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GUIDELINES OF VETERINARY VACCINATION

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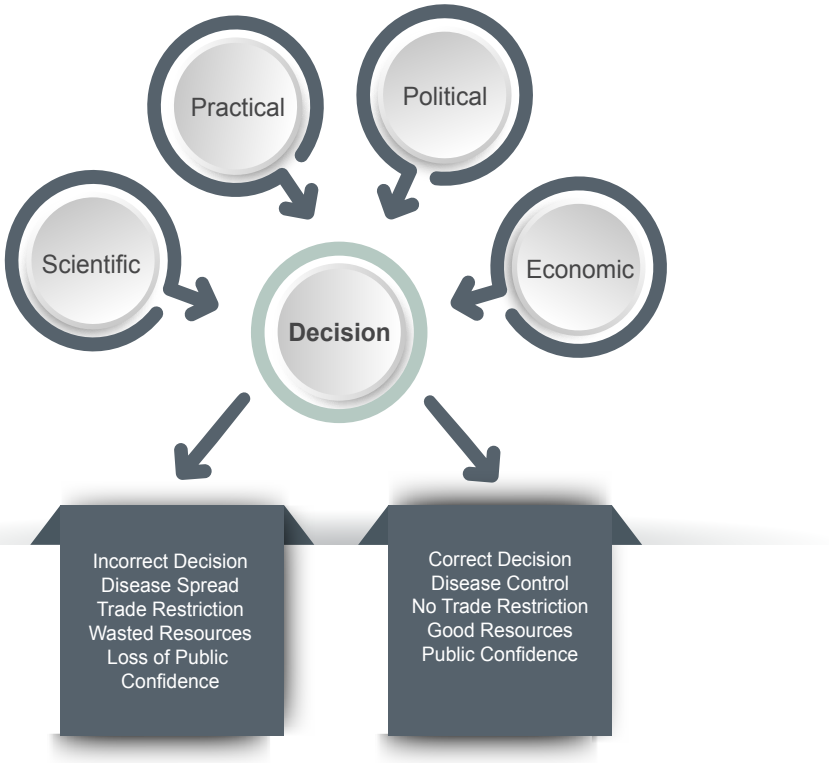

GUIDLINES OF VETERINARY VACCINATION

I. INTRODUCTION

A reliable supply of pure, safe, potent, and effective vaccines is essential for maintenance of animal health and the successful operation of animal health programs. Immunization of animals with high quality vaccines is the primary means of control for many animal diseases. In other cases, vaccines are used in conjunction with national disease control or eradication programs.

The requirements and procedures described here are intended to be general in nature and to be consistent with published standards that are generally available for guidance in the production of veterinary vaccines. The approach to ensuring the purity, safety, potency, and efficacy of veterinary vaccines may vary from country to country depending on local needs. However, proper standards and production controls are essential to ensure the availability of consistent, high quality products for use in animal health programs.

As the pathogenesis and epidemiology of each disease varies, the role and efficacy of vaccination as a means of control also varies from one disease to another. Some vaccines may be highly efficacious, inducing an immunity that not only prevents clinical signs of the disease, but may also prevent infection and reduce multiplication and shedding of the disease-causing agent. Other vaccines may prevent clinical disease, but not prevent infection and/or the development of the carrier state. In other cases, immunization may be completely ineffective or only able to reduce the severity of the disease. Thus the decision whether to recommend vaccination as part of an animal disease control strategy requires a thorough knowledge of the characteristics of the disease agent and its epidemiology, as well as the characteristics and capabilities of the various available vaccines. There is also growing public interest in the beneficial implications for animal welfare of the use of veterinary vaccines as a means of disease control. In any case, if vaccines are used, successful performance requires that they be produced in a manner that ensures a uniform and consistent product of high quality.

1. DECISION TREE FOR VACCINE

Decision Tree for Vaccine Use must balance:

1.1 Outbreak Factors

1.1.1 Contact Rate

A - Kind of farm

* Dairies & Feedlots versus back yard producer B - Direct & indirect movement

B - Direct & indirect movement

* Movement of animals (direct) versus
* People/ Equipment (indirect)
* Distance of movement
* Efficacy of movement controls

1.1.2 Host / species affected

A - Domestic

B - Game farms, zoos, valuable animals, etc.

C - Wild life

D - Public health implications

1.1.3 Status of outbreak

A – Number of affected flocks/herds

B – Number of foci

C – True rate of spread vs. rate of new detections

1.1.4 Environment

A – Livestock density & distribution

B – Livestock management

C – Casual access

D – Geography - natural barriers/ climate

1.2 Mitigation Factors

1.2.1 Physical resources

1.2.2 Human resources

1.2.3 Sociopolitical

1.2.4 Economic

2. ANIMAL VACCINATIONS PROGRAM

2.1 Vaccination Policies in Ruminants

Infectious disease continues to be the most costly source of young and adult animals' loss. While this is especially true in very young animals, less than 3 months of age, infectious agents can cause depressed gain and performance in all ages of growing animals. Economic losses from mortality, treatment costs, and depressed growth rates can be substantial. Economic losses continue even in animals that survive a disease challenge and appear clinically normal on visual inspection. Immunization is one tool in the management of certain infectious diseases. The proper use of vaccines allows the animal to prepare the immune system prior to challenge. While vaccination can be extremely helpful in preventing disease, it is important to remember that no vaccine program can protect all animals or protect animals if the challenge is overwhelming. Good husbandry that provides a sound diet, clean water and fresh air, protection from environmental extremes, and minimal exposure to infectious agents are as important if not more important that the vaccine or immunization protocol.

Vaccination programs for animal herds are designed to protect animals in the herd against disease caused by infectious organisms, such as viruses or bacteria. Vaccines are often ineffective when given to young animals. Their immature immune systems may not be able to respond to the vaccine or antigen. Antibodies acquired from the dam through colostrums that protect the calf from many infectious diseases also may block and destroy the antigens in the vaccine. This phenomenon is referred to as maternal antibody interference and is a major reason for not vaccinating very young animals against several infectious diseases.

Antiserum is made from the blood of animals that are immune to a given disease. It contains antibodies against that disease and affords immediate protection. It is of relatively short duration, usually providing protection for only two or three weeks. Antiserum is given in fairly large volumes, is usually expensive, and is not available for many infectious diseases. It is usually used in the face of a disease outbreak such as Enterotoxemia in nursing animals.

2.2 Types of vaccines

There are basically 3 different technologies available today in animal viral and bacterial vaccines. The development and manufacture of these types of vaccines is very different since the composition of the vaccine itself is so different.

2.2.1 Modified Live (Attenuated) Vaccines

Vaccines contain living bacterial or viral organisms. They are usually collected from a field disease and then grown in abnormal host cells (viral) or media (bacterial) to change or attenuate the pathogen. Each time the pathogen is grown through a replication, it is called a passage, and it is administered back to the animal to see if it can still cause disease. After several passages, the pathogen begins to lose virulence factors, since it cannot cause disease in these unnatural host cells. Once the pathogen can no longer cause disease in the target species, it is then tested to see if it can confer protection. The final vaccine is usually passed a number of times beyond the passage where virulence is no longer seen to decrease the risk of reversion to virulent pathogen.

Both viruses and bacteria, replicate themselves in the animal after injection. This has been termed a “controlled infection.” Because the organisms have been “modified,” they do not cause the disease but will stimulate the immune system. Modified live vaccines are mainly available for diseases caused by viruses, such as Infectious Bovine Rhinotracheitis (IBR). Many modified live vaccines cannot be given to pregnant animals because they will invade the fetus and cause birth defects or abortion. Modified live vaccines generally produce a higher level of immunity than killed vaccines, but may have a degree of risk when given to either pregnant or highly stressed animals.

2.2.2 Killed (inactivated) vaccines

Vaccines are easier to develop since virulence is not a problem. The same pathogen is isolated from a disease outbreak. The pathogen is grown and then chemically or physically killed. Inactivation is usually achieved by either adding a chemical to the pathogens or using ultraviolet rays. The major concern with inactivation is the potential loss of important epitopes. An adjuvant is normally added to inactivated vaccines to heighten the immune response. The vaccine is then tested for efficacy.

2.2.3 Genetically engineered vaccines

Vaccines have been altered genetically usually through a mutation. The mutation may be induced by several different methods, but the ensuing bacteria or virus has different properties that may alter virulence or growth characteristics. These types of vaccines are usually considered to be modified live (although inactivated marker vaccines fall into this category). Examples include temperature sensitive viral vaccines, streptomycin dependent *Pasteurella hemolytica*, and gene deleted IBR vaccines.

2.3 Vaccine Forms

2.3.1 Live Form

Some live vaccines are prepared from low virulence, mild, field isolates of a disease causing agent that have been found to be safe and effective when administered by an unnatural route or under other conditions where exposure to the microorganism will immunize rather

than cause disease. Other live vaccines are prepared from isolates of disease causing agents that have been modified by passage through laboratory animals, culture media, cell cultures, or avian embryos to select a variant of reduced virulence. The development of recombinant DNA (rDNA) procedures has provided some unique opportunities for vaccine production. Modified live vaccines may now be specifically produced by deletion of virulence related genes from a microorganism. Others are produced by the insertion of genes that code for specific immunizing antigens from a disease causing microorganism into a non virulent vector microorganism.

Nucleic acid mediated vaccines containing plasmid DNA are being developed. The DNA is usually in plasmid form and codes for immunizing antigens from disease causing microorganisms.

2.3.2 Killed Form

Killed products may contain:

a) Cultures of microorganisms that have been inactivated by chemical or other means;

b) Inactivated toxins; or

c) Subunits (antigenic parts of microorganisms) that have been extracted from cultures or that have been produced through rDNA procedures.

Both live and inactivated vaccines may be formulated with adjuvants designed to enhance their efficacy. Frequently used adjuvants are typically water-in-oil emulsions (either single or double), made with mineral or vegetable oil and an emulsifying agent. Other adjuvants, such as aluminum hydroxide gel or saponin, are also used. In addition to these traditional adjuvants, vaccines are being developed that include additional ingredients that induce immunomodulatory effects in the host animal and serve to enhance the efficacy of the product. These ingredients may include immunogenic components of microorganisms such as killed bacteria, which stimulate the immune response to other fractions contained in the vaccine, or cytokines, which may be used to regulate specific aspects of the immune system and are included in rDNA constructs used in products manufactured through biotechnology.

2.4 Booster Vaccinations

For young animals being vaccinated for the first time, a second or booster vaccination is often required a few weeks after the first or primary vaccination. A booster vaccination is usually required for killed vaccines that do not replicate in the animal once they are injected. The label directions will indicate when and if a booster vaccination is required. Failure to give the booster at the proper time could result in an incompletely protected adult animal even if that animal is vaccinated every year thereafter.

2.5 Advices for Proper Handling of Vaccines

2.5.1 Advice 1

Best vaccine program can fail if the product is damaged by improper handling. For example, if the label says to store a vaccine at 35° to 40° F, the vaccine should be refrigerated. Vaccines should not be allowed to freeze, nor should they be stored in direct sunlight.

2.5.2 Advice 2

Modified live vaccines must be reconstituted by adding sterile diluents to a dehydrated “cake” in a separate sterile vial. Once the water is added, the vaccine organisms are fragile and will be “live” for only a short time. As a rule of thumb, only reconstitute enough vaccine to be used in 45 to 60 minutes. Use a cooler or other climate-controlled storage container to protect reconstituted vaccines from extremes of cold or heat and from sunlight.

2.5.3 Advice 3

Keep needles and syringes clean to avoid infections at the site of injection. Do not use disinfectants with needles and syringes used for modified live vaccines. Even a trace or film of disinfectant in a syringe or needle can kill the live organisms and make the vaccine worthless. Use mild soap rinsed thoroughly with hot water to clean injection equipment used with modified live vaccines. You can use a mild disinfectant rinsed with water to clean needles and syringes used with killed vaccines.

2.5.4 Advice 4

Do not mix different vaccines together in one syringe or combine other injectable drugs into the same syringe with vaccines. Although this method has been advocated as a method of reducing the number of injections, it will inactivate the vaccine because of incompatibilities with the other compounds.

2.6 Method of injection

The majority of animal vaccines are injectable, although some may be given by other routes, such as intra-ophthalmic. In general, the preferred site for injection is in the neck (both intramuscular injections and subcutaneous injections) particularly in the large animals or in the loose skin of the armpit area or over the ribcage or behind the elbow joint (subcutaneous injections) in sheep and goats. Intramuscular injections of some products can cause significant muscle damage. Avoid the top butt or rump of the animal. Injection site reactions there will cause damage to a valuable meat product.

2.7 Important Information

a) Only animals in good condition and that are not stressed should be vaccinated.

b) All vaccines are biologic products and should be kept cool at all times.

c) Never mix vaccines, including vaccines against different diseases.

d) Try to work as cleanly as possible, especially if a disease outbreak is suspected. In this case a separate sterile needle should be used for each animal.

e) Vaccination does not ensure 100% immunity in all animals.

f) Never administer antibiotics with live bacterial vaccines (anthrax, contagious abortion).

g) Take extra care when injecting contagious abortion this vaccine is potentially harmful to humans.

h) Always read the instructions on the vaccine pamphlet to make sure of the dosage, route of administration and whether administered to pregnant animals.

i) Sterilize syringes and needles by boiling for 15 min. Do not use disinfectants as these may inactivate live vaccines. It is always better to use disposable syringes and needles especially when vaccinating against Brucellosis.

2.8 Critical Control Points (CCPs)

There are four points that are critical for newly born animal's health before vaccines are even considered. These include nutrition, care of the newborn, sanitation and housing.

2.8.1 CCP1

It is critical that the animal receive adequate nutrition during the last 60 days of gestation. The nutrients for the animal that are of special concern for neonatal health are protein, energy, vitamins A and E and the trace elements, especially copper, selenium and zinc. After birth, the newly born must continue to receive adequate nutrients. This is especially critical during winter (cold weather) to provide the newly born with energy for body heat.

2.8.2 CCP2

Newborn calves for instance should receive 2 to 4 quarts of good quality colostrums within the first two hours of life. The navel should be clipped to one inch and soaked in iodine or Chlorhexidine. Especially in cold weather, dry the calf off and provide supplemental heat or cover with a "calf jacket" to help conserve its body heat. Calves are not able to control their body heat well during the first few days of life and are very susceptible to cold stress which decreases their ability to absorb colostral antibodies.

2.8.3 CCP3

It is critical that the environment for the newborn is clean for its birth and early life. The maternity stall must be thoroughly cleaned after each delivery. The newborn hutch or other housing must likewise be

cleaned, sanitized and exposed to the sun prior to placing a newborn calf in it.

2.8.4 CCP4

In addition to being clean the housing must be, and remain, dry. It must also be well ventilated (not drafty) or newborn placed there will die from pneumonia in spite of other efforts that are made.

2.9 Cautions with Vaccine Administration (CVA)

2.9.1 CVA1

Be aware that anaphylactic (allergic) reactions are always possible when administering vaccines and be prepared with at least some epinephrine available or equivalent. Recent work has shown that vaccines prepared from gram negative bacteria may contain sufficient amounts of endotoxins to cause clinical effects. *Leptospira, Campylobacter, Salmonella, Pasteurella* and *E. coli* vaccines could all be potential problems. It has been recommended that not more than two of these products be administered at one time.

2.9.2 CVA2

Cattle tend to hold their body heat in hot weather and may be severely stressed by working them later in the day when it is hot and humid. If the temperature is over 85 degrees Fahrenheit with over 40% humidity, the cattle should be worked in the early morning while it is cooler.

2.9.3 CVA3

It has recently been shown that use of the injectable type of IBR vaccine to calves less than five days of age may result in a massive infection by Bovine herpes virus type one. Even for calves less than three months of age the intranasal product tends to give the best results because it is less affected by colostral immunity.

2.10 Proposed Vaccinating schedule for Diseases that are a Routine Threat

Vaccines are available for many disease conditions. However, many diseases are not a routine threat to most animal herds, and some vaccines are not sufficiently effective to justify their use. Therefore, only a few vaccines are included in a routine vaccination schedule.

Type of disease	Species of animal	Recommendations	Time of vaccination*
Enterotoxaemia	Sheep, goats, cattle and camel	First dose : 1-2 month old and up Booster dose : after three weeks Second dose : after six months old Repeat the dose after each six months	Two times per year
Pox	Sheep and goats	From 2-3 months old and up Repeat the dose after one year	One time per year
Foot and mouth	Sheep, goats and cattle	From 3 months old and up Repeat the dose after each six months	Two times per year
PPR	Sheep and goats	From 3 months old Repeat the dose after 6 months or one year according to the disease status assessment by veterinary authorities.	One time per year
CCPP	Goats	From 2-3 months old and up Repeat the dose after one year	One time per year
Pasteurellosis	Sheep, goats, cattle and camels	From 2-3 months old and up Repeat the dose after six months	Two times per year

*Vaccination program is subjected to be changed according the situation in the country.

2.11 Vaccination Policies in Poultry

Vaccination is a race against time to get the bird to produce a protective response before it meets field infections. Vaccination programs are the key element in addition to efficient management practices and strict biosecurity measurements in healthy flock's maintenance, regardless of the type of poultry involved.

There are numerous vaccines used in the poultry industry in UAE. These include live and killed vaccines. Live vaccines provide short-term immunity, which is relatively fast to develop. In comparison, the immunity afforded by individually administered killed vaccines lasts longer and takes longer to fully develop. The successful response to vaccination depends on choosing the correct vaccine strain, correct preparation, and the accurate administration to each flock or individual bird. Due to the ever-increasing farm size and the relative proximity of one farm to another, the disease status in any given location is constantly evolving. More virulent strains of pathogens have and may continue to emerge in all aspects of poultry. Therefore, it becomes practically evident that no single vaccination program will be suitable for all of the emirate farms in all circumstances, although it is reasonable to unify the general outlines of the vaccination policies adopted by a number of farms in a defined geographical area. It is also important to realize that vaccines recommendations may change as new information regarding bird immunity and disease has accumulated. Therefore it's deemed necessary to consider important factors like the age and production purpose, type of birds, the diseases present on the farm and in the region, the virulence, serotype of the pathogens and susceptibility age when deciding on a vaccination program.

2.11.1 Individual Bird Application

It is one of the methods of poultry vaccination.

a) Subcutaneous injection: Marek's Disease vaccine in the hatchery. Inactivated vaccines such as Newcastle Disease Virus, Infectious Bronchitis Virus, Reovirus and Infectious Bursal Disease Virus may be given to Breeder Hens at housing by subcutaneous injection into the back of the mid-neck region.

b) Conjunctival sac installation: (eye drop) Newcastle Disease, Infectious Bronchitis, Infectious Laryngotracheitis vaccines. Hold the head, with one hand and by thumb pressing the lower eyelid down to administer one drop into the eye. Hold the bird until the vaccine spread. It could be faster operation than transnasal drop.

c) Wing-web puncture: Fowl Pox (pigeon pox), and Avian Encephalomyelitis, Fowl Cholera chickens. Use double-prong sewing machine needle (supplied by vaccine manufacturer), dip into vaccine before each stab, spread the wing to expose the underside (up), stab through, do not touch feather with needles, and avoid vessels. For fowl pox, examine for "take" 6-10 days post, swelling followed by scab formation. Revaccinate non-reactor flock. To vaccinate turkeys, puncture the loose skin between the thigh and abdomen.

d) Feather follicle inoculation: Fowl pox vaccine in turkeys. Remove 2-3 feather follicles over the thigh, brush against the opening of the follicle with vaccine-dipped brush (supplied) or the vaccine may be sprayed on the area with a sprayer, hold the tip 2"-3" away. Examine for "take" 6-10 days post.

e) Intramuscular injection: Vaccines (Infectious Bursal Disease, Newcastle Disease, *Mycoplasma gallisepticum* Fowl Cholera, Infectious Bronchitis, and Reovirus) alone or in combination are used in Breeder birds usually just before housing. IM injection is in the pectoral muscles, using continuous flow, automatic syringe. Prevent contamination by frequent change of needles using a set of sterilized needles by autoclave or by Gama rays.

f) Embryo Injection (In-ovo): Vaccines (Marek's Disease, Infectious Bursal Disease, Newcastle Disease or Infectious Bronchitis) are injected into 18 day old embryonated eggs with an automated machine.

2.11.2 Flock application

In any vaccinated flock, a certain percentage of the birds may not be adequately vaccinated and thus remain susceptible to disease. If a large percentage of the birds are protected, then the pathogens shed from the infected bird are less likely to find another susceptible bird to infect and eventually the threat of spread of disease is drastically reduced.

Methods of mass vaccination are:

a) Aerosol

Aerosol vaccination is used for (Infectious Bronchitis vaccine, Newcastle Disease vaccine and Laryngotracheitis vaccine). Day or

night, house closed sufficiently to prevent cross drafts, use sprayer recommended by vaccine manufacturer, minimum spraying time 3-4 minutes, do not open the house for 15 minutes. Vaccines must be prepared for administration as required and birds must not be disturbed prior to application commencement. Protect worker with goggles and face mask.

Now it is also done in a spray cabinet at day one in hatchery for administering Newcastle, Bronchitis and Infectious Bursal Disease.

b) Water Administration

Newcastle disease, Infectious Bronchitis, (or the two combined), Avian Encephalomyelitis, Infectious Bursal Disease and Infectious Laryngotracheitis vaccines. Waterer with plastic bottom or glass container best, free of sanitizer in water or container, withhold water one hour in hot weather, or longer in cold weather, vaccine in cold water, and provide enough water space so that 2/3 birds of the flock can drink at one time. Add 0.1% powdered skim milk as stabilizer. All vaccine should be consumed within 45 minutes.

2.12 Broilers Vaccination Program

Vaccination programs for broilers begin in the hatchery. Most of the birds coming from the hatcheries will have already been vaccinated for Marek's Disease Virus (MDV) and for Infectious Bronchitis Virus (IBV). Marek's vaccine can either be administered in ovo at 18 days of incubation or by injection at day of age. Bronchitis is delivered via spray cabinets at day of age. There are a number of live MDV and IBV vaccines to choose from. Choices are largely based on the historical challenge in the location. There are two diseases to vaccinate against in the field: Infectious Bursal Disease (IBD) and IBV.

When discussing IBD vaccination programs for broilers producer should consider the vaccination program of the broiler breeders. A large proportion of breeders are hyper- immunized (they receive 2 doses of killed vaccine prior to lay eggs). Maternal derived antibodies (MDA's) play an important role in the bird's ability to generate immunity and prevent disease. As a result, timing is a key element in IBD vaccinations. It is important to

allow sufficient time for the antibodies in the chick to decline so they do not render the vaccine inactive. Bursa sampling, sera sampling and bird performance can be useful tools in determining the most effective age for vaccination.

If field challenge is high, these birds may be susceptible to infection and/or disease. it is sometimes necessary to re-stimulate the immune system with subsequent live vaccinations. The first vaccination provides the primary immune response, induces memory cells. Under high challenge conditions it may be necessary to incorporate a field vaccination. With flocks, under severe challenge conditions, it may also be necessary to add a second vaccination in the field. In young birds the preferred route for administration of live bronchitis vaccines is via coarse spray. In addition to IBV and IBD, some flocks certainly require protection against other diseases such as Newcastle Disease and coccidiosis. In the case of yet other diseases, such as Salmonllosis, Infectious Laryngotracheitis (ILT), vaccine may actually be administered to non-immune birds in the face of an outbreak as an aid in curtailing the spread of the infection within the flock.

Typical Broiler Vaccination Program

Age (days)	Disease	Route
1	Marek's Disease	Subcutaneous back of neck
1	Newcastle & Bronchitis	Beak-o-vac, intraocular, or spray cabinet
9-14	Newcastle & Bronchitis	Drinking water, eye drop, or intranasal or spray
1	Inf. Bursal Disease	SC/water
8-12	Inf. Bursal Disease	In water
14-21	Laryngotracheitis	ONLY IN ENDEMIC AREAS, Drinking water
21	Newcastle-Bronchitis	Some programs combine 1 day and 21 days as a double vaccination

2.13 Layer Pullets

The strategy for devising vaccination programs in leghorn pullets (the breed dominating the egg production sector in the emirate) is vastly different than for broiler chicks simply because the focus is to provide protection to these birds well into maturity and beyond. With regard to IBV/ND (Newcastle Disease) vaccinations, the attempt is directed to protect the birds for the life of the flock. It is acceptable that producers adopt typical vaccination program contains 3 to 4 live vaccinations followed by a killed injection with a 3-week spread between live vaccinations and a 6-week spread between the last live and killed vaccine, preferably via spray. The recommended practices of using a coarse spray in younger birds with a progressively finer spray as the birds get older, and/or milder vaccine strains in younger birds with more virulent strains in older ones, are to promote maximum immunity with minimum post vaccination reaction. In farms with a history of high IBV challenge, live boosting in the laying facility every 6-8 weeks could be a choice, in addition to the administration of a killed vaccine. It is recommended to have at least two live IBD vaccinations during the early pullet period. If the hatch is spread over a greater period than one week, it is appropriate to consider an additional live IBD, as we know that timing of IBD vaccination is critical. IBD is best administered via drinking water. Other vaccines to be included into layers vaccination program as dictated by prevailing circumstances may include MDV (administered at the hatchery), ILT, FP (Fowl Pox), AE (Avian Encephalomyelitis), SE (Salmonella enteritidis) and coccidiosis vaccines. Other vaccines against pathogens like Reovirus (viral arthritis/tenosynovitis), CAV (Chicken Anemia Virus), EDS (Egg Drop Syndrome), and Fowl Cholera (Pasteurella multocida) could be incorporated in the program if the chicks descend from unvaccinated breeders. Deciding to add these to your vaccination schedule will largely depend on the specific challenges in your area. Timing of individual vaccines should be scheduled on times of least stress, as when you are already handling the birds for a move or if you are handling for beak trimming purposes.

Age (days)	Disease	Route
1 day	Marek's Disease	Subcutaneous back of neck
9-14 day	Newcastle-Bronchitis	Drinking water, eye drop or spray
14 day	Infectious Bursal Disease	Drinking water or Spray
28 day	Infectious Bursal Disease	Drinking water or Spray
4 week	Newcastle-Bronchitis	Drinking water or Spray
8 week	Laryngotracheitis Fowl Pox Avian Encephalomyelitis	Eye drop Wing web stab Wing web stab
13-14 week	Newcastle - Bronchitis	Drinking water or spray
16 week	Laryngotracheitis	Spray or eye drop
(Post Housing)	Newcastle- Bronchitis	Every 3 months in some operations - Spray or drinking water
16 week	Inactivated Newcastle - Bronchitis	Injected IM/SC

3. POST VACCINATION ANIMAL CARE

Vaccinations are one of the most important weapons in the fight against infectious diseases in animals. Animals which develop disease often require treatment with medicines so vaccination helps reduce the amount of pharmaceuticals used in the treatment of animals. Vaccination presents no hazard to consumers of produce from vaccinated animals. However, vaccines are not an alternative to good management rather these are part of management. Animals should not be exposed to any stress or adverse climatic condition immediately after vaccination. All new animals should be quarantined and vaccinated against common prevalent diseases before their introduction in to the flock or farm.

3.1 Side Effects and Adverse Reactions

Anaphylactic (or allergic) reactions can sometimes be seen after vaccination. Even though it is uncommon in ruminants anaphylaxis can occur after any vaccine is administered, but have been most commonly seen with vaccines that have large amounts of foreign proteins, are adjuvant (Adjuvant are chemicals that are added to enhance the immune response. Killed vaccines commonly are with adjuvant) .It is virtually impossible to predict that an animal is allergic unless a reaction has been noted. An acute allergic reaction usually happens within minutes after receiving the vaccination. The signs may be hyper sensitivity, salivation, weakness, diarrhea, difficulty breathing, shock and death. Treatment consists of administration of epinephrine, antihistamines and supportive care. This is a condition that needs immediate attention, and it is recommended that the animals should be observed at least 15 minutes after vaccination.

3.2 Local Reactions at injection site

Local reactions include pain, swelling, abscesses, redness and irritation. Hard tissue formations may occur at the site of vaccination. These symptoms can occur within minutes to 1 week after vaccination but usually resolve on their own. A pain reaction will cause animal to become lethargic and may not want to move, and if moved will invoke some signs of pain. It is not recommended to give any drugs as this will decrease the immune response to the vaccine. Animals with local reactions should be treated symptomatically, apply heat and or cold fomentation depending on how the animal responds.

3.3 Systemic reactions

Systemic reactions include fever, depression, appetite loss, lethargy and weakness. They usually appear within 1-2 days of vaccination and then disappear. This is a common phenomenon which needs no treatment.

3.4 Reproductive system problems

Fetal malformations, infertility and abortion can result from the use of modified live vaccines in pregnant animals. Always follow the label instructions of the vaccine manufacturers.

3.5 Interference with serological testing

The results of some disease tests must be interpreted carefully if animals have been recently vaccinated. eg: strain 19 *Brucella abortus* vaccine.

3.6 Causes of Vaccine Failures

3.6.1 Certain drug therapies

For example, high doses of steroids are immunosuppressive and may interfere with vaccinations. The use of antibiotics may also interfere with vaccination.

3.6.2 Maternal antibody interference

Very young animals receive antibodies from their mothers when they nurse that protect them from disease. While these antibodies are present, vaccination will not be effective. These antibodies generally disappear from the body at 12-14 weeks of age. Booster shots are timed to try and protect them when the maternal antibodies wane at that time.

3.6.3 Common causes

Animal with fever or hypothermia, already debilitated, exposed or incubating disease, stress, Vaccine being used is against wrong strain of disease agent, Vaccine inappropriately administered, improper storage of vaccine, and improper route of administration, disinfection of skin or needles.

To check the immune status of animal a profile of antibody level should be monitored at regular intervals after each vaccination schedule.

3.7 Postvaccinal immune surveillance

The core livestock vaccines in Abu Dhabi Emirate are those targeting four transboundary animal diseases that include foot and mouth disease, peste des petits ruminants, sheep and goat pox and contagious caprine pleuropneumonia. Vaccination serves many objectives depending upon purpose for which each vaccination is programmed.

Epidemiological cross sectional immune surveillance studies can be used to monitor vaccination program effectiveness, identify weaknesses in vaccination programs and provide quantitative data for risk assessment. The most practical measure of vaccination program effectiveness bypasses the vagaries of vaccine storage, administration technique, and timing of administration to measure the effect of the vaccine on target animals. Serological surveys can be used to estimate the prevalence of animals protected against any particular disease. When the proportion of protected animals reaches a critical level (probably around 65% - 80%) then herd immunity is achieved and new introductions of disease causing agent will not result in an outbreak of disease.

Seroprevalence surveys to demonstrate vaccination program effectiveness involve the collection and analysis of blood samples from a random selection of animals of vaccinated animals and herds that statistically represent the population within a vaccination zone.

Such sampling is not to take place until at least 30 days after the completion of vaccination. The unit of interest is the individual animal which is going to be evaluated for protective antibody titer. The multistage cluster sampling designs are used to randomly selecting herds, followed by randomly selecting the subsamples of animals to be selected for bleeding. Standard laboratory technique such as ELISA is commonly used to measure the antibody levels in the sera of sampled animals as per disease/test specific protocols.

4. VACCINES QUALITY ASSURANCE

The consistent production of pure, safe, potent, and efficacious vaccines requires quality assurance procedures to ensure the uniformity and consistency of the production process. As production processes for vaccines provide a great opportunity for variability, care must be taken to control variability to the greatest extent possible, preferably using validated procedures, and to protect the product from contamination through all stages of production. Vaccine purity, safety, potency, and efficacy must be ensured by consistency in the production process. Consistent product quality (batch-to-batch uniformity) must be built in at each stage. Final product testing is used as a check to verify that the controls on the production procedures have remained intact and that the released product meets the specification previously agreed with the licensing authority. Regulatory authorities in different countries have developed various approaches

to ensuring the quality of vaccines. Although alike in their ultimate goal, these systems may vary in the emphasis given to control of the production process (process standards) in comparison with control through testing of the final product (performance standards). The control procedures selected should be those that best fit the conditions under which vaccines are being produced and, where possible, comply with good manufacturing practice. The control standards and procedures established for a product define the risk or possibility of producing and releasing a product that is worthless, contaminated, dangerous, or harmful. The acceptable degree of risk may depend on the benefits to be gained by having the product available to prevent disease losses. Thus standards may justifiably vary from country to country or product to product, depending on local animal health conditions. However, control authorities should strive to establish control standards and procedures that ensure a finished product of the highest purity, safety, potency and efficacy possible. The optimal quality assurance system should address both production procedures and final product testing in proper balance. An absolutely fail-safe system that would result in no risk of releasing an unsatisfactory product would probably be too expensive with regard to cost of production as well as control. Thus regulatory officials and manufacturers of vaccines must select control procedures that are capable of ensuring an acceptable low level of risk in relation to hazard. Such procedures, however, must not be burdensome to the extent that they inhibit the development and availability of the products needed to provide proper preventative medical care at a cost that is acceptable to the consumer.

5. VETERINARY VACCINES POTENTIAL PROBLEMS

5.1 General Considerations

All products, including biologicals for veterinary use, derived from animals have some capacity to transmit animal disease. The level of this capacity depends on the inherent nature of the products, their source, the treatment that they might have undergone, and the purpose for which they are intended. Biologicals for in vivo use in particular will have the highest probability of exposure to animals and as such present the highest risk. Products used for in vitro purposes can introduce disease into animal populations through deliberate or inadvertent use in vivo, contamination of other biologicals, or spread by other means. Even products for diagnosis and research have the potential for close contact with animals. Exotic micro-organisms, some highly pathogenic, which may be held for research

and diagnostic purposes in countries free from infection or the diseases they cause, could possibly contaminate other biological products.

Veterinary Authorities of importing countries shall make available specific procedural requirements for approval or licensing of biologicals for veterinary use. They may limit supply to registered institutions or in vitro use or for non-veterinary purposes where such assurance cannot be provided.

5.2 Risk Analysis for Veterinary Vaccines

Risk analysis for veterinary vaccines has to be founded on the principles of quality assurance, which includes quality control, in the production of veterinary vaccines. These recommendations are focused mainly on the risk related to the contamination of vaccines by infectious agents particularly in regard to the risk of importing exotic diseases. The major risk of introducing a disease into a country is through importation of live animals or animal products and rarely through veterinary vaccines. Veterinary vaccines can however be contaminated by disease agents if master seeds, strains, cell cultures, animals or ingredients of animal origin such as fetal calf serum used in production are contaminated or if cross contamination occurs during the production process.

5.3 Principles

Exporting countries and importing countries should agree on a system of classification of risks associated with veterinary vaccines taking into account factors such as purification procedures which have been applied. Exporting countries and importing countries should agree on risk analysis models to address specific issues and products. Such risk analysis models should include a scientific risk assessment and formalized procedures for making risk management recommendations and communicating risk. The regulation of veterinary vaccines should include the use of either qualitative or quantitative models. Risk analysis should be as objective and transparent as possible. Step risk and scenario tree methods should be used in risk assessment whenever appropriate, as they identify the critical steps in the production and use of the products where risks arise and help to characterize those risks. The same conclusions about risk analysis may be reached by differing methods. Where methods may differ in countries, the concept of equivalence should apply wherever possible and the methods should be validated to ensure they are of comparable sensitivity.

5.4 Categorization of Veterinary Vaccines

To assist in risk analysis, countries should establish a system of categorization of veterinary vaccines taking into account criteria such as pathogens used as active ingredients, their inherent characteristics and the risk they pose. In case of live vectored vaccines, the safety of the vector to the targeted and non-targeted species and to human beings must be assessed. Special attention should be paid to potential tissue tropism or host range modification of the recombinant.

5.5 Vaccinovigilance

Exporting countries and importing countries should ensure that a reliable system of vaccinovigilance (post licensing monitoring) is established to identify, at the earliest stage, any serious problems encountered from the use of veterinary vaccines. Vaccinovigilance should be ongoing and an integral part of all regulatory programs for veterinary vaccines, especially live vaccines.

5.6 Risk Management

The best practical risk management options could be adapted right from the decision tree diagram in chapter 1.

5.7 Risk Communication

Reliable data in support of applications submitted in importing countries should be provided by the manufacturer or the Veterinary Authority of the exporting country. Relevant data on risk analysis, changes in animal health situations and vaccinovigilance should be shared by Veterinary Authorities on a continuous basis.

5.8 Failures in Vaccination

In some cases, the vaccine may not be effective because it contains strains of organisms or antigens that are different from the disease-producing agent. In other cases, the method of manufacture may have destroyed the protective epitopes, or there may simply be insufficient antigen. Such problems are relatively uncommon and generally can be avoided by using vaccines from reputable manufacturers.

An effective vaccine may fail due to unsatisfactory administration. For example, a live vaccine may be inactivated as a result of improper storage, use of antibiotics in conjunction with a live bacterial vaccine, chemical sterilization of syringes, or excessive use of alcohol on the skin. Administration by nonconventional routes may also affect efficacy. When vaccine is administered to poultry by aerosol or in drinking water, the aerosol may not be evenly distributed throughout a building, or some animals may not drink adequate amounts. Also, chlorinated water may inactivate vaccines. If an animal is incubating the disease before vaccination, the vaccine may not be protective; vaccination against an already contracted disease is usually impossible.

The immune response, being a biologic process, never confers absolute protection nor is equal in all individuals of a vaccinated population. Because the response is influenced by many factors, the range in a random population tends to follow a normal distribution: the response will be average in most animals, excellent in a few, and poor in a few. Those with a poor response may not be protected by an effective vaccine; it is difficult to protect 100% of a random population by vaccination. The size of this unresponsive population varies among vaccines, and its significance depends on the nature of the disease. For highly infectious diseases in which herd immunity is poor and infection is rapidly and efficiently transmitted (e.g., foot-and-mouth disease), the presence of unprotected animals can permit the spread of disease and disrupt control programs. Problems also can arise if the unprotected animals are individually important, as in the case of companion animals or breeding stock. In contrast, for diseases that are inefficiently spread (e.g., rabies), 60-70% protection in a population may be sufficient to effectively block disease transmission within that population and therefore may be satisfactory from a public health perspective.

The most important cause of vaccine failure in young animals is the inability of an antigen to impart immunologic memory whether or not passive maternal antibodies are present. Vaccines also can fail when the immune response is suppressed, e.g., in heavily parasitized or malnourished animals (such animals should not be vaccinated). Stress, including pregnancy, extremes of cold and heat, and fatigue or malnourishment, may reduce a normal immune response, probably due to increased glucocorticoid production.

REFERENCES

Joseph Annelli, 2010
Foreign Animal Disease Control: Vaccination and Culling, USDA

Kahn C. M. *et al* 2005
The Merck Veterinary Manual
USA 9th Edition (50th Anniversary Edition) Publisher: Merck & CO.INC
Whitehouse Station N.J. in educational partnership with Merial Limited

Radostits O.M. et al 2008
Veterinary Medicine
(A textbook of the diseases of cattle, horses, sheep, pigs, and goats)
Edinburgh 10th Edition Publisher: Saunders Elsevier