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EXTEMPORANEOUS PREPARATION – SPECIFICATION AND TYPES

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ABSTRACT

Extemporaneous dispensing is a manual process where a manufactured product may undergo modification or made from raw ingredients, performed by a dispenser or pharmacist, who has to incorporate all the necessary ingredients according to a physician's prescription, a drug formula, or a recipe in which calculated amounts of ingredients are made into a homogenous mixture. Whilst most medicines are commercially available, however, some medicines cannot be purchased from large companies.

KEYWORDS: Extemporaneous medications, preparation, types.

1. INTRODUCTION

Whilst most medicines are commercially available, however, some medicines cannot be purchased from large companies. Access to a special dosage form of a medication is essential when administration to infants and children and selected other populations is required. Some drugs necessary for pediatric patients are not commercially available in dosage forms appropriate for use in this population. These drugs may be prepared extemporaneously for use in individual patients. Extemporaneous preparation describes the work involved in supplying a medicine in a form or dose that is not otherwise available.

It is hard to determine when humans started mixing and concocting preparations that had therapeutic effects, using material medica of animal or vegetable or minerals sources, however it is believed that ancient civilizations in Greece, Rome, Egypt, Arabia developed compound levels of medical knowledge combining aspects of medicine compounding and

pharmacy. Archeological research gives evidence of medicines compounding in ancient Egypt, as chests containing dried drugs have been found, as well as papyrus describing formulae, remedies measures and weights some of which are also used nowadays. The ancient Greek civilizations contribute to medicine and pharmacy between 1250 BC and 285 BC. Until the fall of the Roman Empire, there was a considerable number of practitioners in evidence; Celsus, Dioscorides, and Galen who left written work with all the information they had on drugs, medicines and compounding forming the basis of therapies.

By the fifteenth century apothecaries became highly specialized in the practice of pharmacy as well as giving advice to patients.

It has been long ago that compounding was recognized as legal and a central component of pharmacy practice. Around 1820 the USP started providing compounding information. Compounding became so important in the early 20th century that a number of pharmacy practice acts not only regulated but also included the term compounding, and wherever compounding took place the facility was termed pharmacy, something which started in 1938 in the US, where more than 250 million prescriptions were compounded annually.

Today, most dosage forms of medications are already pre-packaged by the manufacturer so the pharmacists' role is more in the redistribution of medications and the clinical aspect of Pharmaceutical Care. The role of the pharmacy technician continues to grow, as technicians are taking on more of the dispensing functions once reserved for the pharmacist alone. Pharmacy technicians are also doing extemporaneous compounding of medications.

There are various cases where a drug is not available, or when certain medical needs of individual patients cannot be met by the use of an approved commercial drug product so compounding can provide a solution to the individual's needs. So technically, compounding is the preparation, mixing, assembling, packaging or labeling and supply of a single unit of a drug product in response to a prescription written by a licensed practitioner.

Extemporaneous dispensing is a manual process where a manufactured product may undergo modification or made from raw ingredients, performed by a dispenser or pharmacist, who has to incorporate all the necessary ingredients according to a physician's prescription, a drug formula, or a recipe in which calculated amounts of ingredients are made into a homogenous

mixture. Extempore, true meaning is 'in accordance with the needs of the moment', from Latin.

Even though compounding is most often associated with pharmacists, other practitioners such as naturopaths and herbalists may compound products. It is an integral part of pharmacy practice and is essential to the provision of health care.

There is some trouble distinguishing compounding and manufacturing so there are some guidelines explaining the differences:

- Pharmacists can compound, drug preparations that are commercially available in the marketplace, in reasonable quantities as long as there is a pharmacist–patient–prescriber relationship and a valid prescription is presented.
- Pharmacists may also compound nonprescription medications in commercially available dosage forms or in alternative dosage forms to accommodate patient needs as allowed by individual state boards of pharmacy
- Furthermore, they may well compound drugs in limited quantities prior to receiving a valid prescription, on the basis of a history of receiving valid prescriptions that have been generated solely within an established pharmacist–patient–prescriber relationship, and provided that the prescriptions are maintained on file for all such preparations dispensed at the pharmacy
- Pharmacists should not offer compounded medications to other pharmacies for resale; however, a practitioner may obtain compounded medication to administer to patients, but it should be labeled with the following: “For Office Use Only,” date compounded, use-by date, and name, strength, and quantity of active ingredients. An exception to this may be the outsourcing of some compounded preparations by hospitals to contract compounding pharmacies.
- Compounding pharmacies and pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services.

2. Reasons for extemporaneous compounding today

a. There may be unavailable dosages, strengths and routes of administration of already existing products

b. There may be need for dilution of adult doses of medications to either pediatric or geriatric strengths

c. Solid dosage forms may be converted to solutions or suspensions

d. Topical dermatological products may be combined if not available by the manufacturer

e. Inactive ingredients of commercial products which may possibly cause allergic reactions in individuals.

3. Compounding includes the following

- The drug dosage forms preparations are intended for both human and animal patients
- The drugs or devices are always prepared in anticipation of prescription drug orders, on the basis of routine, regularly observed prescribing patterns,
- It sometimes involves reconstitution or manipulation of commercial products that may require the addition of one or more ingredients,
- Those drugs or devices can be compounded for the purposes of, clinical or academic research or teaching students, or chemical analysis,
- Preparation of drugs and devices for prescriber's office use where permitted by federal and state law

• The product must be prepared in a manner which guarantees its quality, safety, efficacy and appropriateness for use.

4. Compounding Criteria

• A complete auditable trail in respect of each extemporaneous preparation should be generated and maintained for at least two years, with such audit facilitating a checking mechanism at each stage of the procedure.

• Appropriate equipment and of course facilities and must be available to be able to prepare such products in a hygienic manner

• It is imperative that the staff involved in the extemporaneous dispensing of a product must be professional and competent, and maintain skills to safely perform this task.

• The component substances for any extemporaneous dispensing must be obtained from a trusted source, and stored and managed in a manner consistent with their properties.

• The final product should be presented in a manner consistent with facilitating the safe and appropriate storage, retention and use by the patient.

5. Compounding Guidance

When a patient presents a prescription for a product that is required to be extemporaneously compounded, they should expect that it will be compounded by either the pharmacist or by

the pharmacy technician under the direct supervision of the pharmacist, making sure to deliver a safe, effective and high quality product. The facilities where for the extemporaneous compounding of the products prepared should be maintained cleaned and hygienic at all times. The equipment used for extemporaneous compounding should be easily accessible, and always be in an hygienic and operable condition, be regularly calibrated and must include at some of the following items a) an apparatus allowing for the accurate weighing of substance within the range of 10mg to 2kg , b) a range of weighing boats, c) a range of graduated Type A glass measures and pipettes to allow for the accurate measurement of volumes from 0.05mls to 500ml or d) a range of syringes and syringe filters, e) a suitable set of mortars and pestles including one glass set, f) a glass or marble ointment slab, g) a glass stirrer and a stainless steel spatula. Of course, all equipment should be cleaned before and after use.

It is important to state that a pharmacy receiving a prescription or request to compound an extemporaneous product, requires specialist expertise and the appropriate equipment. If for any reason the integrity of the process or the product would be compromised or if there is any risk posed to the employees involved or the patient using the product, the pharmacist or the personnel should not attempt to prepare such product. In this case, the original pharmacy receiving the prescription should refer the patient to a practice equipped, to deal with the request and should facilitate and interact with this practice in the best interest of the patient.
A pharmacy should have guidelines which address the responsibilities of any person involved in extemporaneous compounding including personal hygiene, any health issues for example allergies and protective clothing.

- Any chemicals and materials used for extemporaneous compounding process should be of appropriate pharmaceutical grade and quality. Information on expiry dates and safety material should be available.
- In respect of every extemporaneously compounded product, the pharmacy ought to have a written policy in place, which provides for an auditable trail. Records should be kept clearly indicating the formulation that has been used, along with the material used and their batch and expiry references, the quantities of the materials used, the source of materials, preparation processes and the identity of the compounder and checking system.

For every single preparation, a record sheet should be produced and a duplicate label affixed immediately after that. It is preferred that all calculations and measurements are double checked by a second appropriately trained member of staff. The dispensing pharmacist should be satisfied that the final product of compounding is safe, appropriate and in the best interest of the patient to provide the product.

- The formulation used must be obtained from a trustworthy, closely examined and reviewed source and external expertise obtained where necessary.
- The final compounded product should be packaged in the correct container depending on its properties and taking into consideration its, thermostability and photostability. The label on the product should be clearly and appropriately written to comply with regulatory provisions in place. The directions used should be Clear and legible and indicate precautionary warnings and directions for use. "As directed" is not appropriate and should not be used. Labelling must include an expiry date for the product and any special storage instructions. Regular assessment of the procedures used for extemporaneous dispensing should be carried out.

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