

# Lessons learned about managing treatment protocols

Adlai M. Schuler, DVM, MS

Marshall Ridge Farms, State Center, IA 50247, adlai.schuler@gmail.com

## Abstract

Whenever antimicrobial use is implemented into a food production system, federal regulations require and consumers expect that antimicrobial stewardship is at the forefront of the conversation. By taking a team approach to protocol and SOP development, the dairy can leverage the veterinarian's knowledge of pathogens, antimicrobials, and regulatory requirements to construct a platform for success that ultimately reduces antimicrobial use on farm, meets regulatory requirements, and improves the case outcome for the cow in cases of mastitis.

**Key words:** dairy, mastitis, antibiotic stewardship, treatment, protocols

## Résumé

Lorsque que l'utilisation d'antimicrobiens est mise en place dans un système de production alimentaire, les règlements fédéraux exigent et les consommateurs s'attendent à ce que l'intendance responsable des antimicrobiens soit au premier plan de la conversation. En utilisant une approche par équipe pour le développement de protocoles et de procédures d'exploitation normalisées, la ferme laitière peut miser sur les connaissances du vétérinaire sur les pathogènes, les antimicrobiens et les exigences réglementaires afin de construire une plateforme vers la réussite qui va ultimement réduire l'utilisation des antimicrobiens à la ferme, satisfaire les exigences réglementaires et améliorer l'issue pour la vache dans les cas de mammite.

## Introduction

Public scrutiny of antimicrobial use in production agriculture has accelerated the need for carefully crafted, implemented, and managed treatment protocols. While a dairy may have a valid veterinarian-client-patient relationship (VCPR) and the treatment protocols may have been developed by the veterinarian of record for the farm, protocol drift still exists. Herd size, staffing challenges, changing antimicrobial use laws, and personal preference oftentimes dictate the method by which new intramammary (IMM) infections are not only identified, but also treated.

Although many different disease conditions on the dairy farm are treated using antimicrobials, none is as prevalent or as likely to have an antimicrobial utilized during the therapeutic course as mastitis.<sup>8,9,14</sup> Intramammary infections are treated at both the quarter level and systemically. Choices

for US approved IMM antimicrobials (both lactating and dry) are fairly limited, with only 4 different classes (beta-lactams, aminocourmarines, lincosamides, and macrolides), totaling 7 different compounds available.<sup>9,11</sup> Regulatory guidelines dictate,<sup>1,2,13</sup> and consumers expect, that antimicrobial use is under the guidance of a veterinarian. In addition to having treatment protocols in place, individual treatment records must not only define the condition to be treated, but also specifically state the drug, dose, route, and duration of the therapy, as well as the individual who will administer the treatment and the duration of withholds for both meat and milk.<sup>1,2,13</sup> Each 1 of these points, beginning with case identification and ending with the observation of a meat and milk discard period, provides a touchpoint where confusion may lead to protocol drift.

Several observational studies have been conducted to assess the level of veterinary involvement and/or antimicrobial use on farms in cases of mastitis<sup>5,6,7,8,9</sup> Even though mastitis has been documented as 1 of the most common diseases on a dairy farm for which a protocol could be developed, the opportunity for protocol development and implementation still exists on more than 50% of farms. The need for veterinary oversight in protocol development is further suggested by the documented occurrence of extra-label and illegal drug uses, which have been identified on farms without veterinarian-approved written mastitis treatment protocols. Farm-developed protocols, where the veterinarian was not involved, used language such as a "cocktail" and the most common illegal, extra-label drug use identified on dairy farms (sulfonamides) was in treatments utilizing systemic mastitis therapy.<sup>9,12</sup> These protocols put the dairy at excessive risk for violative residues, not to mention challenges with public perception.

Today, antimicrobial stewardship provides a unique opportunity for veterinary practices to add another revenue stream, while simultaneously bringing value to their client's business. The development of treatment protocols is a great start and veterinarians have a unique opportunity to insert themselves beyond the protocol. This practice is more commonly recognized as the development of a standard operating procedure (SOP). While SOPs have long been a standard in allied industries, they are becoming more common on dairy farms with the advent of national programs (National Dairy FARM [Farmers Assuring Responsible Management] Program and Food Armor®) that provide a framework from which a local veterinarian can reference basis files for both protocol and SOP development. While the format of an SOP may vary among operations, 3 overarching principles are considered to be the foundation of an SOP:

- Descriptive;
- Accurate;
- Clear.<sup>3</sup>

Within the herds I serve, the implementation and management of treatment protocols through SOPs has not come without significant challenges. As both a dairy veterinarian and producer, hopefully the following management case examples are able to not only improve your individual milk quality program, but also staff communication and ultimately case outcome.

### **Descriptive (Case Definition and Selection)**

The definition of mastitis is inflammation of the mammary gland, and it is clinically manifested as abnormal milk. Through a recent survey among the 18 members of our milk harvest team, I obtained 7 different “ideas” for the definition of “mastitis.” On any given day, there are 4 different languages being spoken by this milking crew: Karen, Thai, Spanish and English. The team is comprised of people who have worked for the dairy from 3 months to up to 3 years. I became acutely aware that the clinical definition of “abnormal milk” that they understood from their training lacked sufficient descriptors for correctly removing cows with clinical mastitis from the saleable pool. During a staff meeting, we frequently discussed the what and why of mastitis, but a concrete set of guidelines had never been given for when and how to pull a cow for mastitis.

Until this point, new mastitis cases entered the hospital at an acceptable rate and our bulk tank somatic cell count (BTSCC) had remained under 150,000 cells/mL. When the BTSCC began its seasonal climb, the milking staff was simply instructed to pull every clinical case for the next week. Within 24 hours, the hospital size had doubled, there were no culture plates left, and the shifts were upset with each other because every time they milked the hospital, it took so long that the next shift started late. An outbreak investigation commenced and during the course of examining cases the following morning, 33 of the 52 new cases were California Mastitis Test (CMT)-negative and ultimately came up culture-negative. All samples were submitted for *Mycoplasma* screening via polymerase chain reaction (PCR) and cultured using *Prototheca*-selective media with 100% negative results. Bringing the staff back together, a short discussion revealed that the milking team was extremely consistent about pulling grade 2 (moderate) and grade 3 (severe) cases of mastitis, but were highly variable when pulling grade 1 (mild) cases. By providing milking technicians with a more descriptive definition for grade 1 mastitis, the dairy was able to remove the correct cows from the saleable pool at the appropriate time. This ultimately allowed new cases to be enrolled in the culture-based mastitis protocol in a timelier fashion and improve overall cure risk without using unneeded antimicrobials.

### **Accurate**

Culture-based therapy has long been considered the gold standard in mastitis therapy, and targeted antimicrobial therapy via culture represents 1 of the most judicious implementations of a protocol that exists on a dairy farm today.<sup>4</sup> The 2014 dairy study published by the National Animal Health Monitoring Service noted that over 57% of farms in the United States have reported using at least some degree of milk culturing, and nearly 45% of farms culture milk from individual cows.<sup>11</sup> Culture-based therapy has been demonstrated to effectively reduce treatment cost and milk discard time without negatively influencing case outcome.<sup>4</sup> The efficacy of a culture-based program relies heavily on obtaining a quality milk sample, reading accurate results, timely reporting, and implementation of the correct therapeutic intervention. During the implementation phase of a culture-based program on our dairy, it wasn't uncommon to observe a cumulative error rate of over 35%. Misidentification of the cow and quarter, as well as contaminated samples, resulted in nearly 40% of the cultures either being completely unusable or having the treatment administered to the wrong cow. By providing daily feedback to hospital staff (e.g. <3% error rate), demonstrating how to correctly obtain an aseptic milk sample, and encouraging them to focus on the quality of their work, we were able to reduce the error rate from 35% down to a more acceptable level of 5%. Interestingly, the initial error rate prompted the beginning of a residue testing program in order to maintain milk quality and prevent violative residues from moving out the door. This also provided its own unique set of opportunities.

### **Clear (mistakes happen)**

In 2015, violative milk residues were found in less than 0.015% of tanker loads.<sup>11</sup> Almost 71% of farms reported the use of on-farm testing methods to screen milk for antimicrobial residues prior to either offering tanks for sale or returning individual cows to the saleable pool.<sup>11</sup> For a client's herd, the SOP for returning a cow to the saleable pool included taking a milk sample from all CMT-negative cows for beta-lactam screening. Approximately 2 days after the culture-based therapy program began, the herd was having difficulty getting CMT-negative cows to clear antimicrobial testing (even though no treatment record existed of them ever receiving an antimicrobial). An additional SOP for the hospital staff included the “sample” of all new clinical cases the day they entered the hospital. After culture results were obtained, cows were placed on a 5-day course of IMM ceftiofur (Spectramast LC), which was more commonly known to the staff as “spec.” An inquiry with the hospital manager about the difficulties the dairy was having getting cows to clear antibiotic testing revealed that although he could read and understand a difference between “sample” and “spec,”

he was under the impression that “sample” meant to not only take a milk sample, but also administer IMM therapy of spec; to him “spec” simply meant administration of IMM therapy. The confusion was resolved by changing the directive from sample to test.

### Conclusion

While none of the examples provided here are particularly groundbreaking from a scientific perspective, each reflects a fundamental breakdown in communication that ultimately delayed a therapeutic treatment, removed excess milk from the saleable pool, or potentially altered the ability to responsibly market the milk being produced. The next time you are in a parlor, take a minute to observe what is happening. Give some thought to how protocol implementation and execution might improve case outcome or product quality. Developing and maintaining mastitis treatment protocols and SOPs in order to achieve the best outcome for the cow is the ultimate goal. These protocols and SOPs also provide the framework for simultaneously adhering to the best practices for antimicrobial use put forth by our scientific community and helping to instill confidence in both the processor and consumer. As a result, veterinarians are in a unique position to not only develop mastitis treatment protocols, but also assess case selection, treatment implementation, and cow follow-up through targeted questions and SOP development.

### Acknowledgement

The author declares no conflict of interest.

### References

1. American Veterinary Medical Association (AVMA). Judicious use of antimicrobials for dairy cattle veterinarians. 2016.
2. Code of Federal Regulations. 21 CFR 530.5. Food and Drug Administration. April 1, 2015.

3. Isaman V, Thelin R. Standard operating procedures (SOPs): Reason for, types of, adequacy, approval, and deviations from and revisions to. *Qual Assur* 1995; 4:167-171.
4. Lago A, Godden SM, Bey R, Ruegg PL, Leslie K. The selective treatment of clinical mastitis based on on-farm culture results: I. Effects on antibiotic use, milk withholding time, and short-term clinical and bacteriological outcomes. *J Dairy Sci* 2011; 94:4441-4456.
5. Oliveira L, Ruegg PL. Treatments of clinical mastitis occurring in cows on 51 large dairy herds in Wisconsin. *J Dairy Sci* 2014; 97:5426-5436.
6. Raymond MJ, Wohrle RD, Call DR. Assessment and promotion of judicious antibiotic use on dairy farms in Washington State. *J Dairy Sci* 2006; 89:3228-3240.
7. Redding LE, Bender J, Baker L. Quantification of antibiotic use on dairy farms in Pennsylvania. *J Dairy Sci* 2019; 102:1494-1507.
8. Saini V, McClure JT, Leger D, Dufor S, Sheldon AG, Scholl DT, Barkema HW. Antimicrobial use on Canadian dairy farms. *J Dairy Sci* 2012; 95:1209-1221.
9. Schuler AM, Rice C, Gorden PJ. Survey of treatment practices on Midwest dairy farms. *Bov Pract* 2017; 51:190-199.
10. U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). *Dairy 2007, Part III: Reference of dairy cattle health and management practices in the United States, 2007*. USDA APHIS-VS, CEAH. Fort Collins, CO. #N482.0908, 2008.
11. U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). *Dairy 2014, Milk Quality, Milking Procedures, and Mastitis on U.S. Dairies, 2014*. USDA APHIS-VS, CEAH. 2016.
12. U.S. FDA (United States Food and Drug Administration). New animal drugs; cephalosporin drugs; extra-label animal drug use; order of prohibition. *Federal Register* 2012; 77:725-745.
13. U.S. FDA (United States Food and Drug Administration). Adequate drug treatment records help ensure food safety. Accessed 8/7/2019. <https://www.fda.gov/animal-veterinary/animal-health-literacy/adequate-drug-treatment-records-help-ensure-food-safety>
14. Zwald AG, Ruegg PL, Kaneene JB, Warnick LD, Wells SJ, Fossler C, Halbert LW. Management practices and reported antimicrobial usage on conventional and organic dairy farms. *J Dairy Sci* 2004; 87:191-201.