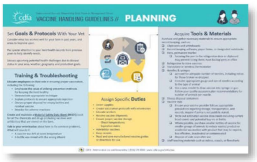
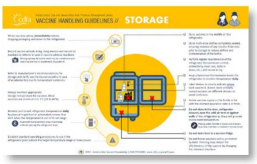
VACCINE HANDLING GUIDELINES // VETERINARY RESOURCES

PLANNING



TRANSPORTATION

STORAGE

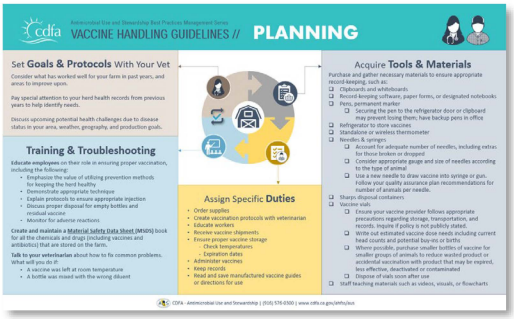


PREPARATION & ADMINISTRATION

FOLLOW-UP, MONITORING & RECORDS

This section is designed to provide additional considerations for veterinarians when setting Standard Operating Procedures (SOPs) for vaccine protocols on-farm and evaluating their own best practices. It contains additional background to support veterinary consults through in-depth information-and resources to supplement the recommendations covered in the Vaccine Handling Guidelines infographics.

PLANNING



- ❑ **Work with producers to set vaccination goals and protocols** based on their farm's needs.
  - ❑ Consider how weather, geography, past herd health and production goals may influence the vaccines you recommend.[1, 2]
- ❑ **Follow the vaccine label.**
  - ❑ Veterinarians can legally exercise discretionary judgment if the use of a vaccine is medically justifiable in a way other than what is described on the label, as long as it complies with all governmental restrictions that may apply. This includes using a vaccine in a non-labeled species. However, failure to use vaccines according to manufacturer-labeled directions may result in potential liability to the veterinarian in the case of an adverse event or lack of efficacy.[3]
- ❑ **Help the producer estimate** vaccine dose needs.
  - ❑ Include current head counts and potential buy-ins or births for the year.
  - ❑ Account for adequate amounts of needles, including extras for broken or dropped needles.
    - Although it is generally not recommended by veterinary organizations to reuse needles, some national industry programs provide guidance on doing so (e.g. 1 per 10 animals according to the BQA National Manual[4]).
    - Use new needles for each animal in blood-borne disease prone areas, such as anaplasmosis-endemic herds, to prevent manual transmission.
    - If the producer reuses needles, confirm the disinfectant will not affect vaccine efficacy (e.g. modified live vaccines may be deactivated by disinfectant residue in needle). Provide recommended disinfecting regimen.
- ❑ **Emphasize the value** of utilizing vaccines and other prevention methods to keep the herd healthy.
  - ❑ Discuss potential economic benefits of preventive strategies for risk mitigation.
  - ❑ Consider the varying benefits of the following practices for animals (especially high-risk animals): low-stress handling, animal spacing, sanitation of processing and treatment areas, palatable receiving diets, and prophylactic antibiotic use.[5]

- ❑ **Ensure the producer has a plan** for proper disposal of empty bottles and residual vaccine.[6, 7, 8]
  - ❑ Emphasize the importance of keeping record of disposal dates.
  - ❑ Follow the manufacturer's recommendations, if provided on the label.
  - ❑ Do not dump unused vaccine down a drain or on the ground.
  - ❑ Disinfectant should be added to unused portions of live or modified-live vaccines to prevent environmental contamination and reduce accidental exposure of animals.
  - ❑ Expired or unused vaccines can often be returned to the manufacturer or place of purchase for proper disposal.
- ❑ **Educate producers or their employees** on their role in ensuring proper vaccination.
  - ❑ The Vaccine Storage and Handling module from the U.S. Centers for Disease Control and Prevention (CDC) and associated PDF toolkit provide in-depth information on vaccine storage and handling that is human-focused but can be translated to veterinary medicine.[9, 10]
  - ❑ Emphasize the importance of maintaining the vaccine cold-chain.
    - Consider sharing pages 4-5 of CDC's toolkit with producers and employees. [9]
  - ❑ Demonstrate appropriate technique, including sterile technique, and appropriate injection sites. For food producing animals, ensure injection site will not affect meat quality. Industry resources include:
    - Beef Quality Assurance (BQA) National Manual (pages 31-35, 68)[4]
    - Sheep Safety and Quality Assurance Program (pages 14-15)[11]
    - For other species, please consult quality assurance guidelines or species-focused veterinary organizations.
  - ❑ Discuss trouble shooting and how to fix problems occurring during or after vaccination, such as adverse reactions; provide appropriate SOPs to follow in case of a reaction, including when to call a veterinarian.
    - A Guide to Writing Standard Operating Procedures from BQA[12]

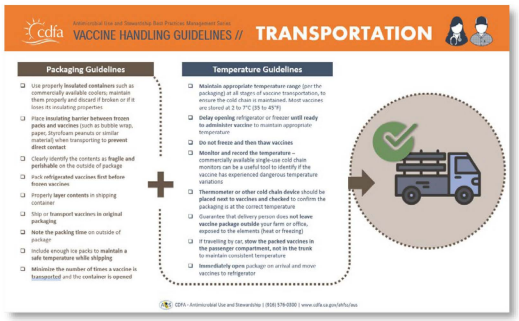
Additional resources:

1. Callan, R. J. (2001). Fundamental Considerations in Developing Vaccination Protocols. *American Association of Bovine Practitioners*, *34*, 14–22. https://doi.org/https://doi.org/10.21423/aabppro20015171
2. Rashid, A., Rasheed, K., & Akhtar, M. (2009). Factors influencing vaccine efficacy - a general review. *Journal of Animal and Plant Sciences*, *19*(1), 22–25. http://thejaps.org.pk/docs/19-no-1-2009/09-906.pdf
3. American Veterinary Medical Association. (n.d.). *Vaccination Principles*. https://www.avma.org/resources-tools/avma-policies/vaccination-principles

Additional resources, continued:

4. Beef Quality Assurance. (n.d.). *National Manual*. https://www.bqa.org/Media/BQA/Docs/nationalmanual.pdf
5. Stokka, G., & Goldsmith, T. J. (2015). Feedlot Vaccination. Does It Really Matter? *Veterinary Clinics of North America - Food Animal Practice*, *31*(2), 185–196. https://doi.org/10.1016/j.cvfa.2015.03.001
6. American Veterinary Medical Association. (n.d.). *Disposal of Unwanted Medications*. https://www.avma.org/disposal-unwanted-medications
7. Burt, A. (2008). A Sticking Point. *Beef Magazine*. https://www.beefmagazine.com/health/0701-proper-veterinary-waste-disposal
8. Grooms, D., & Amass, S. (2019). *Disposal of Farm Medical Wastes*. https://maeap.org/wp-content/uploads/2019/03/Disposal-of-Farm-Medical-Wastes.pdf
9. US Centers for Disease Control and Prevention. (2020). *Vaccine Storage and Handling Toolkit*. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
10. US Centers for Disease Control and Prevention. (2020). *2020 Vaccine Storage and Handling*. https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/index.html
11. Hoffman, T. W., Roeber, D. L., Belk, K. E., Levalley, S. B., Scanga, J. A., JN, S., & GC, S. (2013). *Producing Consumer Products from Sheep: The Sheep Safety and Quality Assurance Program*. 1–56. https://d1cqrq366w3ike.cloudfront.net/http/DOCUMENT/SheepUSA/2013%20Updated%20SSQA%20Manual.pdf
12. Western Region Alliance on Beef Quality Assurance. (2008). *Beef Quality Assurance: A Guide to Writing Standard Operating Procedures*. https://s3.wp.wsu.edu/uploads/sites/2147/2020/02/GUIDE-TO-WRITING-SOPs-FOR-BQA-2008.pdf

TRANSPORTATION

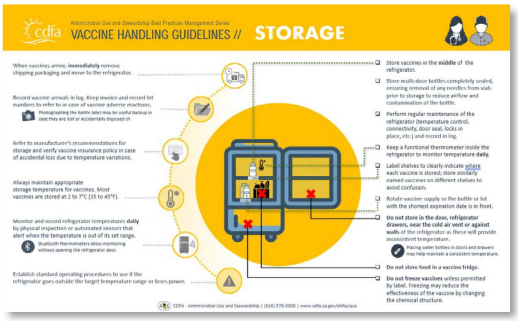


- ❑ **Establish a protocol** to use when receiving vaccines from a distributor.[1, 2, 3]
  - ❑ Ensure appropriate records are kept and correct temperature is maintained.
  - ❑ Apply this at your clinic or provide and discuss a protocol for your client's farms.
- ❑ **If travelling by vehicle:**
  - ❑ Stow the packed vaccines in the passenger compartment, not in the trunk.[1]
  - ❑ If you are using your veterinary truck, store in truck refrigeration unit.
- ❑ **Minimize the number of times a vaccine is transported.**[1]
  - ❑ Only bring out as much vaccine as needed for the day's calls.
  - ❑ Do not store vaccine in truck permanently.
- ❑ **Delay opening refrigerator, freezer, or truck refrigeration unit** until ready to administer vaccine.[1]

Additional resources:

1. US Centers for Disease Control and Prevention. (2020). *Vaccine Storage and Handling Toolkit,* p. 21-24. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
2. US Centers for Disease Control and Prevention. (2015). *Packing Vaccines for Transport During Emergencies*. https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf
3. Pan American Health Organization. (n.d.). *Cold Chain*. https://www.paho.org/en/immunization/cold-chain

STORAGE

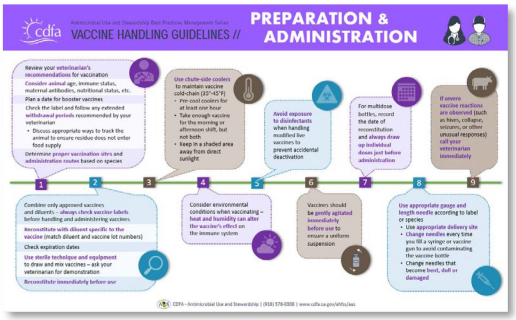


- **Record vaccine arrivals in clinic log.** Retain proof of purchase in a designated location to follow up with manufacturer if needed.
- **Store vaccines at the temperature recommended on the label.**
- **Establish standard operating procedures** to use if the refrigerator undergoes temperature excursion due to electrical failure or emergency shutoff due to wildfire, hurricane, or tornado (consult with vaccine manufacturer).[1, 2]
- **Do not freeze and then thaw vaccines,** except as permitted by label.
  - Freezing may reduce the potency of salt-adjuvanted vaccines by damaging the vaccine-adjuvant matrix. Formation of ice crystals overcomes repulsion forces between aluminum particles, resulting in coagulation and agglomeration of particles and an overall increase in particle size.[3]
- **Location of the refrigerator in the clinic is critical.** Many refrigerators are placed inside barns or garages without the proper insulation. Hot summers or freezing winters can affect the refrigerator operativity and affect vaccine viability.

Additional resources:

1. US Centers for Disease Control and Prevention. (n.d.). *Handling a Temperature Excursion*. https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temperature-excursion-508.pdf
2. World Health Organization. (2015). How To Monitor Temperatures In The Vaccine Supply Chain. *WHO Vaccine Management Handbook, Module VMH-E2-01.1*, 1–44. http://apps.who.int/iris/bitstream/10665/183583/1/WHO_IVB_15.04_eng.pdf
3. Kurzatkowski, W., Kartoglu, U., Staniszewska, M., Gorska, P., Krause, A., & Wysocki, M. J. (2013). Structural Damages in Absorbed Vaccines Affected by Freezing. *Biologicals*, *41*(2), 71–76. https://doi.org/10.1016/j.biologicals.2011.10.011

PREPARATION & ADMINISTRATION



Educate producers on vaccine recommendations and create appropriate SOPs for vaccines according to local disease prevalence and risk factors. Consider the following:

❑ Withdrawal times

- ❑ Discuss withdrawal times (check the label) and appropriate ways to track the animal to ensure residue does not enter food supply. All vaccines intended for food animals include mandatory withdrawal times before animal can enter the food chain. Most vaccines have a 21-day withdrawal period, but those with oil-based adjuvants usually have a 60-day withdrawal period.[1]

❑ Physiologic response[2]

- ❑ Consider stress factors (acute vs. chronic) and the effects on the immune system and vaccine response. It is postulated that acute stress can prime the immune system, and possibly potentiate the vaccine response; whereas chronic stress is known to inhibit the humoral immune response to vaccination.
- ❑ Consider vaccination timing to allow for sufficient development of immunologic protection before natural challenge.
- ❑ A protective immune response may not be elicited if animals are incubating an infectious disease, are malnourished or parasitized, are stressed due to shipment or environmental conditions, or are otherwise immunocompromised.
- ❑ Consider instructing producers to avoid using antimicrobials in conjunction with vaccination. Many antimicrobials can target gram-negative pathogens, resulting in endotoxin release that may lead to severe clinical signs, sepsis, or death.

❑ Environmental factors

- ❑ Heat, ultraviolet (UV) light and humidity can affect vaccine efficacy.
- ❑ Exposure to UV light may result in cellular degradation and release of free endotoxin.[2]
- ❑ Intranasal, temperature-sensitive modified-live virus vaccines should not be administered during extreme heat and humidity.[3]
- ❑ Endotoxin-containing vaccines during time of heat stress should be avoided. Endotoxins are pyrogenic and can increase the heat load in the animal.[2]

Vaccination schedule

- Consider timing for MLV vaccination at stocker yards since research suggests delayed vaccination after arrival improves health and performance outcomes. MLV vaccination in high-risk animals that are immunosuppressed may not be safe, which is a primary rationale for delayed vaccination recommendations.[2]
- Avoid giving multiple gram-negative endotoxin-containing vaccines at one time to prevent endotoxin stacking. There is the potential for endotoxins in bacterins to produce a synergistic or additive response; endotoxin stacking can lead to toxicity that could be fatal.[2]

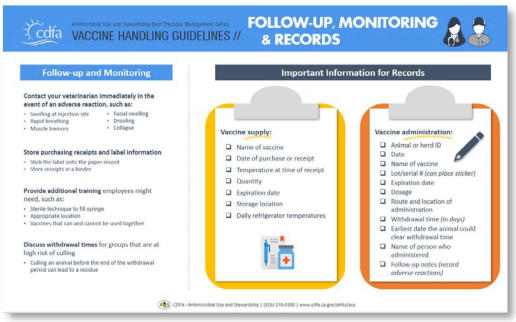
In addition to the producer guidelines, emphasize the importance of:

- Marking multidose bottles with date of reconstitution.
- Discarding bottles of killed vaccines that have been opened for more than 48 hours.[1]
- Not using the same syringe or vaccine gun for different vaccines.
- Adding dye to the water used in oral vaccines so you know it is being administered correctly throughout the barn. Only use dye that is specifically designed for use in vaccines. Dye may also be used in certain injectable vaccines (e.g. Marek's vaccine in poultry) but should never be used in mineral oil-based vaccines.[4] Dyes for use in vaccines are not regulated by the United States Department of Agriculture Center for Veterinary Biologics.[5]
- Avoiding excessive shaking of vaccines, as that may compromise vaccine safety.
- Avoiding vaccine exposure to disinfectants (e.g. alcohol) when handling MLV to prevent accidental deactivation.

Additional resources:

1. Gunn, D., Jensen, K. S., Williams, S., Parsons, C., Hudson, T., & England, J. (2013). Cattle Vaccine Handling and Management Guidelines. *Pacific Northwest Extension Publication*. https://www.extension.uidaho.edu/publishing/pdf/PNW/PNW637.pdf
2. Richeson, J. T., Hughes, H. D., Broadway, P. R., & Carroll, J. A. (2019). Vaccination Management of Beef Cattle. *Veterinary Clinics of North America - Food Animal Practice*, *35*(3), 575–592. https://doi.org/10.1016/j.cvfa.2019.07.003
3. Theurer, M. E., Anderson, D. E., White, B. J., Miesner, M. D., & Larson, R. L. (2014). Effects of weather variables on thermoregulation of calves during periods of extreme heat. *American Journal of Veterinary Research*, *75*(3). https://doi.org/10.2460/ajvr.75.3.296
4. US Department of Agriculture. (2005). *Adverse Event Reporting*. https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/adverse-event-reporting/ct_vb_adverse_event
5. US Department of Agriculture. (n.d.). *Sterile Diluents*. https://www.aphis.usda.gov/animal_health/vet_biologics/publications/pel_4_15.pdf

FOLLOW-UP, MONITORING & RECORDS



FOLLOW-UP

- ❑ **Locate withdrawal time on the vaccine label.**

Precautions: Do not vaccinate within 21 days before slaughter. Store in the dark at 35-45F (2-7C). Avoid freezing. Use entire contents when first opened. In case of anaphylactoid reaction, administer epinephrine.

- ❑ **If unable to determine a withdrawal period,** veterinarians may **contact Food Animal Residue Avoidance & Depletion Program (FARAD)** to estimate a safe withdrawal interval.
  - ❑ Website link: http://www.farad.org/

- ❑ **Ask owner or manager if employees need any additional vaccination training.**
  - ❑ This may include sterile technique for drawing up or reconstituting vaccines, appropriate injection locations, and vaccines that can or cannot be administered together. For example, two or more gram-negative bacterins should not be administered concurrently, as this can lead to endotoxicity.[1]

MONITORING

- ❑ **Remind clients of potential reactions** to vaccinations they may observe in their animals. Vaccines are intended to stimulate the immune system. They may observe mild, temporary side effects such as local muscle soreness or swelling, fatigue, fever, loss of appetite and lack of energy or alertness. If severe effects are observed (hives, collapse, seizures, etc.), they should call you immediately. Consider creating an SOP for producer or employees to follow when confronting a vaccine reaction.

- **Report any adverse reactions** to the USDA Center for Veterinary Biologics and the manufacturer, and document for your own records.
  - Reporting instructions can be found on the USDA APHIS webpage titled "Adverse Event Reporting."[2]
  - Contact information for technical assistance from the manufacturer should be located on the vaccine label, package insert, or company website.
  - Residual virulence and toxicity, allergic responses, disease in immunodeficient hosts, neurological complications, and harmful effects on the fetus are potential risks associated with the use of vaccines.[3]

RECORDS

- **Ensure instructions and templates are given in all languages** needed by employees, communicated either in writing or verbally.
- **Vaccination records should include:**
  - All individual animal identification devices and number(s)
  - Name and mailing address of animal owner
  - Signalment (species, age, sex, breed)
  - Date of vaccination
  - Route of vaccination (intramuscular [IM], subcutaneous [SC], intranasal [IN], oral) and location on the animal
  - Vaccine information
  - Brand or manufacturer
  - Product name or number
  - Lot number
  - Expiration date
  - Withdrawal time and earliest date the animal could clear withdrawal time
- **Upon receipt of a vaccine, your clinic or client's farm should record:**
  - Name of vaccine, date of purchase (or store the receipt), quantity, expiration date, storage location, and daily refrigerator temperatures.
  - Vaccines should be delivered at the correct temperature – if you receive a shipment of vaccines that is not packaged appropriately (for example, a product that needs to be shipped on ice arrives without ice packs), you should contact the distributor and return or discard the vaccines.

Additional resources:

1. Richeson, J. T., Hughes, H. D., Broadway, P. R., & Carroll, J. A. (2019). Vaccination Management of Beef Cattle. *Veterinary Clinics of North America - Food Animal Practice*, *35*(3), 575–592. https://doi.org/10.1016/j.cvfa.2019.07.003
2. *Adverse Event Reporting*. (n.d.). US Department of Agriculture. https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/adverse-event-reporting/ct_vb_adverse_event
3. Tizard, I. R. (2020). Adverse Consequences of Vaccination. *Vaccines for Veterinarians*. https://doi.org/doi:10.1016/B978-0-323-68299-2.00019-8