VMS 361 Agricultural Animal Health

Bovine Health Section

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Class Context - Your Future Role

My Perspective (for the purposes of this class):
- You are the manager of an agricultural animal farm or ranch.
- Your primary goal is to maintain a profitable business that survives a long time.
- You use my veterinary services to further that goal.

Class Context – My Role as Your Vet

My perspective:
- I want to deliver services to you that are profitable to both you and me
- My primary goal is to make you successful
- I can’t keep you from failing but I can help you succeed
- You are unlikely to do as well without me as you will by using my services

Veterinarian – Client – Patient Relationship (VCPR)

What is different about the VCPR in agricultural animal medicine vs. domestic pet veterinary medicine?
Topics for this Section:
• Veterinary – Producer Relationship
  – Impact on this relationship of:
    • Industry trends of increasing enterprise size
    • Advances in communication technology
    • Evolving traceback and accountability requirements
  – What does an agricultural animal veterinarian do?
  – Impact of Federal Regulations
  – Impact of social / consumer expectations

Impact of the Internet:
• Previously to the WWW I had the "corner" on most of the professional information.
  – You had to either buy the veterinary books or go to a veterinary library to obtain it.
  – Now you have virtually the same access to the veterinary literature that I do, can find it when you need it and may have more time to read it than I do.
  - Over half is accessible through the National Library of Medicine's PubMed
  - Cornell Consultant: You can search for diseases causing particular clinical signs and can identify the current clinical literature on a particular disease.
    - [http://www.vet.cornell.edu/consultant/consult.asp](http://www.vet.cornell.edu/consultant/consult.asp)
  - Merck Veterinary Manual is on-line

Impact of the Internet:
Changing Veterinary – Producer Relationship
• Veterinarian becoming less of an information provider and more of an information interpreter.
  – Being prime targets of sales, manager's of large operations need assessment of quantitative information.
  – Determining the internal validity of studies and their applicability to the producer's operation.
• Producer will not replace the veterinarian because of the access to this information.
  – Not cost effective use of the producer’s time.
  – Vocabulary problem:
    - Due to the specialized medical terminology, a veterinary student's vocabulary doubles in veterinary school

Impact of Industry Trends:
The changing scale of livestock operations changes the Veterinary – Producer Relationship
• As operations increase in size:
  – Employees specialize more in specific tasks, becoming more skilled
  – Employees become familiar with a broader range of conditions
    - Health events become more frequent for the employee
      - Better at recognizing a particular problem earlier
      - More likely to develop sufficient skills to handle it
    - Suppose 1 case per 300 cow years
      - 1 case every 3 years on a 100-cow dairy
      - 10 cases per year on a 3,000-cow dairy

Impact of Industry Trends:
As a result, the veterinarian becomes less of a "doer" and more of a trainer of the "doer".
• Veterinarians become more involved in the selection, training and monitoring of employees.
  – Traditional role of feedlot veterinarians.
• Standardized operating protocols (SOP)
  – Managers moving toward more business management and less hands-on
  – More consistent practices in critical areas
  – Better preventive practices reduce treatment needs
• Fewer veterinarians are needed to cover more cows
  – Midwest – small herds: 1 vet to 6,000 cows
  – New Mexico – large herds: 1 vet to 20,000 cows

Impact of Industry Trends:
Rapid communication between like-minded individuals
Specialized e-mail lists, Blogs
• Pet owners concerned about specific issues, diseases
• Activists on health issues
  – PARA - Paratuberculosis Awareness & Research Association
• Activists on philosophical issues
  – Animal welfare / rights - PETA
  – Vegetarian

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Veterinarian’s Primary Role: (Production vs. Traditional)

| Adviser and educator | Hands-on “doer” |

Visit Trigger:

| Regularly scheduled | Called as needed “fire engine” |

Problem Detection:

| Record-based detection of sub-optimal performance | Visual detection of clinical illness |

Application of Treatment:

| Employees trained to treat routine cases | Veterinarian treats routine case |

Evaluation of Outcome:

| Economic performance | Visible difference (healthy vs. sick) |

Potential Economic Impact:

| Great if entire group affected | Small – individual animal salvage |

Management vs. Disease Conflict

Common Fresh / Hospital Pen:

- **Good:**
  - More observation of at-risk animals
  - Less stress
  - Better use of specialized labor

- **BAD** - Transmission of Infectious Agents!
  - Sick animals usually shed infectious agents at the highest levels
  - Fresh animal have the lowest innate resistance

Problem: Procedural Drift

As in feeding cows: Does paper ration = Digested Ration?

- Paper Ration
- Loaded Ration
- Bunk Ration
- Consumed Ration
- Digested Ration

Management Intentions

Employees Execution

Is what is intended being done?

Producer vs. Veterinary Perception of Services?

- Services vet thinks producer should purchase
- Services producer thinks vet should provide
- Services that benefit both!

Impact of being a Family Business

- Intergenerational conflict
  - Experienced 75% of farm families
- Adoption of Change
  - Innovators
  - Early Adopters
  - Late Adopters
  - Traditionalists
- Veterinarian is often in the middle
  - Generational linkages
  - Old Doc <> Dad; Young Doc <> Son
  - Who controls the purse strings?

As my client, how much veterinary medicine do I want you to know?

As my client, I would teach you or your employee how to do anything that either:

- Is done regularly enough to develop and maintain competency
  - Diagnosing DA’s
  - Dystocia
  - Pregnancy palpation?
- Must do immediately to save an animal’s life
  - Uterine prolapse
Why?
- You or your employee will recognize problems at an earlier stage.
  - My interventions are more successful when you call me earlier in the course of disease.
- You will know your limitations better.
  - You will have created less of a mess by the time you call me in.

Win - Win vs. Lose - Lose
- You will involve me more in developing preventive measures.
  - Win - Win situation.
- You will have less need for salvage measures.
  - Lose - Lose situation.
  - Attempting to prevent further loss.

Consequences:
- Traditional "fire engine" practices are disappearing
  - Some areas no longer have any "all creatures" veterinary services, particularly large animal
- Veterinarians have to invest in those practice segments that will pay off
  - Continuing education time
  - Specialized equipment

Your background and future intentions?
On a sheet of paper please write:
- Name and where you are from
- Briefly describe your livestock experience
- What career do you intend to pursue after graduation?
- Briefly describe how you expect to:
  - Work with ag animal veterinarians
  - Use the information in this class
- Do you know any veterinarians well? Who?

Who are the ag animal veterinarian’s ultimate clients?
Same as yours as producers!
Anything perceived to threaten children is ZAPPED!

We continue to have our problems

These problems have consequences.

A Few Headlines for Consumer Consumption

Hamburger recall rises to 25 million pounds. Burger King, Boston Market anticipate shortages
CNN August 21, 1997

Hamburger recall expanded; illness cases reported
The Associated Press Saturday, July 20, 2002

Tainted Meat, Tainted Money: Consumer groups decry coziness between government, agribusiness
Colorado Springs Independent, August 1, 2002
Troubled paradise: Some 70 percent of all outbreaks of foodborne illness are traced back to meat and poultry products.

Recent Headlines

- Mad cow disease a serious fear Miami Herald, Apr. 03, 2004
- Is Your Pet At Risk For Mad Cow Disease? NBC4.TV, CA - Mar 31, 2004
- How safe is that steak? The Age, Australia - Apr 19, 2004

What is worried about?

Selected Emerging/Re-Emerging Candidates:
- Antibiotic resistance
- Foodborne zoonoses
- Foot and Mouth Disease
  - Taiwan outbreak
  - UK outbreak
- E. coli O157:H7
- Chronic Wasting Disease
- "Mad Cow" Disease
- MDR Tuberculosis

Evaluating Risk is not Straightforward!

Which are the jackhammers and which are the cigarettes?

Public's Perspective:

Society’s view of veterinarians:
- First as independent agents for the animals
- Second as acting in their clients’ interests

Society has charged the veterinarian with:
- Assuring that animal origin foodstuffs are safe and wholesome.
  - Freedom from harmful drug residues (antibiotics, hormones)
  - Reduction of harmful bacteria
- Assuring that animals are raised and handled in a humane manner.
  - Animal Welfare concerns (currently greater in other nations)

This has led to the recent development of QA (quality assurance) and HACCP programs, including audits, in which the veterinarian has an integral role.
Result of the consumer being the end of the chain:

- Government is a much larger influence in the veterinary-client relationship for agricultural animal medicine than for pet medicine.
- The relationship between the veterinarian and the producer in food animal agriculture is different from non-agricultural animal species (horses, dogs, cats).
  - Two additional parties – the consumer (indirectly) and the government (directly)

Drug & Biologic Regulation

- All drugs (e.g. antibiotics, anti-inflammatories, diuretics, ...), biologics (e.g. vaccines, bacterins), and veterinary medical devices (including squeeze chutes) fall under federal regulations.
  - The main regulatory focus is on those products used in animals intended for the production of food.
- Some of these regulations involve the producer’s relationship with a veterinarian.

Biologic Regulation: USDA

- USDA
  - Monitors safety and efficacy standards for all biologics (vaccines, bacterins, toxoids).
  - “U.S. Veterinary License No. xxx”
- Note:
  This efficacy standard is a laboratory-based challenge model and is not a field-proven efficacy standard!

Drug Regulation: FDA

- The Food and Drug Administration (FDA) regulates the use of all animal drugs
- Drugs: Antibiotics, hormones, anthelmintics
- 7 Items:
  - Animal Species
  - Disease Condition
  - Route of Administration
  - Dosage Amount
  - Frequency of Administration
  - Duration of Administration
  - Withdrawal Period (food animals)

FDA Drug Classification

FDA categorizes drugs two ways:
- OTC - (Over-the-Counter)
  - purchase anywhere (feed store, ...)
  - Used by producer only according to label instructions.
- Prescription (Rx, Legend)
  - purchase only from pharmacies by prescription or from veterinarians
  - used only under a veterinarian’s instructions with valid VCPR.

OTC Drug Classification Basis

- FDA Classification is based on whether or not “adequate directions for use” can be prepared under which a layperson can use the drugs safely and effectively.
- Precluded by toxicity, potential harmful effects, required method of use.
- The law requires that if such instructions can be written, the drug must be classified as “OTC”.

Drug Safety

For FDA approval, a manufacture must show that the drug is safe:
- for the treated animal
- for persons administering the drug
- for the environment
- in food products derived from the animal

Drug Effectiveness

FDA defines “Effective” as:
- An accurate diagnosis can be made with a reasonable degree of certainty.
- The drug can be properly administered.
- The course of the disease can be followed for assessment of treatment success.

If any of these cannot be done reasonably by the average lay person, the drug cannot be OTC.

Extra-Label (Off-Label) Use (ELU)

- “The use of any drug (OTC or Rx) in any manner that is not in accordance with the FDA approved label directions.”

- 7 Label Items: species, condition, dosage, route, frequency, duration, withdrawal.

- Dogs, cats, horses, sheep, goats, camelids, fish, . . . .
The Federal Law

- **Any** extra-label (non-label dosage, condition, species, ...) use by a lay person (non-veterinarian) is illegal, whether the drug is OTC or Legend!

- Penalties on the involved parties are up to a $500,000 fine and 1 year imprisonment.

Rx (Legend) Drugs

- **Official FDA Rx Legend:**
  
  "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"

- **Note:** Any other wording is not a legend drug but is likely an "ethical" drug for marketing purposes.
  - e.g. “For Veterinary Use Only”, “Sold to Veterinarians only”

6 Extra-label Use Conditions

**Only by veterinarians only when:**

- A careful diagnosis is made within a valid veterinarian-client-patient relationship.
- No drug is FDA-approved for the condition or the approved dosage is ineffective.
- Treated animal ID is recorded for 2 years.
- The animal’s health is in immediate danger.
- The dispensed drug is properly labeled.
- Withdrawal time is increased to prevent residues.

3 Parts of Valid VCPR

A valid V-C-P relationship exists when the veterinarian:

- agrees to be responsible for making clinical judgments and the client agrees to follow the instructions.
- is knowledgeable of the animals, their care, and keeping and has made medically appropriate and timely premise visits.
- readily available for follow-up evaluation.
5 Parts of Proper ELU Labeling

- Veterinarian’s name, address, phone number
- Active drug ingredients
- Directions for use (condition, species, dose, route, frequency, duration, withdraw)
- Cautionary statements
- Veterinarian’s specified withdrawal/discard times for meat and milk.

FDA Discretion

- Veterinarians (and clients) may be subject to regulatory action for any violative residues in human food resulting from their prescriptions, recommendations or treatments contrary to approved label instructions in violation of AMDUCA.
- They will be subject to regulatory action for any detected use of banned drugs (e.g., chloramphenicol, glycopeptides, clenbuterol, diethylstilbestrol, dimetridazole, nitrofuracins (except for approved topical uses), ipronidazole, . . .).

Banned Drugs

These drugs are banned from use in food animals under any circumstances:
- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Fluroquinolones (except as specifically approved)
- Glycopeptides
- Nitroimidazoles (Dimetridazole, Ipronidazole)
- Nitrofurzone, Furazolidone (Used to exclude topical use)

Why the particulars?

Complicated:
- Differences between species
- Differences between routes and frequency
- Problems with withdrawal times
Withdrawal Period: What is it?

The period of time after a drug is given (approved route and dosage) for the residue of toxicological concern (the drug or its metabolites) to reach safe concentrations in edible tissues as defined by the tolerance level.

Note: Once a drug is given to an animal, it NEVER reaches a zero concentration in that animal. Therefore, zero residues are a scientific impossibility. This is the reason that cancer-causing drugs can never be used (Delaney Amendment to Food and Drug Act).

Withdrawal Period: How is it established?

After drug efficacy is established, the manufacture:

1. Establishes the amounts of the drug and its metabolites in edible tissues over time after administration.

2. Establishes the testing methods for the FDA to use in residue screening programs to detect these levels.

- Sensitivity of common testing methods
  - 1 drop in 13,000 gallons of water
  - 1.5 inches in the circumference of the earth (24,860 miles)
Withdrawal Period: **How is it established?**

3. Performs special lab studies to establish the toxicological effects of the drug and its metabolites.
   - Lifetime studies in rats and mice (2 years)
   - Non-rodent mammalian study (usually dogs)
   - 3 generation reproductive study for birth defects
   - Other special studies as indicated by the type of drug

4. From the laboratory exposure data, acceptable daily intake (ADI) levels from edible tissue for “no effect” in humans are established with the following safety margins:
   - Birth defects: 1:1,000 safety margin
   - Carcinogens: None allowed
   - Other effects: 1:100 safety margin

**Why is quality assurance such a big deal?**

Subtitle: How do they (the FDA) catch you using drugs illegally?
Extra-label use conditions (AMDUCA) does not apply to feeds.
Drugs may be added to feeds only at FDA approved levels.
FDA Dairy PMO

The FDA Grade "A" Pasteurized Milk Ordinance (PMO) also dictates that drugs on a dairy farm must:
- Meet the FDA labeling requirements and extra-label use conditions.
- Be stored to minimize the potential for milk contamination (lactating cow drugs separated from the others).

Web Notes:

Conditions for Producers’ Use of Livestock Drugs

Linked off of index page at:
http://www.vetmed.wsu.edu/courses-jmgay/VMADProducerDrugs.htm

Google "jmgay"

US Animal Health Association (USAHA)

- National organization of representatives of:
  - state and federal animal health officials,
  - animal agriculture industries,
  - animal health research scientists, and
  - other government agencies.
- 30 active committees, 8 species oriented and 22 subject oriented.
- Addresses issues of animal health and disease control, food safety, homeland security, animal welfare and public health and
- Serves as a clearinghouse for new information and methods that may be incorporated into laws, regulations, policy and programs.
- Develops consensus for changing law, regulations, policies and programs.

http://www.usaha.org/