

Darts to deliver medications is a serious BQA challenge

Dee Griffin, DVM, MS

Director, Veterinary Education, Research and Outreach Program, WTAMU, College of Veterinary Medicine, Texas A&M University, College Station, TX 77843; dgriffin@tamu.edu

Abstract

Bottom line ... *DON'T DO IT!* Darts for delivery of medication or vaccines to animals intended for food are not under any circumstances or in any way recommended, approved, or condoned by any veterinary organization. There is no indication from dart manufacturers that their darts met FDA and USDA required sterility requirements, and the manufacturers do not provide guidance for sterilization procedures needed to meet sterility requirements. Dart used to deliver fluoroquinolones, ceftiofur, or compounded medications (mixed or diluted other than specifically instructed on the label) is strictly illegal and considered a criminal act under the FDA Code of Federal Regulations. There is no research documenting that dart delivery of medical liquids reaches the labeled SQ or IM requirement. Not reaching the intended SQ or IM compartment eliminates all but 1 food animal medication, oxytetracycline, and there are no darts sufficient in size to accommodate the dosage requirement of the drug. Improper dosing, including under-dosing, of antibiotics can seriously risk antibiotic resistance development. Since darts do not have ballistic characteristics similar to bullets, targeting is unpredictable. This makes delivery to the neck region, the only acceptable IM or SQ injections site, inconsistent and potentially very dangerous to the animal if the cervical vertebrae are hit with a dart's needle. This concern heightens when darts are used beyond 10 yards, and there are no dart delivery charges for this distance which do not pose the potential for embedding the dart's cylinder through the animal's hide into muscle.

Key words: remote delivery darts (RDD), medication darts, drug darts

Current Usage

There seemingly is logarithmic growth in the use of darts for delivering medication in pasture settings. Reportedly Pneu-Dart company sold 4 million darts last year. That said, cattle folks when questioned most often mention Palmer Cap-Chur darts as the system they use. Additionally, Medi-Darts manufactured by a Canadian company sell medication darts in the US. With the growing adoption of darts for remote delivery of medication, undoubtedly new medication dart manufacturers will develop.

The National Cattlemen's Beef Association Beef Quality Assurance (NCBA BQA) Advisory Group developed a dart use

advisory statement. While pro-dart proponents find fault with some of the bullets listed, it is important to note that multiple phone calls and letters sent to the manufacturers from both the NCBA and the AVC starting in 2012 requesting dart use information were ignored. It is vital for efficacy information to be available and accurate for medication usage via remote-delivery. The manufacturers of other alternate medication delivery such as "needleless" systems contracted with university research groups to document the depth of penetration (SQ and/or IM) which the medication was delivered; consistency of delivering the intended volume of medication, which included medications of differing viscosity; tissue response (injection site reaction) to injections delivered by the alternate delivery system; the basic physiologic equivalency response which included Concentration Max (Cmax) and Half-Life (T1/2); and videos demonstrating the animal's response to receiving an injection from the alternate delivery system. With remote-delivery systems, such as dart delivery systems, it is critical to demonstrate the ability to deliver a medication dart safely to the BQA injection triangle located on cattle necks, and a dart's ability to consistently deliver an intended volume of medication at an intended SQ or IM route of administration required by the FDA. The final paragraph in the NCBA advisory statement includes the information requested. This paragraph summarizes critical issues with medication dart usage.

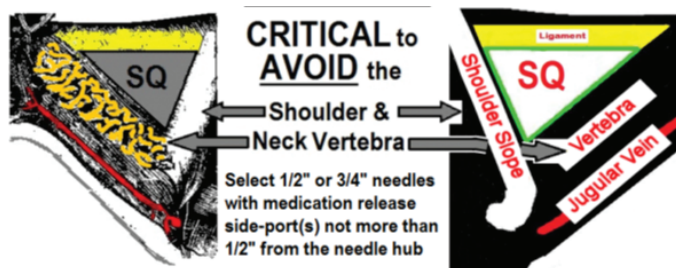
MOST IMPORTANT: It is important to reaffirm the importance of following BQA guidelines for medication use.

In situations in which remote delivery of medication must be used, it should comply with the National BQA Guidelines for injection site selection (Figures 1 and 2), routes of administration, needle selection, medication selection, medication volumes, keeping proper medication use records, and actions required should a broken needle leave metal in the animal.

Besides reaffirming the importance of following BQA guidelines for injectable medication use, there are several pragmatic cautionary statements that should be considered for inclusion in the discussion.

Specific Points of Concern

- The Palmer Cap-Chur manufacturer has refused all communication attempts by veterinary and cattle organizations.
- The Pneu-Dart and Medi-Dart manufacturers have communicated with veterinary and cattle organiza-



Figures 1 and 2. National BQA Guidelines for injection site selection.

tions; however, their darts do not comply with FDA medication use requirements or BQA medication use requirements.

- There are confirmed reports of darts and/or dart components being found in carcasses at packing plants. Adulteration of food by metal violates food safety regulations and is prosecutable.
- There are confirmed reports of injection site abscesses from medication dart usage. These are likely caused by using unsterile darts and/or contamination while filling the dart with medication. Confirmed fatal cases of phlegmonous cellulitis have occurred from contaminated needles.
- There are confirmed reports of violative drug residues being traced to medication dart usage.
- The FDA regulates the approval of routes of administration of all animal drugs. Dart delivery falls under the FDA AMDUCA regulations and therefore all drugs used in medication darts require a valid veterinary client-patient relationship with a licensed veterinarian. These regulations require the use, including route of administration, of all prescription medications to strictly follow the written directions of the veterinarian prescribing the drugs. Without these written instructions, the use of medications in darts is illegal.
- There is no indication the FDA has approved for human consumption the dart retention collar intended to remain in the animal. Having an unapproved implant in tissue for consumption creates a potentially serious, if not criminal, violation of the FDA Code of Federal Regulations.
- Overpowering the dart delivery charge can easily implant the body of the dart through the animal's hide and leave the dart embedded in the animal's muscle. Embedded darts are routinely recovered during carcass fabrication.
- Ballistic tests at the University of Nebraska-Lincoln Great Plains Veterinary Education Center (UNL-GPVEC) with both of the common systems in use (Pneu-Dart and Cap-Chur) using a scoped rifle clamped in a sighting stand demonstrated targeting at 20 yards and beyond failed to keep the darts

delivery within a 6-inch (15 cm) target, therefore the ability to target a 6-inch (15 cm) BQA injection site triangle would be unlikely. In these tests, medication darts failed to deliver the full dose contained in the dart in over 10% of the darts fired. Additionally, the tests indicate charges larger than the green charge in 22-caliber dart rifles should not be used to deliver a medication dart within 20 yards (18 m) of cattle. Within 20 yards (18 m), yellow, red, and black charges are not acceptable.

- Medication darts have horrible flight predictability. UNL-GPVEC tests with a scoped medication dart rifle in a gun vice target at 20 yards (18 m) had a precision of 6 inches (15 cm). When the medication viscosity was changed, the hold on the target changed. When darts were not completely filled, the precision degenerated between 4 to 6 inches (10-15 cm), meaning the darts had a 10 to 12 inch (25 to 30 cm) spread at 20 yards (18 m).
- There are reports of cattle being injured by darts that hit their head, fractured shoulder blades, and of spinal damage from darts hitting cervical neck vertebrae.
- Targeting areas other than the BQA injection site triangle, such as the rear leg, is never acceptable!
- There are reports of cattle becoming so "gun shy" that the entire group became difficult to handle. Some cattle will react wildly with exaggerated movement following darting, trying to shake the dart from their body.

Additional Points

1. Proponents of dart usage to deliver medication often cite animal welfare concerns as justification. However, a dart manufacturer's Internet site indicates the company targets not only usage on grazing cattle, but on confined feeder cattle as well. This is especially concerning, as confinement facilities are designed to allow for proper medication use in an efficient, low-stress manner. Only in very rare emergency situations would dart usage be acceptable in a confinement setting.
2. Medication dart manufacturers continue to ignore repeated requests to responsibly supply efficacy of their systems to deliver the intended volume of medication and to consistently deliver low-velocity medication darts within a 6-inch (15 cm) BQA injection site triangle on cattle necks.
3. Safety to humans and animals is critical, therefore never use a medication in a dart that could cause death or severe tissue damage when injected. Examples include tilmicosin, flunixin, and 300 mg/mL oxytetracycline.
4. Only select remote medication delivery when mov-

- ing an animal to a proper treatment facility that offers adequate restraint is not possible.
5. Never use a medication protocol that requires more than 1 dart to deliver the needed treatment medication. If the animal is so sick as to require multiple drugs, it should be taken to a treatment facility so that proper examination and restraint can be provided.
 6. Darts should never be used unless the animal's health and wellbeing are in jeopardy. Therefore, convenience should never be a consideration when making the decision to use remote medication delivery.
 7. Never attempt to dart a moving animal with a treatment medication.
 8. Darts should never be used for delivery of vaccines or other products not intended to address the animal's immediate health and wellbeing.
 9. Dart delivery should be as close to the animal as practical. Five to 10 yards (4.6 to 9.1 m) if possible, but never farther than 20 yards (18 m).
 10. Use the lowest-powered delivery charge that will allow the dart to reach the animal. For this reason, pneumatic dart delivery guns such as CO2 or pump-up pistols and rifles may be more appropriate than rifles that use 22-caliber charges.
 11. To help avoid using an inappropriate charge size, purchase multiple magazines so that different size charges can be readily available for dart systems that require different size charges for different distances.
 12. Never use dart delivery charges that are not provided by the dart system manufacturer. Never use charges designed for nail guns in medication dart delivery guns.
 13. Improve sighting of the medication dart delivery guns. Example, adding a Red Dot scope.
 14. Maintenance of dart delivery systems is critical.
 15. Dart system usage training and non-animal target sighting and practice are critical. Additionally, re-sighting with practice darts is critical before animal health episodes that may require remote medication deliver.
 16. Cleanliness and sterility of darts is critical!!! Re-fillable darts must be thoroughly cleaned just as reusable syringes are cleaned with hot water, not using soap or disinfectants, and a final sanitizing with boiling water.
 17. The size of the dart selected must match the volume of the medication to be delivered. Partially filled darts have an erratic flight pattern, therefore targeting is not dependable. Currently dart manufacturers do not label the size of the darts they sell, so it is important for dart users to keep the different sizes separate.
 18. Never mix medication in the same dart and never add liquid fillers to completely fill the dart medication chamber ... select the proper size dart.
 19. Never select darts that will hold more than 10 mL of medication.
 20. Never select a medication that will require more than 10 mL to effectively treat the animal.
 21. There are not any over-the-counter antibiotics available that are appropriate for dart use consideration! Therefore, all medications being delivered via dart will require a veterinary prescription. Medications that can be used as a single dart delivery should be selected by the veterinarian prescribing the medication to be used in the dart.
 22. Only ½ inch and ¾ inch dart needles 16-gauge or larger should be selected. Both Pneu-Dart and Cap-Chur darts make dart needles available in 14-gauge stainless steel material which should help avoid needle breakage. Additionally, they have darts with needles available that are ¾ inch or less. Their ¾ inch dart needles are offered with side port (holes) delivery of medication. These side ports should help with the medication being delivered SQ. To better obtain a SQ injection, the ¾ inch needles should utilize medication expelling ports located on the side of the needles.
 23. It is important to know cattle skin is typically ¼ inch to 3/8 inch thick, therefore even ½ inch dart needles will potentially deliver part of the medication IM. Never use dart needles longer than ¾ inch. Never use barbed dart needles.
 24. Only select medications that are labeled for both SQ and IM use, as delivery for either SQ or IM is not dependable. Medications that are not approved for use as either SQ or IM in the neck region, such as Excede which is approved only for injection at the base of the ear or flunixin which is approved only for IV injection, are never acceptable.
 25. There is a potential to deposit medications in damaged muscle, which can result in the need for an extended withdrawal time. The dart's impact when it hits an animal is sufficient to cause the dart's medication charge to ignite and propel the medication into the animal. This level of impact has the potential to damage muscle.
 26. Federal regulations require medication use records be kept that include the date, animal ID (minimum is their description and group), name of medication used, amount of medication used, and assigned withdrawal (the withdrawal can be applied to the entire group based on the last animal treated in the group).
 27. Dart users should make a serious attempt to recover all spent darts! Serious injury to cattle, horses, or especially humans could occur if a spent dart is

stepped on. When possible, select darts that the manufacturer has painted safety orange or safety lime green to make them easier to find following use.

28. Follow all safe gun use rules, such as keeping the safety on until ready to fire, always point in a safe direction, know your target, know what's beyond your target, etc.

Table 1. Restrictions that may preclude various drugs being delivered by remote delivery devices.

Trade	Proprietary	Use	Dose/CWT	Route	Duration	WD	Comments
Advocin	danofloxacin	antibiotic	1.5 to 2	SQ	Multiday	4	ELDU is illegal and labeled for BRD only
Baytril	enrofloxacin	antibiotic	1.1 to 2.3 3.4 to 5.7	SQ	Single or Multi-day	28	ELDU is illegal and labeled for BRD only
Banamine	flunixin mg/ml	NASID	1	IV	Single-day	60+	SQ or IM causes extreme pain & tissue damage
Draxxin	tulathromycin	antibiotic	1.1	SQ	Multi-day	18	Dart SQ delivery not dependable, IM use is illegal
Excede	ceftiofur	antibiotic	1.5	SQ Ear	Multi-day	13	Injections other than ear SQ is illegal
Excenel	ceftiofur	antibiotic	1 to 2	SQ or IM	Single-day	4	ELDU is illegal
Micotil	tilmicosin	antibiotic	1.5	SQ	Multi-day	42	Serious SAFETY & tissue damage concerns
Naxcel	ceftiofur	antibiotic	1 to 2	SQ or IM	Single-day	4	ELDU is illegal
Nuflor	florfenicol	antibiotic	3 to 6	SQ	Multi-day	44	Dose too large for dart use
Pen G	PPG	antibiotic	1 to 4	IM	Single-day	30+	Serious residue issues
Polyflex	ampicillin	antibiotic	0.5 to 1.25	IM	Less <day	6	Needs 4 + treatments per day
Resflor	florfenicol + flunixin	antibiotic	6	SQ	Multi-day	38	Dose too large and too thick for dart use
Zactran	gamithromycin	antibiotic	1.8	SQ	Multi-day	35	Dart SQ delivery not dependable, IM use is illegal
Zuprevo	tildipirosin	antibiotic	1	SQ	Multi-day	21	Dart SQ delivery not dependable, IM use is illegal

Appendix

BQA Advisory Statement Regarding the Use of Pneumatic Darts or Other Remote

Injection Methods in Cattle

NCBA BQA Advisory Board, June 2015

BQA Guidelines for the administration of injectable drugs/products to cattle are available in the BQA National Manual and at bqa.org and other places.

There are no BQA guidelines for the administration of injectable drugs/products by the use of pneumatic darts or other similar methods designed to administer injectable products into cattle from a distance.

There are several challenges associated with the use of pneumatic darts or similar technologies for the administration of injectable drugs/products to cattle, including but not limited to the following:

1. Accurate assessment of cattle weights is not possible in these situations, leading to inaccurate dosing. Under dosing of antibiotics promotes an increase in antimicrobial resistance. Over dosing unnecessarily increases the costs of production and may increase withdrawal times.
2. The volume of many appropriate drug dosages cannot be accommodated with the current dart technology.
3. The product delivery can be administered to non-approved injection site(s) resulting in off-label or illegal drug use. This would include the subcutaneous administration of an intramuscular drug or vice versa.
4. The potential for significant bruising or collateral injection site lesions is directly in conflict with BQA guidelines and principles. Additionally, accurate individual identification becomes much more challenging, leading to mis-identification, inaccurate withdrawal time assignment, increased potential for illegal residues, and/or managing a group of cattle based on the withdrawal time of a single unidentified animal.
5. The needles' potential to penetrate ligaments, joints and other tissues could result in permanent damage to the cattle, raising concerns for animal well-being and additionally, result in ineffective therapy.
6. Injection(s) administered beyond label directions without a veterinarian's approval and prescription is considered an extra label drug use (via method of administration) and may be out of compliance with FDA regulations.
7. The possibility of needles remaining in the tissue following this type of administration presents an additional risk. Darts that remain attached to the animal for a period of time and subsequently become dislodged in the field or pasture can become a hazard to other livestock or personnel.
8. The entire dart can become imbedded in muscle tissue and create a significant BQA issue at the packing plant or at the consumer level if not identified at the packing plant.
9. Experiences with the use of darts in cervid production indicate that "gut shots", broken limbs, darting the wrong animal, establishing the correct animal ID for drug withdrawal records, and other problems are commonplace and do not conform to BQA guidelines for food animal production.
10. The potential for illegal compounding of drugs is probable with these methods.
11. In the process of trying to target the injection triangle in the neck, it becomes more likely for the dart to strike sensitive tissue in the head, such as the eye or cranial nerves.
12. Some antibiotic compounds have significant human health impacts if accidentally injected into people. An accidental occurrence of an injection into a human could result in death.
13. The cylinder of the delivery dart, where the antibiotic or other injectable product is placed, can become contaminated by bacteria. This can promote antimicrobial resistance as well as infections/abscesses at the site of injection.

Companies manufacturing, selling and promoting these methods of drug and product delivery have the responsibility and the obligation to develop data to establish efficacy, safety, animal welfare, food safety, and other concerns as compared to current BQA approved methods of drug/product administration. It is also possible that FDA approval may be required for drug delivery by these methods of injecting drugs/products and that issue needs to be addressed by the manufacturers. Until such time as this critical data becomes available these methods do not meet BQA injectable product administration guidelines.