Ex. colchicine 4 mg/mL labeled as 0.5 mg/mL) - Labeling errors are critical as this is the information the healthcare practitioner will utilize for administration to the patient.

**Avoiding the Error:** The label must be double-checked by a second individual and compared to the original prescription and calculations.

**Error repetition** - The same errors being committed and compounded preparations not meeting required standards.

**Avoiding the Error:** Maintain a file of all analytical and microbiological laboratory results as well as SOP variations and changes. Review these periodically with affected personnel so all will be aware of any issues that may be involved.

**Expired drugs** - When using commercial products or bulk active ingredients, they must be in-date for the projected time of the use of the medication, i.e., stable throughout their beyond-use date.

**Avoiding the Error:** Check the expiration dates of all ingredients and consider the beyond-use date that will be assigned to the finished preparation.

**Incorrect administration route** - Incorrect interpretation of the original prescription has led to labeling errors and the incorrect route of administration. Also, when packaged in containers for ease of removing the exact required dose (as in using a 1 cc tuberculin syringe for measuring creams, etc), the labeling needs to state the exact route of administration with warnings of how it should NOT be administered.

**Avoiding the Error:** Proper labeling and explanation to the patient and/or caregiver will help prevent this error. Also, the use of proper packaging for its intended use will be of benefit.

**Improper BUDs** - This is a common error. Beyond-use date information may have been put into the Formulation Record and not updated when new versions of USP Chapters <795> and <797> are provided. This can result in improper BUDs and the preparation not retaining its original physical, chemical or microbiological characteristics and lack efficacy and safety upon administration to the patient.

**Avoiding the Error:** There tends to be a lack of understanding of the assignment of beyond-use dates. The USP Chapters <795> and <797> contain valuable information and it needs to be read and re-read very carefully.

**Confusing two medications with similar names** - This can result in an improper drug being used for compounding for the patient. It can result from
poor legibility of the original prescription or from lack of attention by the compounder.

**Avoiding the Error:** Triple check each ingredient used in compounding the preparation. First, when it is removed from its shelf; second, when it is weighed or measured; and, third, when it is returned to the shelf. In each activity, it should be checked with the prescription order.

**Not considering overfill** - Many injections are allowed a percentage of “overfill” in the container to enable the entire contents to be withdrawn. If not considered in the compounding process, it can result in the drug being diluted excessively in the case of overfill of a vehicle and a lower drug concentration; or, if an entire vial/ampule is used and placed into a defined volume, it may result in a higher concentration than what is needed for the preparation.

**Avoiding the Error:** Be aware of the overfill allowed in different containers and make adjustments as required so the quantity administered to the patient will be correct.

**Mismatch units** - A number of cases have occurred where handwritten “ug” or “μg” has been misinterpreted for “mg”, resulting in a thousand-fold increase in the concentration required for the prescription, and patient harm and even death. Another misinterpreted designation has been “u” where “units” was intended but “mg” or “μg” was used instead.

**Avoiding the Error:** Double check the original order. Also, check to see if the dosage the patient will receive is reasonable for the patient.

**Incorrect Ingredients**

**Incorrect active pharmaceutical ingredients (API) used** - A number of different occasions can arise involving an incorrect API. For example, the incorrect ingredient accidently is obtained; the incorrect salt form, the incorrect ester form, the incorrect hydrated form, the incorrect particle size or other form can be mistakenly used.

**Avoiding the Error:** Double check the EXACT name and form of the ingredient to be used for the prescription. If any questions arise, check with another compounder to confirm the exact name and form of the API to be used. If appropriate, check with the prescriber to confirm the exact form of the API that was ordered. For suspensions, confirm that the particle size is reduced appropriately.

**Incorrect form of API used** - As above, the incorrect form can involve an incorrect salt, ester, hydrate or even particle or crystalline form to be used.

**Avoiding the Error:** Confirm the EXACT form of the API that was prescribed and if necessary, check with the prescriber. Also, check the USP/NF monographs or official product labeling of commercial products for clarification on which form is to be used. Compatibility information of excipients can be obtained from the Handbook of Pharmaceutical Excipients.

**Incorrect excipients used** - Excipients can market-edly alter the final preparation and its bioavailability/efficacy. In fact, there are numerous instances of “incompatibility” that can occur between an excipient and an API and even between excipients.

**Avoiding the Error:** Confirm the compatibility of each of the excipients with the API and with each of the other excipients to confirm their suitability for the preparation. When levigating agents are used, confirm that they will be compatible/miscible with the finished preparation.

**Incorrect supplies used** - The use of incorrect packaging, compounding personnel protective equipment (PPE), etc. can result in an altered preparation and potential harm to the compounder.

**Avoiding the Error:** Confirm the appropriateness of the packaging and other supplies used in compounding the preparation. Also, confirm the proper use of PPE for the compounder.

**Unintended presence of another medication** - This generally involves the accidental use of another medication instead of the one prescribed. It can also result from interactions between ingredients and the degradation of ingredients to produce another ingredient with some untoward effects.

**Avoiding the Error:** To avoid this, confirm each and every ingredient that is to be used and confirm there are no interactions involving chemical reactions that may occur. This can be done by checking each item three times during the weighing process. Interactions can be checked in Remington’s.

**Incorrect concentration**

**Drug quantity/concentration too high** - Too high a drug concentration can result from improper weights, incorrect form of the drug used, loss of vehicle during preparation (evaporation, loss from the weighing or measuring device/container during transfer, etc.) and improper packaging.
Incorrect and/or insufficient cleaning of equipment to an aqueous preparation with no cosolvent may cause contamination by microorganisms. This issue of contamination can be avoided by calibrating the hot plate so the items are heated with water first, then with alcohol or suitable solvents. Avoiding the Error: This is often caused by excessive heat resulting in loss of activity in a low humidity room due to improper storage and handling of the final product. Lowering the heat and covers on beakers, etc. can help.

Avoiding the Error: See the responses above. Also, when weighing hygroscopic/deliquescent powders, caution should be observed to perform the activity in a low humidity room to prevent the materials from taking up moisture from the air and increasing the weight while decreasing the actual amount of API obtained. Care in transferring chemicals (powders, semisolids, liquids, etc) is of utmost importance to confirm all the material has been completely obtained. Sorption problems can generally be obtained from the literature; it is mostly concerned with very potent, low concentration drugs. Also, when mixing liquids and some semisolids, excessive air can become trapped in the preparations making it difficult to “qs” to final volume. The mixing should be done to minimize any incorporation of air into the preparation. Another issue that can occasionally occur is the use of a “nonsolvent” to make a liquid dilution of a potent drug; this can be eliminated by confirming that the potent drug is soluble in the liquid used for the dilution. Solubility information is available in the USP, Remington’s and other pharmaceutic references. Also, the proper alcohol and solvent concentrations must be maintained for ensuring complete solubility of the API in a solution dosage form. Also, in working with alcohol and water, it is important to maintain as high an alcohol concentration as possible by adding the water to the alcohol solution, not the reverse. When pipettors and micropipettors are used, insufficient volume will be delivered if the user is not aware of how to correctly use the pipettor.

Drug concentration too high/too low - Analytical results from laboratories have reported out-of-specification (OOS) results when using manufactured drug products as the drug source. Avoiding the Error: Compounding pharmacists do not have access to the actual analyzed concentration/quantity of drug in a specific manufactured dosage form. With USP tolerances ranging up to 80-120% and even greater, the compounder does not know the actual quantity of drug in the capsules, injections, etc. that are used as the drug source in compounding. Compounding allows only a 90-110% variation so it is easy to see that the finished compounded preparation may be outside the acceptable range through no fault of the compounder.

Stratification and lack of uniform appearance - If heated semisolids are poured into containers while hot, they may tend to separate and stratify. Separation can also occur among particles that are different in size and density. Avoiding the Error: For semisolids, cool to just above the congealing point prior to pouring into containers. For powders, reduce them to the same particle size range prior to mixing.

Lack of uniformity of capsule weights - Improperly filled capsules will result in several capsules being outside the acceptable weight range. Avoiding the Error: When filling capsules at the powder incorporation stage, keep the spatula or plastic card in a vertical position as it is moved over the capsules holes to allow the powder to “fall in” to the cavities; tamp lightly, then repeat until all capsules are uniformly filled. Do not slant the spatula or plastic card at an angle to force the powder in the holes as it will be done non-uniformly and result in weights that are outside the range. Allow the powder to simply fall into the capsule openings of its own weight.

Improperly filled or nonuniform suppositories or medication sticks - Contraction or dimpling of suppositories and medication sticks results in insufficient preparation for each dosage form.
Avoiding the Error: Contraction or dimpling occurs when the melt is poured while too hot. It needs to cool to just above its congealing point and then poured. The melting range of the bases can be found in Remington’s and in most pharmaceutic reference books.

Drug missing - Occassionally, a drug product that has been analyzed has reported to have no API in the prescription.

Avoiding the Error: Care in obtaining, weighing/measuring etc each ingredient can eliminate this potential error. Generally, when weighing, it is good practice to have the ingredients on one side of the balance and as each is weighed, it is moved to the opposite side or to a different location. Marking the weigh-boats has also been used effectively.

Equipment used incorrectly
Incorrect equipment used - This results in preparations that are of less than desired quality and esthetics. They may be improperly mixed, insufficient particle size reduction, separation of phases, discoloration, precipitation etc. Electrostatic charges that may be present during weighing are problematic.

Avoiding the Error: Confirm that each compounder knows how to correctly use each piece of equipment with which they will be involved. This includes not just actual operation, but actual maintenance and in some cases, simple repair or replacement of disposable items. A number of techniques are available to minimize electrostatic charges and devices can be purchased from suppliers to accomplish this.

Stirring rod in graduated cylinder while measuring - Improper volume of the required vehicle can result in a higher than desired concentration of the API.

Avoiding the Error: Remove the stirring rod during final measuring of the volume of vehicle to be added to the compounded preparation.

Magnetic stir bar in measuring device while measuring - When using a calibrated beaker, etc., if the magnetic stir bar is left in the beaker an improper volume of the vehicle will result in a higher than desired concentration of the API due to less vehicle being present.

Avoiding the Error: Remove the magnetic stir bar from the beaker or container when adding the vehicle to the calibrated volume line of the container.

pH meter not calibrated prior to use - An improper pH reading can result in a decrease in the stability of the drug as well as a decrease in the solubility of the drug resulting in precipitation, etc.

Avoiding the Error: Always calibrate the pH meter prior to using it each day and several times throughout the day. Clean/rinse the electrodes between each measurement.

Electronic balance not calibrated daily - Improper weighings result in too little or too much of an ingredient in the final compounded preparation.

Avoiding the Error: Calibrate each balance at the beginning of each work shift and throughout the shift as required.

Physicochemical Issues
Nonhomogeneous mixing - Large standard deviations in powdered dosage forms (capsules, papers, ointments, creams, gels, etc) due to mixing that does not result in a homogenous blend of the API in the bulk of the prescription.

Avoiding the Error: Confirm the mixing procedures that are used in compounding for different types of preparations. Uniform use of equipment, mixing times, powder particle size, etc. is critical for homogenous mixing. Dissolve salts in a minimum quantity of water before adding to a semisolid vehicle to prevent grittiness. Stir constantly when combining two liquids to prevent a layering effect and a potential incompatibility. The particle size may be too large and require comminution or levigation.

Solubility issues/Precipitation - Issues involved here result in too little API in some liquid doses and then excessive API in doses at other times.

Avoiding the Error: Solvent, pH, cosolvents, temperature and other factors can alter the solubility/precipitation of API in compounded preparations. The compounder must be aware of these variables and control them properly to prevent precipitation, haze formation etc.

Not following instructions - This can even involve official labeling as in the reconstitution of manufactured antibiotics, if the correct volume of water is not used, an incorrect concentration of the API will result. An example was reported where the powder was not reconstituted and the patient measured and took the powder. This also applies to lack of following precise instructions on the Formulation Record.
Avoiding the Error: Official labeling and the Formu-
lation Record steps must be followed exactly to
compound a correct prescription.

Contamination-Microbiological

Contamination-Nonsterile - Bacterial, mold and
fungal growth has been reported in some nonster-
ile compounded preparations.

Avoiding the Error: Confirm all equipment and
supplies are clean, dry and properly stored. Con-
firm that preservatives are present and appropri-
ately used or the preparation is “self-preserved”. If
using commercial preserved vehicles, confirm that
the vehicle has not been diluted to the point that
the preservative effectiveness is no longer present.
The effective preservative concentration informa-
tion can be obtained from the Handbook of Phar-
maceutical Excipients. Clean and rinse the
dispensing container to remove any potential
microorganisms.

Contamination-Sterile - Nonsterile prescriptions
(injections, ophthalmics, etc) have been reported
and have caused death and injury.

Avoiding the Error: Strict compliance with all
aspects of USP <797>. Errors that have been
reported have been traced back to noncompliance.
Many state boards of pharmacy report lack of com-
pliance during their inspections. Critical review of
the Standard Operating Procedures (SOPs), facili-
ty, equipment, chemicals, personnel training and
performance, packaging and quality control/ass-
urance activities should be routinely done.

Analytical Testing Issues

Sample preparation and handling - Improper sample
submission has resulted in (OOS) results.

Avoiding the Error: Contact the analytical laborato-
ry for the proper method of sampling (number of
samples, packaging, storage, etc) and shipping.
Ship overnight if possible and do not ship where
the sample will be in transit over the weekend.
Develop and implement standard operating proce-
dures for the different samples that are submitted.
Use FDA licensed and inspected laboratories that
will work with you when OOS results.

Potential problems with labs - Some laboratories
use improper sample handling methods, exaction procedures and analytical methods for
the analyses being done.

Avoiding the Error: Provide the laboratory with the
complete formulation of the sample so they can
appropriately perform the extraction as required
for the API. This is especially critical when cellu-
lose derivatives, polymers, etc. are used that may
entrapped the API and prevent their complete
extraction. Confirm the analytical methods being
used provide you the information that is needed
and is complete. If OOS results are received, con-
tact the laboratory to help identify the problem
and methods of correction. Occasionally, send
duplicate samples to two different laboratories and
compare results.

Improper Beyond-Use Dates - Some beyond-use
dates have been assigned by pharmacists using
laboratories that perform only “potency over
time” or “strength over time” testing.

Avoiding the Error: Beyond-use dates must be
determined utilizing stability-indicating analytical
methods. Confirm the laboratory is doing using
the proper testing method. There can be a signifi-
cant difference between a “potency/strength”
method and a “stability-indicating” method.

Microbiological Testing Issues

Sample preparation and handling - Some com-
ounded preparations are not prepared or han-
dled properly prior to testing for microbiological
growth, sterility or endotoxins.

Avoiding the Error: Confirm the proper method of
sampling, handling and transporting the samples
to the laboratory so they will be properly received.
Ship them overnight and do not ship them over the
weekend.

Potential problems with labs - Some laboratories
may actually contaminate the samples after they
are received at the microbiological laboratory,
resulting in reporting incorrect results.

Avoiding the Error: Check with the laboratory to
confirm they are registered and inspected by the
FDA. Confirm their personnel are properly trained
and follow strict SOPs. Occasionally, send dupli-
cate samples to two different laboratories and com-
pare results.

Miscellaneous Issues

Brittle suppositories and mediation sticks - Sup-
positories and medication sticks can be brittle and
break easily resulting in loss of the preparation.
Avoiding the Error: This is often caused by excessive powder in the suppository or medication stick and can often be corrected by reducing the powder quantity or incorporating a liquid that is miscible with the base.

Oils floating on top of oral or topical liquids - Oils have been reported to be floating on top of liquids, both oral and topical. When used, there is a very strong “flavor or odor”.

Avoiding the Error: This occurs when an oil is added to an aqueous preparation with no cosolvent or surfactant agent added to disperse it. Simply mixing the oil with a solvent like propylene glycol or glycerin often corrects this. Also, a few drops of an oil in water surfactant can correct the problem.

Incorrect and/or insufficient cleaning of equipment - Improper cleaning technique can result in dirty and contaminated equipment that is used.

Avoiding the Error: Follow a strict SOP for cleaning different types of equipment. For example, clean items with water first, then with alcohol or suitable solvent. If alcohol is used first, it may precipitate proteins, etc. that will be more difficult to move as they will tend to stick to surfaces.

Excess heating - When using a hot plate, boilover and loss of the preparation can result when the heat is initiated at too high a level.

Avoiding the Error: Calibrate the hot plate so the compounder knows the approximate temperature of the container contents at different dial settings on the hot plate. Microwaves should not be used unless the preparation has been demonstrated to be suitable. If used, a carousel type microwave should be used to minimize “hot spots”.

DISCUSSION

Errors can occur in any profession. However, in pharmacy, an error can result in harm to the patient or loss of life. Table 2 lists the general sources of error that have been discussed in detail in this paper. These sources of error need to be addressed, beginning with the Colleges of Pharmacy. As an example, compounding errors have been observed in pharmacy student training. Kadi and colleagues (Kadi A, Francioni-Proffitt D, Hindle M, Soine W. Evaluation of basic compounding skills of pharmacy students. Am J Pharm Educ. 2005;69(4) Article 69.) examined the accuracy of the compounding of two simple solutions by pharmacy students. For one of the solutions, only 54% of the students prepared the medications within 10% of the desired concentration. Errors for the remaining mixtures ranged from less than 75% to greater than 200% of the desired concentration. Results for the second solution showed 78% of the students within the +/- 10% of the desired concentration., however, the range of concentration errors was greater (-89% to 269%). Another study by Pignato and Birnie (Pignato A, Birnie CR. Analysis of compounded pharmaceutical products to teach the importance of quality in an applied pharmaceutics laboratory course. Am J Pharm Educ. 2014 Apr 17; 78(3):61) showed an error range of 0.6% to 140% with an average error of 23.7%.

Pharmacists are taught to be extremely focused and careful when preparing medication to be administered to a patient.

However, these numbers indicate that insufficient time is being spent on the science and technology involved in pharmaceutical compounding and dispensing. There needs to be a renewed focus within Pharmacy Schools and continuing education on both the basics and advanced topics. Quality control/assurance topics need to be covered in detail as well as the advantages of certification and advanced education.

SUMMARY

Errors can and must be prevented. This will be a process that begins at the Colleges of Pharmacy and progresses through the practice years via continuing education programs, reading current literature, and sharing experiences with colleagues. It can, and must, be as patients put their trust in the pharmacists that serve them.

REFERENCES

## Table 1: Adverse Events Related to Compounding Errors 2001-2013

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Cases Reported</th>
<th>Deaths Reported</th>
<th>Adverse Event</th>
<th>Error That Occurred</th>
<th>Preparation Involved</th>
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<tbody>
<tr>
<td>2001</td>
<td>4</td>
<td>3</td>
<td>Infection</td>
<td>Contamination</td>
<td>IV infusion</td>
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<td>Contamination</td>
<td>Spinal/joint injection</td>
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<td>Medication sticks</td>
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<td>Eye infection, Eye infection, Loss of vision, Loss of eye</td>
<td>Contamination</td>
<td>Ophthalmic Solution</td>
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<td>Overdose</td>
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*PN = Parenteral Nutrition; Chemo=Chemotherapy; IV=Intravenous
*Abstracted from: Pew Report, U.S. Illnesses and Deaths Associated with Compounded or Repackaged Medications, September 2013"
### Table 2: General Causes of Compounding Errors

- Lack of education and training - Pharmacists and Technicians
- Lack of available education and training by Colleges/Schools of Pharmacy
- Lack of complete, implemented Standard Operating Procedures.
- Improper use of equipment or lack of maintenance and calibration
- Improper chemicals and supplies
- Calculation errors
- Improper form of drug used (salt/ester, hydrate form)
- Incorrect potency calculations
- Commercial products used with unknown actual strength
- Lack of proper documentation
- Improper pH, buffers
- Misinterpretation of orders/formula instructions
- Lack of focus and/or attention