SAND2013-1062P

Clinical Pharmacology

INTRODUCTION

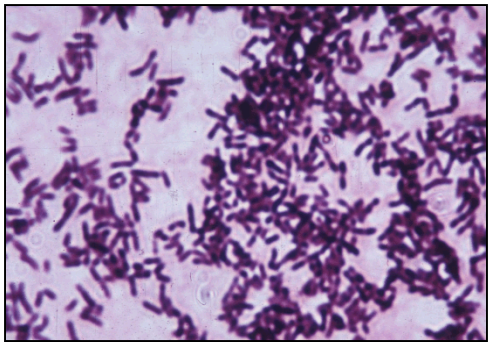
Clinical Pharmacology

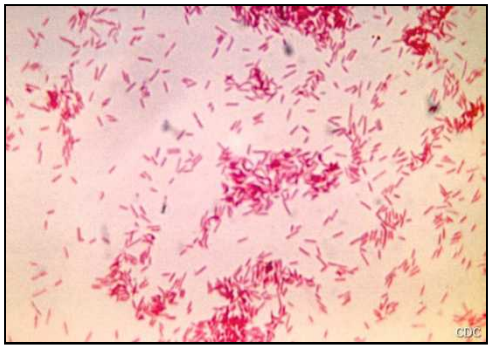
- **Pharmacology deals with the science of drug preparation, the use of drugs, and the effects of drugs**

- **As veterinarians, we work to optimize drug therapy in our patients, which include individual animals, flocks, and herds**
  - Much of our concerns in livestock medicine involve the treatment of infectious diseases and inflammation

Considerations for Therapy

- **What are we treating?**
  - Infectious diseases - It is important to have an idea what is the most plausible pathogen
    - **Bacteria**
      - Gram positive or gram negative
      - Anaerobic or aerobic
    - **Parasite**
      - Round worm
      - Blood parasite
      - Protozoa
    - **Viruses**
  - Inflammation – It is important to know whether the inflammation is associated with infectious or noninfectious causes
  - Anesthesia – Local or general anesthesia





Considerations for Therapy

- **What species are we treating?**
  - Drug recommendations are species specific
    - **Recommendations are based on clinical trials that have been conducted in that species and experience using the drug in a given species**
  - Administration of drug that is not recommended for use in a given species can have adverse effects and could result in death
    - **Antibiotics**
      - Antibiotics approved for use in cattle can cause death in other species
        - **Tilmicosin is routinely used in cattle, but can cause death when given to horses**
    - **Anesthetic agents**
      - Horses require a much higher dose of Xylazine Hydrochloride than cattle
    - **Anti-inflammatory medications**
      - Aspirin is routinely used in cattle but can cause gastric ulceration in other species
      - Acetaminophen is used in people to treat minor pain, but can cause death in cats
  - Drug withdrawal times are dependent on the type of production animal

Considerations for Therapy

- **What is the most appropriate route of administration for the situation?**
  - Follow the manufacturers recommendations
    - **Improper administration of certain drugs can result in death**
      - Only drugs recommended for intravenous use can be given intravenously
  - The rate at which you need to get the drug to the affected location can affect the route which you choose to administer the drug
  - Certain oral medications are broken down by bacterial flora in the rumen of cattle, sheep, goats, and camels, and are therefore, ineffective
  - Injection site reactions can occur and may alter the quality of the meat in meat producing species

Considerations for Therapy

- **What drugs are approved for the clinical problem?**
  - In the United States, rules and regulations dictate which drugs can be used in certain species
    - **Many drugs are illegal to give to food producing animals because of the negative impact on humans**
  - Certain drugs are believed to cause antibiotic resistance, and as a result are only approved for specific conditions in food animals
    - **Example: Enrofloxacin is only approved to treat respiratory disease in cattle that are not lactating because of the potential link to antimicrobial resistance**
  - Always follow the manufacturers recommendations

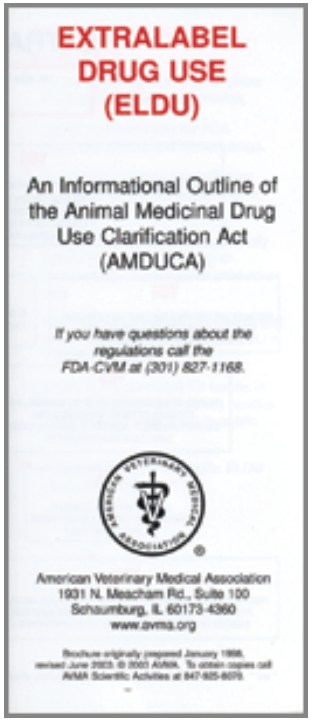
Regulatory Considerations

- **Drugs are selected based on efficacy in animals, safety in animal populations, safety of the food supply, and resistance of microbes to antibiotics**

- **In the United States drug administration is regulated by Food and Drug Administration's Center for Veterinary Medicine**
  - Approves drugs and labels for use
  - Enforces laws related to the use of veterinary drugs
  - Determines and enforces standards of drug efficacy and safety
  - Oversees practices of drug distribution entities
  - Accepts reports of adverse drug reactions

Extra Labeled Drug Use

- **Animal Medicinal Drug Use Clarification Act**
  - Extra-label drug use refers to the use of an approved drug in a manner that is not in accordance with the approved label directions
  - Extra-label use of new animal drugs was considered illegal and permitted only as a matter of enforcement discretion until the Animal Medicinal Drug Use Clarification Act was passed
  - The act amended the Federal Food, Drug, and Cosmetic Act, legalizing extra-label drug use by and under the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and became effective in 1996 when implementing regulations were published


EXTRALABEL DRUG USE (ELDU)

An Informational Outline of the Animal Medicinal Drug Use Clarification Act (AMDUCA)

If you have questions about the regulations call the FDA-CVM at (301) 827-1168.

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Schaumburg, IL 60173-4360
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Extra Label Drug Use

- **The Animal Medicinal Drug Use Clarification Act**
  - Allows veterinarians to prescribe extra label use of drugs that have already been approved for use in animals or humans
  - Must have an established relationship with the client
  - Extra label use must not cause harmful residues in food producing animals
  - Restriction of certain extra label drug use
  - The Food and Drug Administration can prohibit extra label if the drug poses a potential public health risk or if safety studies do not exist

Extra Label Drug Use

- **Extra label use of these drugs is prohibited in the United States because of the potential for severe reactions in humans:**
  - **Chloramphenicol**
  - **Clenbuterol**
  - **Diethylstilbestrol**
  - **Dipyrone**
  - **Nitroimidazoles (dimetridazole, ipronidazole, metronidazole)**
  - **Nitrofurans (furazolidine, nitrofurazon)**
  - **Sulfonamides in lactating dairy cattle (except sulfadimethozine, sulfabromomethazine, sulfaethoxypyridazine)**
  - **Fluoroquinolones**
  - **Glycopeptides**
  - **Phenylbutazone**
  - **Crystal violet**
  - **Cephalosporin class 1 antibiotics except cephapirin**

Assistance on Drug Residues and Prohibited Drugs

- **The Food Animal Residue Avoidance Databank**
  - Was developed by a collaboration of veterinary universities in the United States
  - Created to provide guidance to veterinarians on the use of drugs in food producing animals
    - **Drug doses**
    - **Routes of administration**
    - **Withdrawal times**
  - http://www.farad.org/index.asp

Summary

- **Many factors are involved in selection of an appropriate therapeutic plan**
  - Clinical and/or laboratory diagnosis plays an important role in the selection of antibiotics and anti-inflammatory medications
  - Drugs behave differently in different species, therefore species type should always be considered when developing a therapeutic plan
  - Drug properties and distribution impact therapeutic plans
  - Drug residues and their impact on the public must be considered when prescribing medications for animals intended for food