

Designing protocols/SOPs and monitoring for implementation

David A. Rhoda, DVM

311 S. 3rd Street, Evansville, WI 53536

Key words: dairy, food armor, treatment protocols

The VCPR is the Foundation to Build the Rest Upon

A dairy's first step in establishing protocols and standard operating procedures (SOPs) for use by the on-farm personnel is naming a Veterinarian of Record (VOR). This veterinarian will fulfill the responsibilities which are clearly defined in the AABP VCPR Guidelines. If you haven't read these guidelines recently I encourage you to go to the AABP website to review the VOR's responsibilities along with the responsibilities of supporting veterinarians who do not hold the VOR role. If you are serving food animal farms, it is time to decide which role you will serve.

The second needed step is making certain that everyone involved in the VCPR team communicates clearly and knows the expectations when discussing protocols and SOPs. The title of this presentation as shown was the title proposed by the AABP program committee, and I let it stand because it highlights the lack of clear communication, which in turn creates a bottleneck to the field implementation of written protocols. This type of bottleneck occurs because people do not share a standard definition of what they mean when they use the words "protocol" and "SOP". As our herds have gotten larger, the number of people represented in the VCPR team has also gotten larger, therefore our attention to clear communication has gotten increasingly more significant.

The title as proposed by the program committee represents the mindset that protocols and SOPs are a pair, not 2 individual tasks we should accomplish independent of each other. The Food Armor® program is a Hazard Analysis and Critical Control Points (HACCP) for proper drug use and was developed as 6 separate sections to address the mindset that these 2 are not a pair. The 6 sections in Food Armor® are: VCPR (Veterinarian-Client-Patient-Relationship), Drug List, Protocols, SOPs, Records, and Oversight. Protocols and SOPs are defined individually and their development done separately. The people (VCPR) and the drugs used by those people are where drug residue risks and the risk of inappropriate drug usage occur. The control points for these risks include the development of protocols and SOPs for use by the VCPR team. Verifying the implementation of the HACCP plan allows for transparency and accountability through records review and regular oversight of the treatments delivered.

The Food Armor® committee has been steadfast in defining what the difference is between these 2; developing protocols independently from SOPs because of our experi-

ence with the difficulty in finding a common definition on farms. Make no mistake, we have full recognition and also expect there will be merging of protocols and SOPs when these plans are developed cow-side and while training personnel in their application. I'd encourage you to go back and note the emphasis placed on the VOR role in Food Armor® program. Clear communication must be the cornerstone of the VCPR team's success. In order to be clear in our definitions, we define the word "protocol" as developing the 4 parts of "what to do" while the SOP is about deciding "how to do it" and "who" is responsible for the job. When we are describing training for the SOPs we recognize that the attitude, previous experience, and the educational goals of the student will all factor into individual lesson development.

So What is the Difference?

A protocol is the "what to do" in a specific situation and includes 4 parts:

- 1) Precisely define a common condition we are expecting will occur and be treated in our name
- 2) Precisely define the drug usage the VOR authorizes in his/her name (dose, route, duration, etc.)
- 3) Precisely define what records to keep when a condition is identified and a protocol is used
- 4) Precisely define the food safety information that matches the treatment prescribed

An SOP is "how to do" that specific task:

- 1) It defines what people are involved and their individual responsibilities
- 2) It contains as many steps and words as are required for clarity and consistency to do the job

Food Armor® has been equally adamant that the protocols and SOPs must be specific to the dairy and that no universal template exists that is adequate, regardless of the expertise or business motivations of whoever wrote it, because each dairy is unique in the people involved, in the drugs the dairy chooses to use, in the condition definitions shared by the personnel, in the records plan used by the dairy, in the dairy's expectations for effective therapy, and in the level of training previously achieved by personnel. Food Armor® does have materials that can aid in the process but there are no shortcuts that can replace communication between the student and teacher ensuring all lessons are understood and can practically be applied. In the previous VOR discussion the most significant point of determining who will play the role as VOR is identifying who wants to remain in the student role

and apply what they have learned vs who is willing to teach others what they have learned.

Previously we identified the people involved in the VCPR team as being a hazard on the farm; something that has not been completely accurate in my experience. Only unethical people are a true hazard, ethical people are only hazards if their level of training and understanding of the process needs improvement. The lesson plans developed for training personnel on proper implementation of a protocol have the 4 parts of the protocol definition, but also address the SOPs that cover the variability in technical skills of the people involved.

As bovine veterinarians, we have a responsibility as individuals to serve our clients and to also address society's expectations about the use of drugs in food animals. Certainly, I don't need to verbalize the strengths, deficits, politics, and misconceptions in the general population regarding the comprehension of appropriate drug usage. In actuality it is usually easy to find opportunities to find value in assuring appropriate drug use at each and every dairy.

Certainly the VOR has opinions about what the protocols should be, and equally as certain is the fact that other veterinarians involved are not always going to agree with the specifics proposed in some protocols. The VOR is the individual assuming the responsibility for protocols to be used in his/her name in his/her absence, and therefore holds the responsibility of writing them and overseeing their use. With that being said, we should never understate the power and subsequent value to the dairy of allowing these differences in opinion within the VCPR team to be resolved for the benefit of the farm's specific plan. From the practical standpoint of building relationships with people, it serves us well to remember that our first obligation is to have the protocol address what needs to be done for the animal. However, we need to remember to also include what the owner wants, as long as it does not have a detrimental effect and we maintain consistency of treatment. If an add-on increases the cost, does no harm, and is wanted by either the people paying the bills or those doing the work, I'm satisfied as long as everyone understands the decision, supports it, and we achieve consistency of therapy.

The "What"

The 4 parts of a protocol are listed above, but before we continue let's describe what a protocol actually means to the VOR and the dairy. Protocols are simply the VOR leaving instructions about common, easily defined conditions that the VOR expects to see on the dairy which include detailed plans about what to do when these conditions are recognized. The VOR is empowering farm personnel to treat in his/her name in his/her absence. The AABP has written excellent guidelines defining both the VCPR and VOR, and now the ball is our court as we carry out these actions 1 dairy at a time. Food Armor® is simply an action plan for accomplishing

these tasks on an individual farm in an organized manner, with the option of certification and third party verification.

A bottleneck we often create for ourselves when writing protocols is the thought that we need to write a doctorate thesis that encompasses everything we know might happen in our absence. Our goal should remain to simply start and remain focused on defined conditions that can be treated with label therapies. The Animal Medical Drug Usage Clarification Act (AMDUCA), as presented to us back in the 90's, came with the expectation that extra-label drug use should be the exception, not the rule. Experience has taught us that identifying and defining common conditions, which are treatable with label drug use, has been very effective allowing us to automatically accomplish the objectives set forth through AMDUCA. Our first step in protocol development is to start with the treatment plans already being used on a dairy and either justify any extra-label drug usage currently being used through the AMDUCA algorithm or, if not justifiable, adjust the protocols to include appropriate drug use.

The discussions brought forth when developing protocols often bring us to another bottleneck which always seems to appear. A question is usually raised about the rare, desperately sick, life-threatening animal as part of the condition we are addressing, which in turn diverts focus away from the common case presentation we really want to address. Expect that this will happen and set these questions aside to address at a future time, which you can do after you are satisfied everyone is on the same page with the common condition definitions. Ultimately those difficult questions will need to be addressed and some less commonly occurring conditions will need to be dealt with. In those situations, the VOR can still clearly define these cases and in turn, want to empower either the entire team or an individual on the VCPR team to address these cases in their absence. This is the point in the discussion where the skills and motivation of the students come into play. Oversight of the implementation and usage of the farm's protocols quickly reveals current levels of employee understanding, highlighting the personnel capable of advanced training to address more challenging, less common conditions.

As defined, we need only 4 pieces; condition definition, detailed therapy, appropriate records to keep for transparency and accountability and specific withdrawal times required, to match the drug usage prescribed. As the VOR gains confidence in the competency and compliance for the more commonly used protocols, it then allows for the development of protocols for less commonly occurring conditions. We need to remember that we want to make as few protocols as possible to get the job done.

The "How"

The Standard Operating Procedures are prepared separately from protocols because we easily could write a textbook if we were going to consider writing the SOPs for

the management and health care plan addressing the questions of who and how. There is nothing wrong with writing a textbook other than the fact they don't get read except by the most serious of students. We must ask ourselves, are we dealing with a novice or experienced person? Does the experienced person have 20 years of experience or 1 year of experience 20 times? Is the person seeking the next level of knowledge or getting to the next payday? Considering our protocol writing, are we focused on bugs and drugs or rather identifying management deficits?

The goal in protocol development is to establish an atmosphere of consistency of therapy. The objective of developing SOPs is to ensure consistency of care and competency in health care management. This includes consistent early detection of disease, examinations that achieve condition definition satisfaction, and a recording of data that demonstrates understanding of the health care plan.

There are multiple styles and guidelines for writing SOPs such as simple steps, hierarchical steps, graphic format, or flow charts. The choice is between you and the personnel following the SOPs. The final consideration is the depth of detail to put into the SOP, because ultimately we are mixing protocols and SOPs into the lesson plans for teaching, and these are tailored to the personnel and your satisfaction as VOR that it can be used in your absence.

Involvement in the writing of SOPs also focuses the VOR on the care package offered to the animals through not only the medical SOPs, but also in the care SOPs that accomplish the management of the animal. For the calf, this is managing the 5 C's of colostrum management: Calories fed, Cleanliness provided, Comfort, and Consistency of Care. The objective for the VOR is to progress from clinical medicine to production medicine. My simplistic definition of production medicine is expanding from a "bugs and drugs" attitude to the inclusion of management deficits as a part of the health care plan's diagnostic responsibility.

Oversight Needs Records And Creates Teachable Moments

Now, since we have addressed the development of protocols and SOPs, that only leaves us to monitor the implementation of the process by deciding what needs to be recorded when a protocol is used. Having transparency and accountability for our critics about our drug usage is simply a matter of including in the records information that demonstrates competency, consistency, and documentation of the care given. Expect there will be push back when accomplishing all that the FDA expects in our daily records log and establish an individual animal medical history which will satisfy you, as the VOR, that drugs are being used in an appropriate manner. Experience will teach you that when you utilize these records for the benefit of animal treatment (by monitoring dosages, routes, durations of treatment, consistency of detection, examinations, and prevention of food safety issues for the dairy) the push back will be neutralized by the value added for those doing the work.

There also seems to be no better time to build the relationship amongst VCPR members than finding hidden teachable moments regarding individual animal care that in turn support the training of the frontline care and health providers of our food animals. The most productive teaching happens with 1-on-1 mentoring within the VCPR team. To this end, the most rewarding perk is being taught ourselves rather than teaching others.

We must be transparent

There is an urgency for us to be proactive in demonstrating transparency and accountability for how drugs are used in food animals instead of allowing fabrication of what we do by critics of our current practices. The time is now for addressing what is expected by consumers by advancing our own understanding of when drugs should be included in animal care.