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Case Study - Use of Compounded Antibiotics for Treatment of Mastitis

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Abstract

Extralabel treatment of mastitis in dairy cows may be of questionable efficacy and legality. This study examines the extralabel use of an antibiotic mixture compounded by a veterinary clinic to treat cows for mastitis on three farms. The mixture contained penicillin, spectinomycin and dexamethasone. The literature and regulations regarding use of each of these drugs for treatment of mastitis are discussed. The requirements established by the Animal Medicinal Drug Use Clarification Act (AMDUCA) were not met. The objective of this report is to increase awareness of risks involved in extralabel use of antibiotics. Adulteration of the compounded product, and potential for drug residues in foods from animal origin, are of particular concern.

Introduction

Antibiotics are valuable tools to combat bacterial infections in the mammary gland. They are intended to kill or inhibit growth of microorganisms that cause inflammation of the mammary gland, thereby improving milk quality. The appropriate use of antibiotics is an important component of a mastitis control program.

Antibiotics are often prescribed or recommended by a veterinarian, and are available through veterinary clinics or other sources. The veterinarian plays an important role in antibiotic selection and usage on dairy farms. Veterinarians have training and knowledge of the etiology, pathophysiology and treatment of disease, and are licensed to prescribe antibiotics to patients under their care. With this, the veterinarian also assumes responsibility for protecting public health.

Rational use of antibiotics in the dairy industry includes knowledge of the most frequently isolated pathogens causing mastitis and their antimicrobial susceptibility patterns. With the privilege to prescribe drugs for use on dairy farms comes the responsibility to use licensed antibiotics as directed by the label. In 1994, the Animal Medicinal Drug Use Clarification Act (AMDUCA)[1,2] was signed into law. Effective December 9, 1996, this law allows the veterinarian to prescribe approved drugs for extralabel use under special circumstances. This report examines extralabel use of antibiotics and the interpretation of the AMDUCA.

Case Description

In September 1999, the New York State Quality Milk Promotion Services (QMPS) program was contacted by three farms having problems with yeast mastitis. Several yeast strains were cultured from multiple cows in each herd. Investigation revealed that each farm used an antibiotic mixture compounded by a veterinary clinic (to be called "Vet Mix") to treat cows for mastitis. This solution was dispensed to the producers in 500 ml (1/2 quart) bottles intended for multiple-dose use. The label contained information about the prescribing veterinarian, the drugs in the mixture, dosage instructions (25 ml per dose for 3 milkings), and milk and meat withholding times.

All three producers used a syringe with disposable teat canulas to treat cows by intramammary infusion. The syringes were not sterilized or disinfected between treatments. In all herds, a sample of the antibiotic mixture was obtained and submitted for culture. Two of the three herds did not maintain treatment records for clinical cases. In all cases, owners indicated that the Vet Mix was obtained from their veterinarian as an "over-the-counter" product.

The antibiotic mixture was used in an effort to reduce somatic cell count problems. The major concern in each herd was *Staphylococcus aureus,* which was confirmed when the cows were sampled for microbiological culture. Results of the yeast culture[3] are summarized in Table 1. On two farms, unopened bottles of Vet Mix were also sampled, neither of which were culture-positive for yeast.

The label on the Vet Mix bottles indicated that it contained penicillin, spectinomycin and dexamethasone. We were unable to determine whether the mixture contained spectinomycin sulfate or a spectinomycin hydrochloride formulation. The recommended withholding times were 4 days for milk and 30 days for slaughter.

Drug Use Rationale

The veterinarians' rationale for using compounded drugs on these dairy farms with a known history of *S. aureus* mastitis is unclear. Extralabel use of the drugs in this compounded mixture will be discussed later in this paper.

Penicillin is approved for use in lactating dairy cows and is present in a number of products currently approved for intramammary infusion. *S. aureus* strains cultured from New York dairies are reasonably sensitive to penicillin (Figure 1). The Kirby-Bauer method was used by the QMPS laboratories to evaluate sensitivities; zone diameters were evaluated using NCCLS standards as published in the M31-A document. In herds where the sensitivity patterns of the microorganisms are known, penicillin can be a rational choice for intramammary treatment, recognizing that cure rates for *S. aureus* are still low.[8,9]

Spectinomycin sulfate (an aminocyclitol antibiotic) is approved for treating bovine respiratory disease, but is not approved for female dairy cattle over 20 months of age or lactating dairy cattle. While looking for efficacy data in published literature, a search in *Medline* using the key words "spectinomycin" and "mastitis" yielded only five publications during the last 20 years. All articles indicated that a relatively high percentage of *S. aureus* strains were resistant to spectinomycin. This was in agreement with the antibiotic susceptibility testing results from *S. aureus* strains isolated from mastitis samples in New York state (see above for methods) (Figure 2). Clearly, *in-vitro* susceptibility should not be used as the single predictor for clinical efficacy, however, no published *in-vivo* efficacy studies were found either.

The combination of penicillin and aminocyclitols in the same syringe or bottle is not approved by the Food and Drug Administration (FDA), and may not be chemically compatible. Because spectinomycin is not approved for use in lactating dairy cattle, there is no information on milk withholding times on the label or in the literature. A search of the US Food Animal Residue Avoidance Databank (US-FARAD)[5] web site failed to yield any information on milk withdrawal times following intramammary infusion of spectinomycin.

Table 1. Yeast culture results from intramammary infections and from samples of opened bottles of Vet Mix obtained on the same farm.

Yeast species	Cows Infected	Vet Mix (CFU/ml)
Herd I		
Candida famata	51, 60, 63, Sarah	Present
Candida rugosa	31, 54, 63, 71, 101, 170, 277	Present
Candida lipolytica	32, 278, 291, Blackie	Not identified
Candida pseudotropicalis	29, 52, 75	Not identified
Herd II		
Candida famata	90	76,000
Candida bordinii	-	460,000
Candida lipolytica	15, 27, 41, 75, 91, 98, 129	61,800
Candida rugosa	-	600
Pichia membranaefaciens	-	400,000
Herd III		
Candida guiliermondii	-	1,440,000
Candida rugosa	36	1,600,000

Figure 1. Antibiotic sensitivity of *S.aureus* isolates to penicillin. Data from all four New York QMPS laboratories 1985 – 1999.

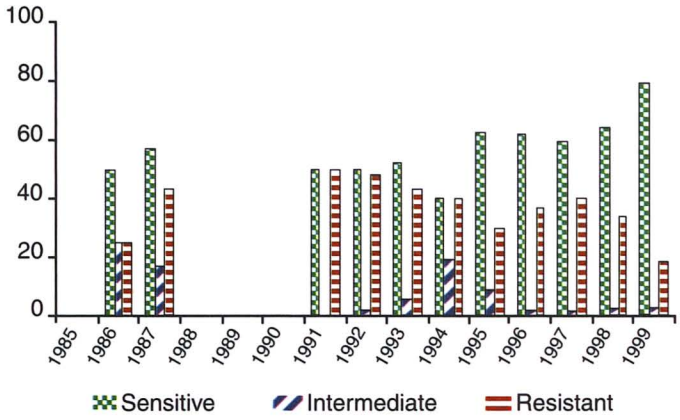
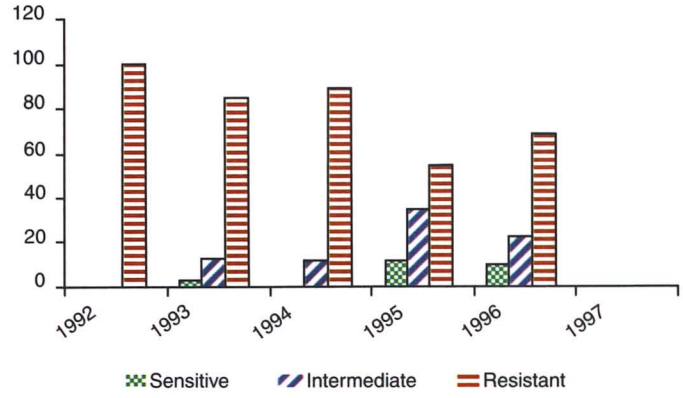


Figure 2. Antibiotic sensitivity of *S.aureus* isolates to spectinomycin. Data from all four New York QMPS laboratories 1992 – 1999.



Dexamethasone is approved for dairy cattle as an intramuscular treatment, but is not labeled for intramammary use or for treatment of mastitis. An experiment where *S. aureus* infected cows were treated parenterally with dexamethasone resulted in increased shedding of *S. aureus* and decreased milk yield. Dexamethasone usage caused profound down-regulation of adhesion molecules on neutrophils, leading to leukocytosis and, in some quarters, to clinical mastitis.[4] Dexamethasone has been reported to be effective in reducing the acute inflammatory response associated with coliform mastitis.[6]

AMDUCA Interpretation

According to the extralabel drug use algorithm compiled by the Wisconsin Veterinary Medical Association,[1] use of compounded drugs is only acceptable when:

1) There is a carefully established diagnosis;
2) A valid veterinarian-client-patient relationship is present;
3) There is no approved drug available that is labeled for the intended use and is clinically effective;
4) There is no drug available that is approved for food animals and that can be used in an extralabel manner;
5) There is no drug available that is approved for humans or non-food animals that can be used in an extralabel manner;
6) There is adequate scientific information available to determine the withdrawal time.

When extralabel drug use is the only option to treat a disease, there are specific requirements for usage, record keeping and labeling information. The drug must be used under the supervision of a veterinarian, a valid veterinary-client-patient relationship must exist, and steps must be taken to ensure that no violative drug residues occur in the milk or meat. Perhaps more importantly, the practitioner must establish that available approved products are ineffective for treating the disease condition diagnosed. The basis for proof must logically include supporting laboratory data and clinical records. Record requirements include animal identification, condition(s) treated, product(s) name and dosage(s), duration of treatment and stated withholding periods for meat and milk. Labeling requirements include name and address of the veterinarian, name of the drug(s), withholding times, and specific directions for use, including identification of the animals to be treated, dosage frequency, duration of therapy and route of administration.

There is additional guidance outlined in section 530.13 of the Federal Register regarding compounding of approved drugs.[2] This section requires that a veterinarian or pharmacist do the compounding, that there are adequate procedures and processes in place to ensure the safety and effectiveness of the compounded product, and that the scale of the compounding operation is commensurate with the established need for the compounded product.

Discussion

This study illustrates a case where many of the requirements for extralabel use of antibiotics set forth by the AMDUCA were not met. The combination of drugs used in the Vet Mix for treatment of *S. aureus* mastitis in lactating dairy cattle was questionable. Spectinomycin is not FDA approved for treatment of *S. aureus* mastitis in lactating cattle. The risk of antibiotic residues using these specific products in a compounded mixture is substantial. From our investigation

we could not determine that a specific diagnosis was made at the animal level, or that requirements for recordkeeping were met. Furthermore, there were no laboratory data or clinical records which would suggest the compounded mixture was clinically superior to available approved products.

From the available data, it appears likely that the Vet Mix bottles became contaminated with yeast on the farm. Yeast species multiplied in the bottles, and subsequently infected some cows that were treated with the drug mixture. Additionally, the compounded mixture was dispensed as an over-the-counter product.

Aside from cost to the producer associated with yeast mastitis outbreaks, there are also broader consequences. The World Health Organization (WHO) has expressed great concern over antibiotic use in farm animals.[10] This is specifically due to transmission of antibiotic resistance by pathogens from animals to humans, and the presence of antibiotic residues in foods from animal origin. The objective of this case study was to increase awareness of risks involved with extralabel drug use and compounding. These practices can result in direct liability for the veterinary profession, and also compromise the credibility of the dairy industry. When situations such as the one described in this case study occur, the ability of the veterinary profession to deal with the challenges put forward by the World Health Organization could be questioned.

Conclusions

Antibiotic use is a valuable privilege. With this privilege comes great responsibility for both dairy producers and veterinarians. It is important to continually review the rationale for use of specific antibiotics to treat food animals.[11] There is no place in the current societal and regulatory environment for extralabel antibiotic usage unless the AMDUCA stipulations are carefully met and followed. Publications are readily available to provide the veterinarian and dairy producers with guidelines on proper drug usage and residue avoidance.[1,2,5,7] This is a challenge as well as an opportunity to implement good clinical practices on dairy farms.

Footnote

We at QMPS would like to obtain input with regard to this case study. We would also be happy to provide further information on the susceptibility of commonly isolated mastitis causing microorganisms and the expected treatment success for the currently approved antibiotics.

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Veterinary Record (2000) 146, 338-341

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