KEMIN® BIOLOGICS

LUMPY SKIN DISEASE
THE FACTS

Contents

Welcome to this e-book on lumpy skin disease

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Lumpy skin disease is a growing global threat to the cattle industry. A highly infectious viral disease, the geographic distribution of the infection has increased to unprecedented levels. Lumpy skin disease is endemic across most of Africa and there have been many recent outbreaks across Asia. Action needs to be taken if we are to stop continued spread.

The economic losses due to infection are substantial. To individual farmers, the impact of lumpy skin disease can be devastating, with loss of income, food and draught power. This has a knock-on impact on economies on a local and national scale, as well as having severe trade implications.

With such a profound impact on the global cattle industry, as well as consequences for cattle welfare, it is important that all stakeholders involved, from farmers to veterinary surgeons and local authorities to government agencies, work together to stop the onward march of infection.

Initial attempts to control lumpy skin disease focused on stamping out policies, with very limited success.

Stamping out is not economically viable in countries with limited resources, and the first case must be detected without delay if there is to be any chance of achieving control.

After systematic implementation of diverse approaches in affected geographies, it became clear that the only means to build reliable immunity for lumpy skin disease control, is the use of Neethling strain vaccines. Field experience has demonstrated that prompt large-scale vaccination with a Neethling strain vaccine can successfully bring an outbreak to a stop. Safe and effective[1], one such vaccine is the MEVAC™ LSD vaccine from Kemin Biologics which has been instrumental in placing control back in the hands of livestock farmers.

This e-book covers all major aspects of lumpy skin disease, from clinical signs and diagnosis through to the economic implications of infection and of course, the importance of vaccination. I hope you will find it a useful resource in combatting this devastating disease.

References: *1. Bazid A1, Rashwan S2, Fawzy M3, Mahdy S2, Yousry R, Kilany W2, 4, Wasfy M2, Elsayed M2, Emergency vaccination of cattle against lumpy skin disease (LSD); evaluation of potency and efficacy of MEVAC LSD vaccine containing Neethling strain.*

Lumpy skin disease:

tackling a global threat

Lumpy skin disease (LSD) is a highly infectious disease of cattle and Asian water buffalo caused by the lumpy skin disease virus (LSDV). The virus belongs to the *Capripoxvirus* genus which also includes the sheep pox and goat pox viruses. Cattle infected with LSDV typically have large painful skin nodules covering all parts of the body and whilst the severity of symptoms is variable, the economic impact of infection is consistently high.

The geographical distribution of LSD has reached unprecedented levels; the disease is now endemic across most of Africa and in recent years there have been outbreaks in many of the major cattle producing regions of Asia, with science-based estimates that it will continue to spread further. Effective outbreak control through vaccination is vitally important in reducing the impact of this disease on farm incomes and improving animal welfare.

THE ECONOMIC IMPACT OF LUMPY SKIN DISEASE

LSD leads to severe economic losses. The impact of these losses is often greatest in herds with no previous exposure to the virus as their immunity to infection will be minimal. Direct losses result from:

- Decreased milk production
- Reduced weight gain
- Infertility and abortions
- Reduced fertility in bulls
- Damaged cattle hides
- Death of severely affected cattle

There may also be indirect losses caused by national and international cattle movement and trade restrictions.

LSD severely impacts the individual livestock farmer, and at a regional or national level, it can be devastating to the cattle industry. Even after recovery from infection, cattle may never regain the same level of production as before. Due to the substantial economic impact, together with the potential for rapid spread of the virus, the World Organization for Animal Health (WOAH) has classified LSD as notifiable.

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Lumpy skin disease:

tackling a global threat (cntd)

LUMPY SKIN DISEASE SYMPTOMS: KNOWING WHAT TO LOOK OUT FOR

The first phase of infection when the virus enters the bloodstream is known as the viraemic stage. At this time, infected cattle may have:

- Fever (40-41 °C)
- Loss of appetite
- Depression
- Discharge from eyes and nose
- Enlarged glands (lymph nodes)
- Increased salivation

The characteristic skin lesions start to develop in the following days and often in multiple animals at the same time:

- Circular, firm, elevated nodules (up to five centimeters diameter, sometimes larger)
- Lesions may be localized to the head, neck and limbs or may cover the whole body
- Scabs form within one to two weeks which usually slough to leave an ulcer
- High risk of myiasis (fly strike) on open sores

CONFIRMING DIAGNOSIS

A field diagnosis of LSD can be based on the following:

- Characteristic skin nodules
- Contagious disease with multiple animals affected
- Other clinical signs including fever
- Low mortality

Samples including scabs, saliva, nasal secretions or blood may be taken for laboratory testing. The polymerase chain reaction (PCR) test is one of the least expensive and quickest methods available for detecting LSDV.

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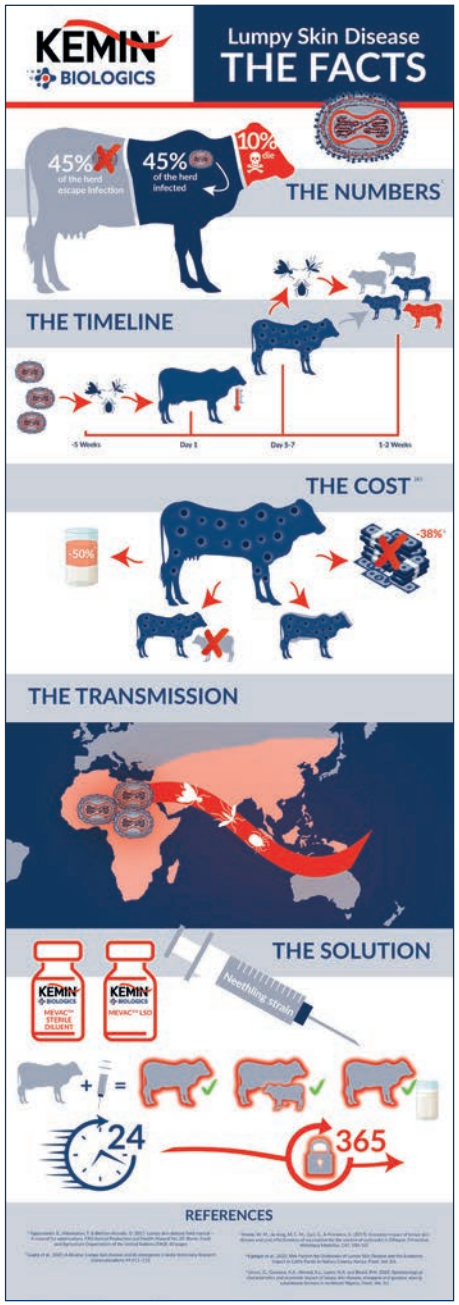

Lumpy skin disease:

tackling a global threat (cntd)

TRANSMISSION OF THE VIRUS: HOW DOES IT SPREAD?

The first (index) case in a herd is often associated with movement of cattle. In the early stages of an infection, clinical signs are usually mild and difficult to recognize even by experienced farmers or veterinarians. The incubation period of the virus can be as long as five weeks and by the time the characteristic skin lesions associated with more severe cases are detected, the virus has probably been circulating for some time and is likely to be well established within the herd.

LSD is mainly transmitted with the help of insects (known as 'vectors'). These vectors pick up the virus when they bite an infected animal and spread it to uninfected animals at their next blood meal. The most likely vectors are stable flies (*Stomoxys calcitrans*), mosquitoes (*Aedes aegypti*) and ticks (*Rhipicephalus* and *Ambylomma* species). Biting insects thrive in the warm, wet seasons and so there tend to be seasonal spikes in LSDV infection at these times, whilst disease incidence reduces in cooler winter months.

Once infection is established, morbidity rate (the percentage of ill cases within a herd) ranges from 5% to 45%. Mortality rates tend to remain fairly low and are usually below 10%.

The recent multi-national spread of LSD has been concerning and with global warming looking set to continue, insect vectors are likely to flourish, providing the perfect conditions for virus multiplication. Without adequate control measures, LSD is likely to become more of a threat to livestock in the coming years.

POSITIVE STEPS TO TACKLE LUMPY SKIN DISEASE ON FARM

The reality is that LSD is an incredibly difficult disease to contain once it is established in a region. However, the arrival of a number of safe, effective commercially available vaccines has been instrumental in placing control back in the hands of livestock farmers.

Farmers are the first line of defense against lumpy skin disease and protecting herds through vaccination is the single most important thing that these individuals can do to safeguard cattle health and farm livelihoods. Large scale regional vaccination has proven to be a very effective measure to prevent spread of the disease, therefore, in affected geographies it has been broadly embraced to manage the risk against this devastating disease.

Lumpy skin disease:

tackling a global threat (cntd)

1. Sheep and goat pox virus vaccines against LSDV
Due to cross-protection within the *Capripox* genus of viruses, sheep and goat pox vaccines provide some degree of protection against lumpy skin disease. Poxvirus vaccines have been widely used in several countries but protection against LSD has been shown to be incomplete and in addition, these pox virus vaccines have been associated with adverse reactions in cattle.

2. Lumpy skin disease live attenuated vaccine
A recent scientific study[1] indicated that a vaccine based specifically on the lumpy skin disease virus provides better protection than sheep and goat pox virus vaccines. Live attenuated vaccines containing the Neethling strain of LSDV are recommended and one such vaccine is the live attenuated vaccine branded as MEVAC™ LSD, provided by KEMIN BIOLOGICS.

The whole herd should be vaccinated in the spring before the higher risk seasons and booster vaccinations should be given annually. Calves from vaccinated mothers should be immunized from three months of age, with maternal immunity conferring protection in the first few months after birth. In any case, the vaccine can be safely used at any age to ensure protection of those calves born from unvaccinated mothers. Complementary to the above, another study showed that the vaccine gives high levels of immunity and no significant adverse effects are expected when given at the recommended dose.

VACCINATION: PART OF A WIDER PREVENTION AND CONTROL STRATEGY

Vaccination is just one part of the wider strategy used to prevent and control LSD. Specific control strategies vary in different countries so advice should be sought from the relevant national authorities and veterinarians.

Most control strategies in the event of an outbreak will include:

- Movement control (quarantine)
- Vaccination
- Slaughter
- Biosecurity measures including cleaning and disinfection vector control and safe carcass disposal

In relation to the above, however, quarantine restrictions have proven to be of relatively limited use, whilst slaughter programmes rely on detecting disease early, thus being expensive to implement while having a substantial financial impact on farmers. In this context, widespread vaccination campaigns associated with prompt detection of the index case, remains the cornerstone for effective LSD control.

Calves from vaccinated mothers should be immunized from three months of age, with maternal immunity conferring protection in the first few months after birth.

References: 1. *Experimental evaluation of the cross-protection between Sheeppox and bovine Lumpy skin vaccines - PubMed (nih.gov)*

The economic impact of lumpy skin disease

Lumpy skin disease (LSD) is a highly contagious disease affecting cattle and Asian water buffalo caused by a poxvirus belonging to the genus *Capripox*. The disease is predominantly transmitted by insect vectors and is characterized by the development of large painful skin nodules. Whilst LSD mortality rate is generally low (usually less than 10 percent), morbidity rates can be much higher, resulting in a significant negative long-term impact on livestock industries.

LSD: A HIGHLY CONTAGIOUS EPIDEMIC DISEASE

LSD is classified as a transboundary animal disease (TAD) meaning it is a highly contagious epidemic condition with the potential to spread rapidly across the globe with devastating effects on both local and international trade. The substantial economic impact of LSD led the World Organization for Animal Health (WOAH) to categorize LSD as a notifiable disease (WOAH, 2015). Whilst LSD generally has lower morbidity and mortality compared to some other WOAH listed livestock diseases, the prolonged loss of production in both dairy and beef cattle, together with the impact on international trade, means that LSD is one of the most important infectious cattle diseases facing the global livestock industry. Indeed LSD has been reported to produce chronic debility in affected cattle comparable to that caused by foot and mouth disease.[1]

LSD was first detected in Zambia (Northern Rhodesia at the time) in 1929 and it was not until 1989 when it was first identified outside Africa, in neighbouring Israel. Since then, LSD has continued to spread. It is now endemic in Africa and the Middle East and has spread through parts of Europe and Asia. Without prompt action and effective disease control this is likely to continue. Assessing the economic impact of LSD is critical for planning disease control programs and allocating resources.

THE ECONOMIC IMPACT OF LSD AT A FARM LEVEL

LSD leads to severe economic losses and while all stakeholders in the cattle industry suffer income losses, poor small-scale and backyard farmers tend to be hit the hardest. The impact of these losses is often greatest in herds with no previous exposure to the virus as their immunity to infection will be minimal. Direct losses result from:

- Decreased milk yield
- Mastitis
- Reduced weight gain
- Reduced draught power
- Infertility and abortions
- Reduced fertility in bulls
- Damaged cattle hides

LSD was first detected in Zambia (Northern Rhodesia at the time) in 1929 and it was not until 1989 when it was first identified outside Africa, in neighbouring Israel.

The economic impact of lumpy skin disease (cntd)

• Death or culling of severely affected cattle

These direct losses are devastating to individual farmers not least because in large parts of the world, cattle play an important role in the socio-economic fabric of the region. Not only is livestock a source of income and food but they can also provide draught power, helping to provide a means of overcoming poverty especially where agriculture is not yet mechanized. A diseased ox may be unable to plough or at least will provide reduced draught power, leading to effective working days lost and reduced crop production. Consequently, this loss of draught power can have a knock-on effect on other sources of farm income.

Production losses can remain long after recovery from the disease with many severely affected animals never regaining pre-infection levels of productivity. One study showed that 38 percent of the value of a herd was lost after an outbreak of lumpy skin disease.[2]

The impact of these direct losses has profound negative consequences for economies on a national as well as local scale and should not be underestimated - for East and South Asian countries the economic impact of LSD due to direct losses in livestock and production has been estimated to be up to 1.45 billion US dollars.

The economic impact of LSD is further compounded by indirect losses such as the huge cost of treating affected animals, including antibiotics which are often used for treating secondary bacterial infections associated with the disease.

THE ECONOMIC IMPLICATIONS OF LSD ON A GLOBAL SCALE

With Asian cattle and buffalo accounting for more than 30 and 97 percent of the global population respectively (FAOSTAT, 2020), the spread of LSD through Asia has serious implications. Reflecting these population figures, Asia accounts for 31 percent of global cow milk production, 98 percent of buffalo milk production and 29 percent of cattle slaughtered for meat production. The financial consequences of the continued spread of lumpy skin disease are substantial.

In addition to direct losses to individual farms, detection of lumpy skin disease usually has severe trade implications especially in newly infected countries. Those countries free of the disease often impose movement and trade restrictions, banning the import of cattle and buffalo products from infected countries, in an attempt to protect their national herd.

The economic impact of lumpy skin disease (cntd)

A Food and Agriculture Organization of the United Nations (FAO) report showed that Asian exports of live cattle and buffalo, meat, dairy products and hides accounted for 5.5 million US dollars, so it is easy to see that trade losses can be devastatingly high and are directly proportional to spread of lumpy skin disease.

VACCINATION: KEY TO COMBATTING LSD

Vaccination provides the key to combatting the global economic threat of LSD and the advent of a number of safe, effective commercially available vaccines has been instrumental in placing control back in the hands of livestock farmers together with regional and national authorities. Indeed, large scale regional vaccination has proven to be a very effective tool to prevent spread and vaccination is now key to controlling the disease.

Vaccines based specifically on the lumpy skin disease virus provide better protection than sheep and goat pox virus vaccines. Live attenuated vaccines containing the Neethling strain of LSDV are recommended and one such vaccine is the MEVAC™ LSD vaccine from Kemin™ Biologics.

The sooner such vaccines are used, the less severe the economic impact of an outbreak is likely to be. Following a vaccination program in Turkey in 2014, losses due to LSD decreased by 31 percent, with a net benefit of 19 US dollars per animal.[3]

Cost effectiveness of any vaccination program depends on the vaccine used, coverage rate and costs associated with vaccine delivery and administration. However, even accounting for these variables, vaccination is justified from an economic viewpoint, as costs of vaccination compare favorably with those of other less effective control strategies such as slaughter programs.

Indeed, large scale regional vaccination has proven to be a very effective tool to prevent spread and vaccination is now key to controlling the disease.

References: *1. Dr F. Glynn Davies, Lumpy skin disease of cattle: A growing problem in Africa and the Near East, FAO 2. Limon, G., Gamawa, A.A., Ahmed, A.L., Lyons, N.A. and Beard, P.M. 2020. Epidemiological characteristics and economic impact of lumpy skin disease, sheeppox and goatpox among subsistence farmers in northeast Nigeria, Front. Vet. Science 3. Abutarbush SM. Efficacy of vaccination against lumpy skin disease in Jordanian cattle. Vet Rec. 2014;175(12):302*

Lumpy skin disease:

The basics of vaccination

Lumpy skin disease (LSD) is a highly infectious vector transmitted disease of cattle and Asian water buffalo caused by the lumpy skin disease virus (LSDV). The virus belongs to the *Capripoxvirus* genus which also includes the sheep pox and goat pox viruses. Whilst LSD mortality is generally low, morbidity can be much higher, resulting in a significant negative long-term impact on livestock industries. Large scale vaccination of cattle and water buffalo is the only effective way to prevent spread of infection and reduce production losses in endemic and newly affected regions.

In the event of an outbreak, prompt selection of an appropriate vaccine is needed. Vaccine quality is of great importance to farmers, veterinarians and cattle alike and consideration should also be given to affordability. Cost effectiveness of any vaccination program depends on the vaccine used, coverage rate and costs associated with vaccine delivery and administration. However, even accounting for these variables, vaccination is justified from an economic viewpoint, as costs of vaccination compare favorably with those of other less effective control strategies such as slaughter programs.

PROTECTING THE HERD: LUMPY SKIN DISEASE VACCINES

Due to cross-protection within the *Capripox* genus of viruses, sheep and goat pox vaccines provide some degree of protection against lumpy skin disease and heterologous poxvirus vaccines have been widely used in several countries to try and control the spread of LSD. However, the protection that such vaccines provide against LSD has been shown to be incomplete[1] and in addition, these vaccines are associated with a number of adverse reactions in cattle.

Live attenuated homologous vaccines based on LSDV (Neethling strain) are now considered preferable, with better efficacy and a reduced incidence of side effects. Attenuation of the virus strain ensures that the live virus is still able to stimulate an immune response to create immunity but is not capable of causing disease.

> Whilst LSD mortality is generally low, morbidity can be much higher, resulting in a significant negative long-term impact on livestock industries.

Lumpy skin disease:

The basics of vaccination (cntd)

EFFICACY OF LIVE ATTENUATED LSD VIRUS VACCINE (NEETHLING STRAIN)

High quality LSD vaccines (Neethling strain) are advised to ensure adequate protection against LSDV infection. Poor quality vaccines with lower efficacy give a false sense of security and ultimately higher production losses, so should be avoided.

The degree of protection provided by a vaccine depends on a number of factors, including the level of attenuation and the titre of the vaccine virus. High antigenic concentration (LSDV Neethling strain > $10^{3.5}$ TCID50 in MEVAC™ LSD vaccine) will ensure a good immune response and high level of protection.

Whilst experimental data is of value, proven field protection is of the utmost importance to farmers and their livestock, and at a wider regional and national level too. One such field study in the Balkans, demonstrated excellent efficacy of Neethling strain vaccines, when LSD outbreaks in 2016 and 2017 were successfully eliminated by mass vaccination.[2] The effectiveness of these vaccines was further confirmed by a challenge trial, in which vaccinated animals were purposefully exposed to LSDV – none of these experimentally challenged animals showed clinical signs of LSDV.[3]

Lumpy skin disease:

The basics of vaccination (cntd)

SAFETY OF LIVE ATTENUATED LSD VIRUS VACCINE (NEETHLING STRAIN)

Safety is just as important as efficacy when it comes to vaccine selection. LSD vaccines need to be safe for use in the whole herd, to include all age groups, all breeds and bovine species and both sexes, including pregnant cattle. The use of live attenuated LSD virus vaccines has been associated with mild side effects, sometimes termed a 'Neethling response'. These are generally self-limiting with no long-term adverse effects and can be considered a good indication that the vaccine is triggering an immune response.

If adverse reactions are seen, they tend to develop within one to two weeks and most commonly include local skin reaction at the vaccine site or generalized small skin nodules. Skin nodules caused by the attenuated virus Neethling strain are smaller and more superficial than those caused by the more virulent field strain, and they heal within two to three weeks without developing into ulcers.

It should be emphasized that adverse effects due to Neethling strain vaccination are negligible. In one study conducted in Israel, a self-limiting Neethling response was seen in only 0.38% of vaccinated cows.[4] Another study on the use of LSDV vaccines in the Balkans indicated vaccines only caused side effects when used for the first time in a country that was previously free of LSD, and no adverse reactions were seen following booster doses of vaccine.[5]

Field studies have shown that even at ten times the recommended data sheet dose, the MEVAC™ LSD vaccine from Kemin Biologics is safe, with local reaction and swelling resolving by day 12 post vaccination.[6]

With no significant milk production loss following live-attenuated Neethling vaccination and no negative influence on mortality or culling rate,[7] vaccination against LSD can be recommended without reservation.

VACCINE ADMINISTRATION FOR LSD CONTROL

Whole herd vaccination is necessary to control the spread of LSD, to include calves and pregnant cows, with one report suggesting 80 to 100 percent vaccine coverage is required.[8] Calves from vaccinated dams or dams that have been naturally infected, can be vaccinated from the age of three months old, whilst calves from unvaccinated dams can be vaccinated at any age.

Data sheet instructions should be followed to determine the frequency of booster vaccinations. Usually, an annual booster vaccination is required which should be administered before the early spring risk period when there is large-scale movement of cattle to seasonal grazing.

Whole herd vaccination is necessary to control the spread of LSD, to include calves and pregnant cows, with one report suggesting 80 to 100 percent vaccine coverage is required.[8]

Lumpy skin disease:

The basics of vaccination (cntd)

The vaccine should be reconstituted with sterile diluent, according to data sheet instructions. Once reconstituted, the vaccine is ready to use and should be administered without delay, normally by subcutaneous injection in the neck region.

It is important to bear in mind that vaccination campaigns are often started when the virus is already widespread. Immunity develops from ten days post vaccination and cattle can still get infected and show clinical signs during this time. Equally, cattle who are already incubating LSD at the time of vaccination may develop signs of infection.

CORRECT VACCINE STORAGE FOR MAXIMUM EFFICACY

Correct storage of vaccines can be challenging in the warmer climates where LSDV thrives. Freeze-dried vaccines must be refrigerated and kept at 2-8°C including during transportation. In addition, all *Capripox* virus vaccines are believed to be sensitive to direct sunlight and so should be stored accordingly.[9]

Once opened, multi-dose vaccine vials need to be used promptly, and the general recommendation by manufacturers is that this must be within six hours. The timescale for vaccine use after reconstitution limits the possibility to share vials between farmers, but with vaccines coming in a range of vial sizes from ten doses up to fifty or more, this is not normally a concern.

ACCURATE RECORD KEEPING FOR GOOD VACCINE COVERAGE

All livestock need to be clearly identifiable and accurate records must be kept to ensure a vaccination program achieves good coverage in an efficient manner. Vaccination provides the key to combatting the global economic threat of LSD and the advent of a number of commercially available vaccines with proven safety and efficacy has been instrumental in placing control back in the hands of livestock farmers.

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Management of lumpy skin disease by vaccination

Lumpy skin disease (LSD) is a transboundary epidemic disease of cattle and Asian water buffalo that has serious economic consequences for the global livestock industry. Caused by the lumpy skin disease virus (LSDV), this vector borne infection is a threat to cattle welfare, farm livelihoods and international trade across large parts of the world. Establishing effective means of controlling the onward march of LSD is imperative.

CASE STUDY ONE: THE THAILAND VACCINATION SUCCESS STORY

On April 5th 2021, the first case of LSD was reported in Thailand. The virus spread rapidly with cases in 68 out of 77 provinces and a total of 273,298 farms affected. The economic and welfare implications of this outbreak were significant, so it was vital that an effective control policy was implemented without delay.

Lumpy skin disease (LSD) is a transboundary epidemic disease of cattle and Asian water buffalo that has serious economic consequences for the global livestock industry.

Management of lumpy skin disease by vaccination (cntd)

An emergency vaccination program targeting dairy cattle, beef cattle and buffalo was instigated, using live attenuated Neethling strain LSD vaccines. This was divided into two main phases:

PHASE ONE: RING VACCINATION

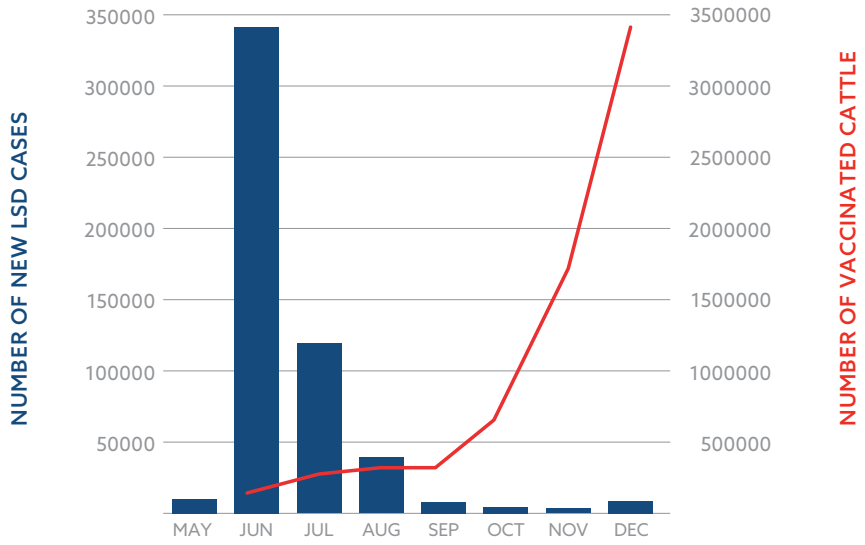
In the initial immediate response to the outbreak, 360,000 doses of a live attenuated Neethling strain vaccine were administered to control the LSD outbreak by ring vaccination. Ring vaccination targeted all susceptible animals in a delineated area surrounding the outbreak and commenced soon after detection of the first case.

PHASE TWO: WIDESPREAD VACCINATION

After phase one, the vaccination program was rapidly scaled up and five million doses of the MEVAC™ LSD vaccine from Kemin Biologics were administered. Initially areas where there were outbreaks, or regions of forest or natural park were prioritized with 80% coverage of the cattle population. Other areas were assessed individually, and vaccination programs determined on a local basis. Blanket vaccination, with vaccination of all susceptible animals in an area or province was frequently employed. A total of three million animals were vaccinated out of a total population of 5.3 million (Figure 1).

In 2021, there were a total of 1,747 outbreaks of LSD in Thailand. However, through the implementation of a prevention and control policy which focused on vaccination, by the end of 2021, 1,722 of these outbreaks had been resolved. With no outbreaks of LSD in the vaccinated population, the vaccination program was very effective.

Figure 1 - Case Study: Thailand 2021



Management of lumpy skin disease by vaccination (cntd)

MANAGEMENT OF LSD: THE CHALLENGES

In addition to vaccination, control of infectious diseases of cattle typically involves movement restrictions, culling and heightened biosecurity measures. However, the management of LSD presents a number of challenges:

- **LSD is transmitted by insect vectors.** Effective insect repellents will reduce the rate of mechanical transmission but will not prevent it.
- **Farming practices in at-risk countries.** Nomadic and seasonal farming often involves the large-scale movement of cattle which is known to increase risk of transmission.[1]
- **Farmers may be reluctant to report cases.** As the first line of defense against LSD, it is vital that farmers report suspected cases of LSD to the relevant authorities without delay. A reluctance to report is likely to stem from the consequences for cattle movement and trade that an on-farm LSD outbreak will have.
- **Implementing cattle movement restrictions is difficult.** Movement restrictions usually form part of any LSD control policy, but in many affected countries there is a lack of reliable individual animal identification with poor central record keeping. Illegal movement of cattle presents an additional obstacle to effective disease control.

These challenges highlight the importance of the prompt and large-scale vaccination of cattle and buffalo using a live attenuated Neethling strain vaccine such as MEVAC™ LSD from Kemin Biologics.

EMERGENCY VACCINATION IN THE FACE OF AN LSD OUTBREAK

Emergency vaccination programs, such as in Thailand 2021, are used as an immediate response to an LSD outbreak. They may also be implemented pre-emptively where there is a high risk of introduction of infection – where there is an LSD outbreak in a neighboring country or territory for example.

Movement restrictions usually form part of any LSD control policy, but in many affected countries there is a lack of reliable individual animal identification with poor central record keeping.

Management of lumpy skin disease by vaccination (cntd)

Due to the difficulty of detecting early cases of LSD, blanket vaccination of all susceptible animals is usually preferable. However, ring vaccination, combined with rigorous movement restrictions, is an effective immediate response to a localized outbreak, straight after detection of the first case.

Vaccine efficacy is key to the success of any vaccination program. Live attenuated vaccines containing the Neethling strain of LSDV are recommended, such as the Kemin MEVAC™ LSD vaccine. Close attention should be paid to correct storage and transport of vaccines and they should be administered according to data sheet instructions. At least 80 percent of the cattle and buffalo population need to be vaccinated to ensure herd immunity and avoid continued virus circulation.

CASE STUDY TWO: ERADICATION OF LSD IN ISRAEL AND THE BALKANS

Eradicating LSD from a country or region may be the aim of any control and prevention policy. In 2012, there was a large outbreak of LSD in Israel - the first time that a large-scale outbreak had occurred outside Africa. In subsequent years, LSD spread through Turkey, Greece, Bulgaria and other Balkan countries.[2] A policy of mass vaccination against LSD was implemented and by 2016, this vast epidemic was successfully contained. Since 2016, there have been no new outbreaks of LSD in South-East Europe.[3]

To achieve such an effective result, mass vaccination of whole herds, including pregnant cows and calves was carried out, continuing annually for several years after the cessation of clinical cases.

Timing of vaccination campaigns was based on risk periods. For example, the aim was that all cattle were vaccinated at least 28 days before any large-scale movement to seasonal grazing.

At least 80 percent of the cattle and buffalo population need to be vaccinated to ensure herd immunity and avoid continued virus circulation.

Management of lumpy skin disease by vaccination (cntd)

ADDITIONAL CONTROL MEASURES TO SUPPORT VACCINATION

While vaccination is the mainstay of any LSD control strategy, a number of additional control measures should be implemented as well:

- **Insect repellant** – effective insect repellants help reduce transmission of LSD. Consideration must be given to milk and meat withdrawal times as well as the environmental consequences of using these products.
- **Reduce insect breeding grounds** – remove on-farm areas where insects thrive, such as standing water, slurry and manure.
- **Raise biosecurity to the highest level** – heightened biosecurity should include restriction of farm visitors together with disinfection of vehicles and footwear.
- **Movement restrictions** – strict movement restrictions should be enforced in the event of an outbreak.
- **Quarantine** – cattle should be examined before movement to a new farm and quarantined from the rest of the herd for 28 days on arrival. In the event of an outbreak, all herds with confirmed or suspected cases should quarantine on farm.
- **Accurate record-keeping** – if there is no existing cattle identification system, vaccinated animals should be permanently marked with vaccine-specific ear tags.
- **Culling** – severely affected cattle should be removed from the herd. They present a constant source of infection and increase transmission risk due to insect vectors feeding on skin lesions.

Considering the success of vaccination programs in Thailand and the Balkans, it can be concluded that mass vaccination using a live attenuated Neethling strain vaccine such as MEVAC™ LSD from Kemin Biologics, represents the most effective means of controlling the global threat of lumpy skin disease.

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***References:* 1.** *Data from Thailand Bureau of Disease Control and Veterinary Service, Department of Livestock Development*
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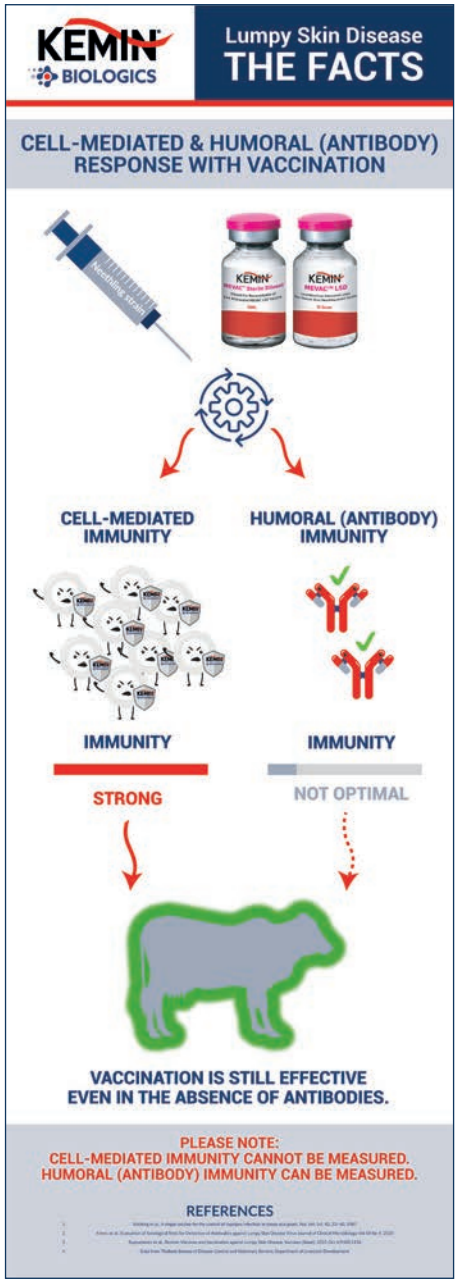

Successful vaccination against lumpy skin disease:

the role of seroconversion and surveillance

Lumpy skin disease (LSD) is a transboundary epidemic disease of cattle and Asian water buffalo that has serious economic consequences for the global livestock industry. The lumpy skin disease virus (LSDV) belongs to the *Capripoxvirus* genus, and this vector borne infection is a threat to cattle welfare, farm livelihoods and international trade across large parts of the world. The control of LSD presents significant challenges and is dependent on the mass vaccination of cattle and buffalo with a live attenuated Neethling strain vaccine. Given the large scale of most LSD vaccination programs, the substantial economic impact of an LSD outbreak and the global threat that the continued spread of LSD presents, it is important that vaccine effectiveness is thoroughly evaluated.

THE IMMUNE RESPONSE TO THE LUMPY SKIN DISEASE VIRUS

Protective immune mechanisms against the LSDV involve two components, termed humoral immunity and cell-mediated immunity. The humoral response is the production of antibodies by the animal's immune system, and it is thought to play an important role in the early stages of infection. However, immunity to *Capripoxvirus* infection is thought to be largely cell-mediated,[1] in other words it is initiated by white blood cells. This is because most of the LSD virus particles remain inside infected cells and so are out of reach of circulating antibodies. Vaccination with a live attenuated Neethling strain vaccine stimulates both types of immune response. In addition, vaccines such as MEVAC™ LSD from Kemin Biologics have high antigenic concentration (LSDV Neethling Strain > $10^{3.5}$ $TCID_{50}$) to ensure this immune response is strong and effective.

SEROCONVERSION AS A MEASURE OF VACCINE EFFICACY

Seroconversion is the development of detectable antibodies in the blood that are directed against an infectious agent, in this case the lumpy skin disease virus LSDV, and it measures the humoral response to infection.

Seroconversion can be measured using virus neutralization tests (VNT), indirect fluorescent antibody tests (IFAT) or enzyme-linked immunosorbent assays (ELISA). To date, VNT is the only serological test that has been validated by the World Organization for Animal Health (WOAH) and is considered the gold standard.

Successful vaccination against lumpy skin disease:

the role of seroconversion and surveillance (cntd)

Seroconversion does correlate with the protection provided by vaccination and studies have shown that local reactions at the vaccine site, including skin lumps, correlate with good antibody production.[2]

However, when assessing the results of serological tests, the role of cell mediated immunity must be considered and the absence of antibodies does not mean the absence of protection. Some animals may remain seronegative after infection with the LSDV or after vaccination even though they have full protection against the disease.[3]

It is clear that if not all vaccinated animals seroconvert, measuring antibody levels alone is not a good measure on which to determine the success of vaccination. Serological tests may be more useful for investigation of relatively recent outbreaks and demonstrating the disease-free status of a country.

MONITORING FOR OUTBREAKS IN A VACCINATED POPULATION

Monitoring for outbreaks in a vaccinated population remains the cornerstone of evaluating vaccine efficacy and observational field studies have been carried out which conclusively demonstrate the success of widespread vaccination.

Metrics that should be recorded include:

- Number of new cases in a region
- Number of new outbreaks
- New regions affected
- Vaccine coverage

NUMBER OF NEW CASES: THE ROLE OF SURVEILLANCE

A significant decrease, or complete lack of new cases is a strong indicator of an effective vaccination program. Immunity starts to develop from 10 days after vaccination, and if cases are occurring 28 days or more after vaccine administration, investigations should be carried out to determine possible reasons for lack of efficacy. To ensure sufficient protection of vaccinated cattle, live attenuated Neethling strain vaccines should always be used, with close attention to correct storage and administration. In 2021, a large LSD outbreak in Thailand was successfully controlled by a policy of blanket vaccination of cattle[4] using the MEVAC™ LSD vaccine from Kemin Biologics.

Even once an outbreak has been contained and case numbers dropped, surveillance should continue. Passive surveillance, based on monitoring for clinical signs can be effective in unvaccinated cattle populations or those with no history of exposure to the LSDV.

Some animals may remain seronegative after infection with the LSDV or after vaccination even though they have full protection against the disease.[3]

Successful vaccination against lumpy skin disease:

the role of seroconversion and surveillance (cntd)

In these populations, clinical signs of LSD tend to be very visible and are highly characteristic of the disease, namely circular, firm elevated skin nodules. Clinical signs tend to be less obvious in vaccinated populations so passive surveillance may be less useful.

In vaccinated cattle populations, active surveillance is likely to be more effective. This is generally based on thorough clinical examinations of 10 percent of the herd every month for example. Examinations should include the mucous membranes, udder and palpation of the skin. Combined with PCR testing on skin and blood samples for confirmation of infection, this can prove to be very effective.

ADEQUATE VACCINE COVERAGE FOR HERD IMMUNITY

Adequate vaccine coverage of the cattle and buffalo population is needed to ensure herd immunity and avoid continued virus circulation. Vaccine coverage can be calculated by dividing the number of animals that have been vaccinated by the total eligible cattle and buffalo population. For a vaccination program to be effective, it needs to achieve between 80 and 100 percent coverage.

Successful vaccination campaigns can stop the global spread of LSD in its tracks. Monitoring of such campaigns is necessary to ensure ongoing control of infection and should include passive and active surveillance for new cases and outbreaks, together with laboratory diagnostics where indicated.

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How to achieve lumpy skin disease free status

Lumpy skin disease (LSD) is a highly contagious epidemic disease of cattle and water buffalo. It is a vector-borne infection caused by the lumpy skin disease virus (LSDV), a pox virus belonging to the genus *Capripoxvirus*. With devastating consequences for livestock industries across the globe and a significant impact on international trade, it is imperative that the spread of LSD is contained. Control of the disease by the widespread use of live attenuated Neethling strain vaccines, such as the MEVAC™ LSD vaccine from Kemin Biologics, has proven to be highly successful. Once control has been achieved with no new outbreaks, attention must then be turned to planning an exit strategy. Usually, the ideal outcome for a country following an LSD outbreak and vaccination program, is successfully regaining disease-free status.

LUMPY SKIN DISEASE AND THE IMPACT OF TRADE RESTRICTIONS

The impact of LSD on the cattle industry should not be underestimated. As well as substantial welfare and economic consequences on a global scale, detection of lumpy skin disease usually has severe trade implications, especially in newly infected countries.

Following the guidance from the World Organization for Animal Health (WOAH), LSD-free countries often impose movement and trade restrictions, banning the import of cattle and buffalo products from infected countries in an attempt to protect their national herd. Food and Agriculture Organization of the United Nations (FAO) data showed that annual Asian exports of live cattle alone accounted for 419 million US dollars in 2020.[1] It is easy to see that trade losses can be devastatingly high and are directly proportional to spread of lumpy skin disease.

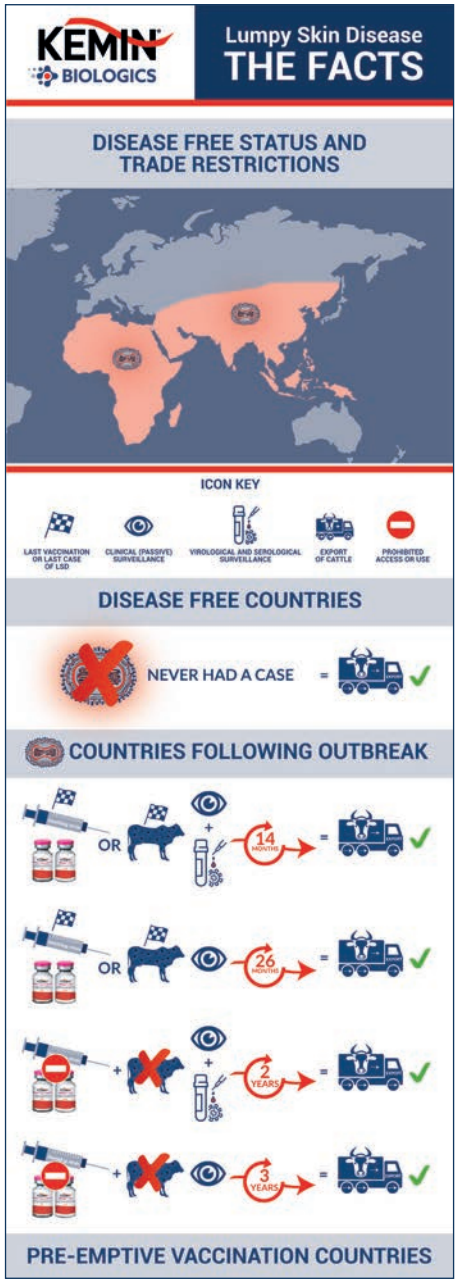
LUMPY SKIN DISEASE VACCINES AND ACHIEVING DISEASE-FREE STATUS

It is widely accepted that during an outbreak, large scale vaccination of bovines combined with movement restrictions, provides the most effective means of LSD control.[1] Indeed, no country has successfully managed LSD without vaccination.

However, international trade restrictions affecting cattle and cattle products are also imposed following LSD vaccination. This is the main reason why pre-emptive vaccine policies, in the absence of an outbreak are rarely used and very often prohibited. Exceptions to this may be made where the risk of an LSD outbreak is considered high – if there is an LSD outbreak across the border in a neighboring territory or country for example.

Therefore, regaining LSD free status is dependent on both an absence of outbreaks in new cases but also on vaccine use.

With devastating consequences for livestock industries across the globe and a significant impact on international trade, it is imperative that the spread of LSD is contained.



How to achieve lumpy skin disease free status (cntd)

THE LONG-TERM: MOVING FROM VACCINATIONS TO SURVEILLANCE

Determining when a vaccination program can be ceased is challenging. Following an LSD outbreak in Israel, vaccination was mandatory from March 2013 to June 2016 and spread of LSD stopped. From June 2016, vaccination was voluntary and a sharp reduction in vaccine coverage was seen. The virus was still circulating in the region and the reduced levels of protection in the cattle population resulted in the re-emergence of disease in 2019.

When vaccination programs are stopped, continued surveillance for new cases is imperative and contingency plans must be put in place to allow for swift action in the event of a new outbreak. This should include the stockpiling of sufficient Neethling strain vaccines.

REQUIREMENTS FOR GAINING DISEASE FREE STATUS

The WOAH Terrestrial Animal Health Code sets out requirements which determine whether a country is regarded as disease free. The requirements vary depending on the LSD history of the region.

A country or region has disease free status if:

- The country has never had a case of LSD.
- Vaccination has been prohibited in the country for at least three years, and no cases of lumpy skin disease virus (LSDV) infection have been detected by a clinical (passive) surveillance program.
- Vaccination has been prohibited in the country for at least two years, and no cases of LSDV infection have been detected by an active surveillance program using clinical, virological and serological monitoring.

Following an outbreak of LSD, a country can regain disease free status when:

- 26 months has elapsed following the last vaccination or last LSD case (whichever is later) and there is no evidence of LSDV infection as demonstrated by a clinical surveillance program.
- 14 months has elapsed following the last vaccination or last LSD case (whichever is later) and there is no evidence of LSDV infection as demonstrated by an active surveillance program using clinical, virological and serological monitoring.

How to achieve lumpy skin disease free status (cntd)

Following pre-emptive vaccination in response to a high risk of LSD infection (but without the occurrence of a case of LSD), a country can regain disease free status when:

- Eight months have elapsed following the last vaccination and no cases of LSDV infection have been detected by an active surveillance program using clinical, virological and serological monitoring.

PROPHYLAXIS AND STAYING DISEASE FREE

In regions of the world where LSD is prevalent, the vector-borne nature of LSD can make remaining disease-free challenging. Strict biosecurity policies and border control are essential but even the tightest of controls will struggle to prevent vector spread. Specific national control plans vary between countries but for LSD free countries include:

- Import restrictions on domestic cattle and water buffalo and selected animal products
- Surveillance measures to detect LSD, over a distance of at least 20 kilometres from an infected country or region.

Through the implementation of well-organized vaccination programs using live attenuated Neethling strain vaccines, alongside effective surveillance policies, achieving disease-free status is a realistic aim. Commercially available Neethling strain vaccines, such as MEVAC™ LSD from Kemin Biologics even make the global eradication of LSD a possibility.

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Lumpy skin disease:

learning from other areas

Lumpy skin disease (LSD) is a transboundary animal disease (TAD) meaning it is highly contagious and has the potential to spread rapidly across the globe with devastating effects on both local and international trade.

The first recorded case of LSD was in Zambia in 1929. Since then, the disease has spread progressively, affecting large parts of Africa, the Middle East, southeastern Europe and parts of Asia. It is currently endemic in several countries including Africa, parts of the Middle East (Iraq, Saudi Arabia, Syria) and Turkey.

With the global spread of LSD, a number of field studies have given valuable information regarding the disease, from epidemiology through to best practice for control.

FIRST ATTEMPTS AT CONTROL OF LUMPY SKIN DISEASE

Initial attempts to control LSD had limited success. Stamping out policies were used in many countries, however this did not achieve effective control for several reasons:

- Not economically viable in countries with limited resources
- Not possible in most of Asia due to religious or cultural beliefs
- Challenges of humane slaughter and disposal of infectious carcasses
- Needs first case detected without delay to have a chance of success
- Stamping out is not as effective as vaccination (EFSA, 2016)

The culling of animals with clinical disease, or partial stamping out, may reduce rates of infection but it will not eradicate disease or control spread.

LUMPY SKIN DISEASE CONTROL SUCCESS

Field experience has demonstrated that prompt large-scale vaccination with a Neethling strain vaccine of high efficacy, can successfully bring an outbreak to a stop. In 2012, LSD was found in Israel, the first time that a large-scale outbreak had occurred outside Africa. In subsequent years, LSD spread through Turkey, Greece, Bulgaria and other Balkan countries.[1] A policy of mass vaccination against LSD was implemented and by 2016, this vast epidemic was successfully contained. However, LSD re-emerged in Israel in 2019 after vaccination became voluntary,[2] highlighting the need for stringent ongoing surveillance.

In addition, data collected during the Israel and Balkans outbreak, showed that using a live attenuated homologous LSD vaccine was more effective at controlling and eradicating LSD than the use of heterologous sheep pox vaccines in other regions.[3]

Lumpy skin disease:

learning from other areas (cntd)

Further illustrating the efficacy of Neethling strain vaccines, is the Thailand LSD success story. In April 2021, the first case of LSD was reported in Thailand. The virus spread rapidly with cases in 68 out of 77 provinces and a total of 273,298 farms affected. However, through the implementation of a prevention and control policy which focused on use of the MEVAC™ LSD vaccine from Kemin Biologics, by the end of 2021, almost all outbreaks had been resolved. With no outbreaks of LSD in the vaccinated population, the vaccination program was deemed an overwhelming success.

RISK FACTORS FOR LSD OUTBREAKS

LSD thrives in warm humid climates with large vector populations. Field studies focusing on the epidemiology of LSD have established a number of risk factors for LSD outbreaks. This information is useful for understanding when surveillance needs to be heightened and for targeting timing of vaccination.

- Outbreaks are common in wet seasons, due to the associated increase in insect activity
- During dry seasons, outbreaks typically start along water courses[4]
- In dry areas, LSD often subsides at the end of the rainy season but resurgence of disease is associated with the return of rain[5]

Geographical factors can also impact patterns of disease. LSD control Is easier for countries that are geographically isolated, such as islands or those surrounded by mountains. Conversely those with long land borders tend to have a significant amount of informal, unregulated trade in livestock and animal products. This is thought to be one factor in the spread of LSD between Bangladesh and India in 2019.

Political instability in a country may also favor the spread of LSD due to uncontrolled animal movement across borders and the collapse of veterinary services.

In April 2021, the first case of LSD was reported in Thailand. The virus spread rapidly with cases in 68 out of 77 provinces and a total of 273,298 farms affected.

Lumpy skin disease:

learning from other areas (cntd)

RINDERPEST: SUCCESSFUL CONTROL OF A TRANSBOUNDARY ANIMAL DISEASE

The global economic consequences of TADs are substantial, and the potential for human suffering should not be underestimated. LSD is by no means the only disease threatening global livestock industries and livelihoods, and there is much that can be learnt by studying previous experiences with other epidemic diseases, such as Rinderpest (RP).

RP is an infection of cattle and buffalo caused by the rinderpest virus. The effects of this disease over the last two centuries are astounding. In the late 19th century, the loss of most of Ethiopia's cattle to RP, directly contributed to widespread famine that led to the death of one third of the country's human population.[6] In 2011, thanks to a 20 year global campaign which centered on vaccination, RP was declared eradicated, with the economic benefit of the campaign estimated at approximately 43 million US dollars.[7]

Lumpy skin disease:

learning from other areas (cntd)

FOOT AND MOUTH DISEASE: A WORK IN PROGRESS

Foot and Mouth Disease (FMD) had a global distribution prior to the 20th century. It is currently endemic in many countries including parts of Asia, Africa, the Middle East and South America. The estimated global economic losses vary but are between 6.5 and 20 billion US dollars.[8] Extensive eradication efforts have reduced distribution of the virus and it is not thought to be present in the majority of Europe, North America, Australia or New Zealand.

Vaccines are available against FMD, but their use is hampered by the relatively short duration of protective immunity they produce, with repeat vaccination generally being required every four to six months. Such vaccines have been successfully employed in the US and parts of Europe, but vaccination frequency increases cost and is time-consuming, which has hindered success in resource-poor parts of the world.[9]

Putting together all that has been learned from studying lumpy skin disease and other TADs, some firm conclusions may be drawn.

VACCINATION KEY MESSAGES

- Use a Neethling strain vaccine matching with current circulating LSD field strain
- Vaccines need a fast and long duration of action
- Vaccines should have proven (experimental and field) protection in cattle against LSDV infection
- MEVAC™ LSD vaccine from Kemin Biologics meets all these criteria

THE FUTURE: AREAS OF UNCERTAINTY AND OUTSTANDING KNOWLEDGE GAPS

There are still outstanding gaps in knowledge around LSD and much that needs to be learned. What is not in doubt is the high efficacy of vaccination campaigns using live attenuated Neethling strain vaccines such as the MEVAC™ LSD vaccine from Kemin Biologics.

To increase vaccine coverage, consideration could be given to simultaneous administration of LSD vaccines with other vaccines (such as those against FMD). Studies to look at any adverse effect on seroconversion or protective immunity may be warranted. Consideration could also be given to the inclusion of LSD vaccination in existing health testing regimes, such as tuberculin testing.

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MEVAC™ LSD

INJECTABLE LYOPHILIZED LIVE ATTENUATED VIRUS VACCINE FOR IMMUNIZATION OF CATTLE AGAINST LUMPY SKIN DISEASE VIRUS INFECTION (NEETHLING STRAIN)

MEVAC™ LSD Neethling strain vaccine matching with current circulating LSD field virus provide high level of cell mediated and humeral immune response rather than sheep pox vaccines[10].

MEVAC™ LSD High antigenic concentration (LSDV Neethling strain > $10^{(3.5)}$ $TCID_{50}$) to ensure a high immune response & proven protection.

MEVAC™ LSD Safe to be used with cattle even 10-fold of the recommended dose.

MEVAC™ LSD Fast & long duration of action from 10 days of vaccination & solid protection for more than 1 year.

MEVAC™ LSD Manufactured with the highest international quality standards GMP (following WHO guidelines).

MEVAC™ LSD Proven (experimental and field) protection in cattle against field LSDV infection.

Vaccination schedule

Primary Vaccination:
Cattle: all healthy animals should be vaccinated.
Calves from vaccinated dams: at 3 months
Calves from unvaccinated dams: at any age.
Pregnant animals: can be used during pregnancy (safe during all stages of pregnancy)

Booster vaccination:
Annual vaccination. It is recommended to vaccinate the animals before the risk period: early spring.

Reconstitution

The vaccine must be reconstituted in a sterile diluent (provided):
- by mean of sterile syringe transfer 2-5 ml of sterile diluent to the vial containing the freeze-dry vaccine - mix thoroughly until the pellet dissolve, transfer the suspension back to the remaining diluent and mix well again
- the vaccine is ready to use and must be injected without delay

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