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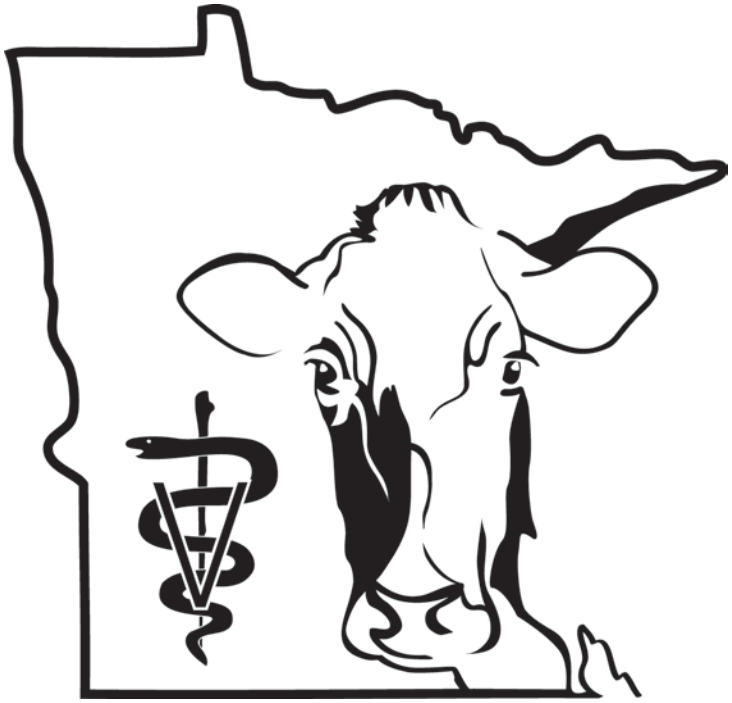

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Toward the Development of a "Best Practices" Model for Dairy Practice in Minnesota

Preliminary concepts for presentation at the Minnesota Dairy Herd Health Conference
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General Principles and Background:

The practice environment faced by today's dairy veterinarian in Minnesota has changed dramatically. The dairy industry is consolidating into larger and fewer dairies operating under very tight financial conditions. The regulatory environment is changing as well, with drug use stricture unique to food animal practice (AMDUCA) and increasing demands by consumers that laissez faire use of drugs is unacceptable. Clients see a wider choice in channels for purchasing drugs and lose sight of the role of professional veterinary input into drug use. Many channels of distribution completely circumvent the veterinarian who legitimately has a valid veterinary / client / patient relationship in providing drugs to dairies.

This is a radical change for some practitioners, who in the past had enjoyed a dominant role in drug sales to their clients. When the practicing veterinarian was the dominant channel for drug distribution, the distinction between the medical role of determining the need for and overseeing the use of drugs on the farm) and the distributor's role (drug sales and delivery) were blurred and less critical. By analogy to human medicine, the veterinarian was both the internist and the pharmacy.

Because the two functions were blurred, the key and proper medical role of the veterinarian has been weakened. Despite the clear mandate and legal requirement of AMDUCA, dairymen and others have come to believe that they can determine what prescription drugs they will use on their farm and how they are to be used. Some distributors have used the confusion to circumvent proper medical oversight of a dairy's use of prescription drugs. It is increasingly clear that the profession must learn to hold these two functions (medical and distributor) distinctly separate. As required by law, veterinarians must insist that medical decisions are made by veterinarians. In this changing competitive environment, there is the risk (and in some cases the fact) that some practitioners are responding in ways that run counter to good medical practice, do not serve the interests of consumers or clients, and may cross the generally understood boundaries of professional ethics and the law.

In the face of these changes, the dairy veterinary profession, through the auspices of the MVMA, is seeking to develop a set of guidelines and models for what the best practice of dairy veterinary medicine might be in Minnesota. The goal is to set a level of practice that provides a practical but rigorous guide that serves our clients, their animals, consumers of dairy and beef products, and the veterinary profession. If successful, dairy practitioners will look to these "best practices" as a template to illustrate how they should conduct themselves in daily practice. Further, it should provide a baseline for dairy producers describing what they should expect of their veterinarian. The guidelines should also support the veterinarian when they must inevitably refuse a specific request by a client for behavior that does not meet the "best practices" model.

The principles underlying these "best practices" are fundamental to being part of a healing profession that serves the interests of society in a pragmatic arena. These ideal principles are:

- In food animal production, the wholesomeness of the human food supply and the welfare of the animals must be paramount. Veterinary actions in food animal medicine should be consistent with the best available science, the law and regulations, sound economics for the producer, and public policy whenever food production is involved.

- Veterinarians must play a central role in determining how and what drugs are used in food animal production. With this role comes the responsibility to continually update ones knowledge of the use and fate of drugs in food animals and their proper application in animal production systems. It is appropriate for veterinarians to expect to be compensated for the exercise of medical judgment in determining what prescription drugs should be used on a dairy and how they should be used.

- The systems of decision-making regarding drug use and distribution of drugs to the end user cannot be structured simply to provide a monopoly to a practitioner or practice or to favor the veterinary profession as the distribution channel for drugs to dairies. The guiding motivations must be a) using drugs properly for the proper animals at the proper time, b) protecting of the safety of food, and c) serving the client's interests in operating their business. This is not to say that veterinarians must provide services or product without regard to their own financial well being, but rather to emphasize that until the first three motivations are met, financial gain is insufficient justification for professional action.

In order for prescription drugs to be used on a dairy, State law, AMDUCA regulations and good medical practice would dictate that a veterinarian should have sufficient understanding of the dairy's operation, the reasons for the drugs use, and the steps that will be taken to protect the food supply so that they can reasonably be assured that in practical application the drugs will be used properly, in short, a "Veterinary / Client / Patient Relationship" (VCPR). The rules laid out by AMDUCA define this relationship, but leave many issues open for interpretation and potential abuse. While AMDUCA's definition serves as the minimum legal basis for prescription and extra-label drug use in food animal production, the goal here is to lay out templates that more clearly define what behaviors by the veterinary practitioner would both satisfy the letter of the law and set a quality standard of service to the client and the consumer. Those "best practices" actions will be different depending on the drug(s), their intended use, and the circumstances on the individual dairy.

In a "best practices" context, it does not seem reasonable for a veterinarian to assume there is a valid VCPR for all areas of the dairy when their working knowledge is limited to only particular areas. Even when the practitioner is the only veterinarian serving the client, knowledge of the dairy with respect to reproduction does not necessarily confer a VCPR with respect to clinical mastitis. Thus the veterinarian should deliberately seek to understand the status and practices and clinical issues of the particular dairy in each area where drugs might be prescribed. These areas might separately include:

- Reproduction
- Mastitis
- Clinical disease therapy: metabolic, respiratory, and gastrointestinal disease in adult cows
- Calfhood disease (esp. diarrhea and pneumonia)

A VCPR should legitimately extend to the veterinarian's practice in the topic area being considered. Thus if one member of the practice has done the work necessary to establish a valid VCPR in reproduction with the dairy, then the practice can reasonably prescribe drugs for the dairy's reproductive program under the limits set by that veterinarian.

A VCPR does not extend without limit into the future based on an initial contact with the dairy. Dairies are forever changing and circumstances (both biologic and economic) may require that the dairy modify its approach to clinical and managerial problems. If those changes involve the use of prescription or extra-label drugs, then the veterinarian must re-evaluate their recommendations and the herd's status on a regular basis to maintain a valid VCPR. The frequency may be different for different areas. For example for reproduction and mastitis, evaluation at quarterly intervals would be required to adequately respond to changing conditions. Parasite control programs, however, might be well served by annual evaluation and planning.

Fundamentally, there two broad categories of drug **use** on dairies:

1. Management drugs: drugs used as a routine part of the management of the management system, not to respond to ill health. Examples might include prostaglandin or GNRH for reproductive synchronization programs or vitamin E / selenium products used in dry cows.
2. Therapeutic drugs: drugs targeted at the treatment or prevention of disease. This would include antibiotics, anti-inflammatory compounds, steroids, calcium products, etc.

The drug itself does not necessarily determine its category, although some drugs tend to fall predominantly on one side or the other. Prostaglandin to treat uterine infection is a therapeutic application; prostaglandin to synchronize heifers is a management application. Other drugs seem to blur the distinction in the other direction. Dry cow antibiotic tubes are obviously meant to deal with disease, but seem to fit better as a routine management use than a deliberate therapeutic use. The distinction is important because the role and responsibility of the veterinarian may be different for management use of drugs and therapeutic use.

For a valid VCPR and best practices for management use of drugs, the veterinarian should probably focus on the herd's policies, status, record keeping system, and the protocols in place for the drug's use and proper withdrawal.

For therapeutic drug use, the veterinarian should probably emphasize how the condition to be treated will be diagnosed and by whom, protocols for therapy, proper identification of the treated animal(s) and systems for meat and milk withdrawal.

In neither case can the veterinarian assure best practice guidelines without regular presence on the dairy. This means not only conversations with the dairyman, but also thorough personal observation of the facilities, the cows, and the work systems in place.

In addition to the way a drug is used, other dimensions will influence what it means to be doing "best practice". The degree of risk for drug residues, the difficulty of making a distinct diagnosis, the difficulty of using the drug and its risk to the patient must be considered. Drugs for use in clinical mastitis can probably be prescribed for most dairies based on protocols even when the veterinarian does not examine the individual sick cow. Protocols for treating abomasal ulcers probably cannot be developed, since it is not likely that the dairyman can accurately make the diagnosis.

Practical Implementation of the Proposed "Best Practices" Model

The proposed "best practices" model needs to be implemented in daily practice. While the model requires some additional effort by both the veterinarian and the dairyman, it should not place an unreasonable economic burden or logistic effort on either party. It should satisfy the legal requirements for record keeping and documentation of a legitimate VCPR. There is a diagram at the end of this document that illustrates the flow of effort proposed.

One model for implementing this "best practices" approach would be:

1. The veterinarian and the dairyman would work together to examine the farm's records in the management area, including computer and farm records, animal and facilities examinations, and relevant laboratory data.

2. Once the data required for a VCPR are assembled, the veterinarian and dairyman / employees would discuss the protocols for proper drug use within the management area to be sure that the people who would administer the drugs would know under what indications the drugs were to be used, the dose, the route, any warnings or contraindications, and the proper withdrawal times for both milk and meat.
    - *These described protocols for proper drug use would be provided to the dairy in writing. Templates for these uses would be developed by the MVMA in partnership with the College of Veterinary Medicine and be made available to practicing veterinarians via the web.*
    - *For each drug specified by the veterinarian, a drug use sheet could be provided that detailed the specifics about the drug and its use that would be needed by farm personnel. Templates for these uses would be developed by the MVMA in partnership with the College of Veterinary Medicine and be made available to practicing veterinarians via the web.*

3. The veterinarian would then write a prescription for each drug specified in a protocol, including the time limit for the prescription and a limit of quantity for the drug that could be dispensed under the prescription. This prescription would be kept on file in the practice. A tracking form would be printed on the back of the back of the prescription.
    - *For each drug specified by the veterinarian, a prescription template could be used to produce the template. The spreadsheet could use data from the farm (type of use, herd size, doses per bottle, etc.) and prepare an estimate of the use for the period covered by the prescription. This estimate could be used to specify the limits on quantity of the drug that could be dispensed under the prescription.*

Spreadsheet templates for these uses would be developed by the MVMA in partnership with the College of Veterinary Medicine and be made available to practicing veterinarians via the web.

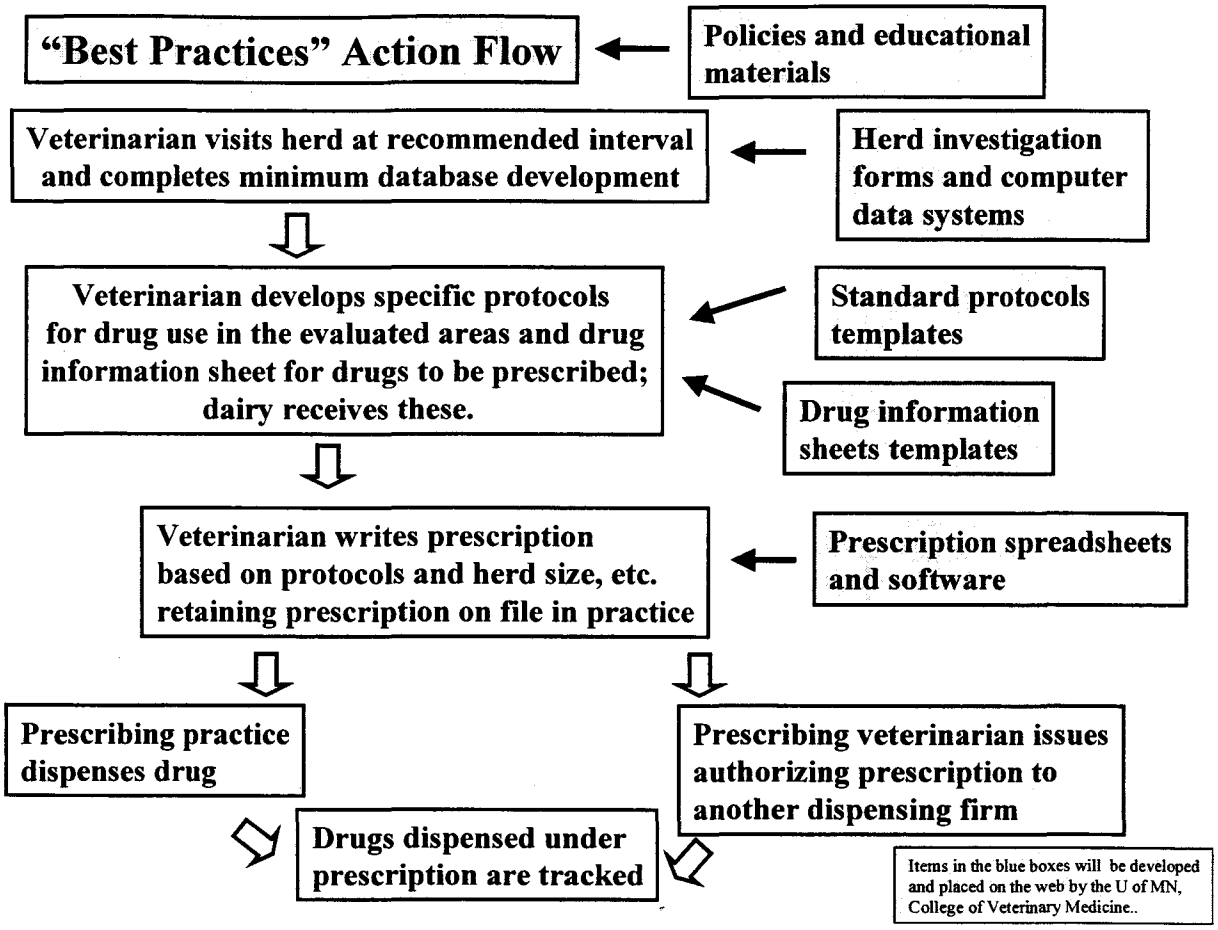
4. As the dairy purchases the prescribed drug, a running tally would be kept of the amount dispensed. If the dairy chooses to purchase drug from another vendor under the prescription, the practice would send (fax) them a prescription authorizing them to dispense a specific quantity of the drug within a limited time frame. These authorizations for dispensing would also be recorded on the back of the original prescription on file at the practice. Lay staff could dispense drugs from the practice to the client up to the limits of the prescription without further involvement by a veterinarian. If the veterinarian dispenses quantities of the drug from the truck during a herd visit, these should also be recorded on the back of the original prescription. This would involve the lay staff scanning the call charge sheets from the practitioner for dispensed quantities of drugs. It would probably be useful for the practitioner to make a note such as "on prescription" next to these sorts of dispensing items on their call charge sheets.

These steps would require that the practice create a file for every farm with which they have a VCPR. Computer files available on the web with templates for farm data collection records, protocols, drug sheets, and prescription spreadsheets would ease the burden of creating the necessary paper records and client information. The system would not require a computer to track drug use by the client to monitor for appropriate quantity of drug use. The veterinarian could consult the paper records at will, and lay staff could alert the veterinarian if the volume of use seemed inconsistent with the prescription. The prescribing veterinarian would not need to be available for colleagues to see what drugs have been prescribed for the dairy, for what indications, and in what quantities.

None of these procedures would have any bearing on drugs dispensed on the farm to treat conditions specifically examined by the veterinarian at the time of their visit.

The process of herd data collection, client education, prescription development, record keeping would probably take 1 to 3 hours about every three months. This is a legitimate veterinary professional effort and the client should be charged for the veterinarian's time and expenses. Assuming a gross charge of $100 per hour, 3 hours * 4 times per year, the cost to the dairy would be $1,200 per year. Some of this total would offset efforts already undertaken by the veterinarian on the dairy, while some would be additional efforts. For a 50 cow dairy, this would increase their medical expenses per cow a maximum of $24 per year, probably less. These expenses are an unavoidable part of complying with the regulations under AMDUCA.

The process could not be implemented across all management areas and all dairies at once. The practice should probably develop a plan to work toward full implementation over the course of a year. The practice might pick one area at a time to implement, for example mastitis, then reproduction, then calf disease, etc. They could combine specific work with individual dairies with client education programs for more general presentations and education. Once the initial evaluation of a dairy was completed, quarterly reviews and renewals would take less time.


"Best Practices" Action Flow
Policies and educational materials
Veterinarian visits herd at recommended interval and completes minimum database development
Herd investigation forms and computer data systems
Veterinarian develops specific protocols for drug use in the evaluated areas and drug information sheet for drugs to be prescribed; dairy receives these.
Standard protocols templates
Drug information sheets templates
Veterinarian writes prescription based on protocols and herd size, etc. retaining prescription on file in practice
Prescription spreadsheets and software
Prescribing practice dispenses drug
Prescribing veterinarian issues authorizing prescription to another dispensing firm
Drugs dispensed under prescription are tracked
Items in the blue boxes will be developed and placed on the web by the U of MN, College of Veterinary Medicine..