World Organisation for Animal Health

TECHNICAL ITEM I

Animal Vaccines and Vaccination: Development, Registration, Use, Surveillance, and Impact on Trade

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1. Introduction

Veterinary vaccines, like human vaccines, have been in use for many years, contributing to saving, extending, and improving lives of young and adult animals and people. There has been exciting technological progress in vaccine design and manufacture, but we still have some way to go, in assuring their quality and suitability of their design, to meet the diverse needs among different species and husbandry systems. Yet, despite the progress in science and industry, we are still facing many challenges in vaccine effectiveness, and in some situations, diseases are spreading faster and wider than before. This is mainly associated with global warming, increased global movements of live animals, animal products or people. Big challenges are here and are likely to stay for the foreseeable future.

2. Part 1 – Vaccines

2.1. Vaccine development

Vaccines are a valuable tool in the control of infectious diseases, but they should not be considered a “universal panacea”. Vaccine applicability to a particular disease challenge varies greatly, as do their composition and designed use, so it is very important to take a structured approach, when considering them as a tool in control of a particular disease.

The methodology comprising the development of a Target Product Profile (TPP) is increasingly accepted as the standard approach to defining the requirements of a vaccine for a particular disease, along with its epidemiology in a specific environment. [10] (UK Vaccine Network). This approach is very useful, both as a means of defining the particular requirements of a vaccine for a known disease, in order to make an informed choice among existing commercially available vaccines and also in defining the requirements of a vaccine which needs to be developed in combating a new or emerging disease.

Where available, WOAH’s minimum requirements of a vaccine for a specific disease can provide a valuable baseline for a TPP, along with scientific advice which may be provided by WOAH Reference Experts, as well as FAO and international consortia such as STAR-IDAZ.

By using the TPP approach, sound, informed choices can be made regarding choice of vaccines, to ensure safety and applicability to a particular disease scenario. This approach can also help to ensure new vaccines are developed which are appropriate to the epidemiology of the disease in a particular husbandry system. This approach can also help to stimulate discussion among the many stakeholders involved (e.g., scientists, marketers, business development managers, policy makers, veterinary and public health officials, third party funders, etc.) both at concept stage and during the development of a new vaccine. This can ensure a vaccine more fully meets the required need, that field trials provide the required level of assurance and that it gains ethical and regulatory approval.

2.2. Vaccine access

Vaccines exist for many priority diseases in Asia and the Pacific, such as foot & mouth disease (FMD), classical swine fever (CSF) and rabies. These have been subjected to rigorous safety testing, also with established protocols for their production, as well as their use in different production systems. Nevertheless, it is essential that their deployment is overseen by a fully empowered and operational national regulatory authority, to ensure correct use and that vaccinated animals are identifiable.

WOAH provides guidelines and standards for vaccine procurement to ensure the quality, safety, and efficacy of veterinary vaccines, so facilitating international trade and control of transboundary diseases of importance in this context [15]. (WOAH 2024). Key aspects include the development and trial use of novel vaccines, vaccine quality control, cold chain management and vaccine bank operations, as well as essential downstream elements such post-vaccination surveillance and monitoring.

2.3. Vaccine technologies

Vaccines may be simply divided into two main types – non-infectious vaccines and live vaccines. Until relatively recently, non-infectious vaccines comprised either inactivated stocks of the whole pathogen or derived proteins, also sometimes modified versions of toxins excreted by a pathogen. There were generally very safe, but often not so effective. Immunity could take time to develop and often required more than one inoculation. In contrast, live vaccines were either live strains of an agent related to the pathogen, or an attenuated form of the pathogen. Such vaccines are generally more effective, since they stimulate a more diverse and long-lasting immunity, but their safety can be more variable, depending on the particular pathogen and derived vaccine. Many pathogens exist as multiple genotypes, which may reflect the existence of different seroptypes – ie the serological immune response may be specific to one or more genotypes. In such case, vaccines need to be matched to the specific serotype causing the outbreak or predominating in the region.

FMD vaccines provide a good example of non-infectious vaccines – commercial versions are generally derived from chemically inactivated and purified virus cultures. This virus exists as multiple, discrete serotypes, so it is essential to match the vaccine against the specific topotype/lineage and more than one dose of vaccine is required to provide optimum immunity. It is therefore essential to engage with a WOAH Reference Laboratory if this matching capability is not available domestically. Some Members use locally made and even “autogenous” FMD vaccines, which can represent major risks, both in production and deployment.

An excellent example of a commercially available attenuated vaccine is the C Strain vaccine for CSF, which was created through sequential passage in rabbits. A single dose of vaccine induces likely lifelong immunity in around 1.5 days, to all known genotypes of CSFV, since there is only one serotype. It does not transmit to non-vaccinates, nor to fetuses in pregnant sows.

In contrast, commercially available vaccines for porcine reproductive and respiratory syndrome (PRRS) virus are specific only to homologous genotype/serotype and some of these vaccines may transmit to non-vaccinates and also in utero, to fetuses.

Another major attribute of vaccines is the ability to be able to differentiate between infected and vaccinated animals. This “DIVA” capability can be of great value, both in surveillance and in international trade, particularly where a vaccine has been deployed as part of an eradication campaign, where it allows demonstration of lack of circulating field virus in a vaccinated population. This can be achieved through the development of tests which detect antibody in the animal to antigens of the virulent pathogen, but which are not induced when an animal has only been vaccinated. As an example, vaccines for FMD derived from inactivated cultured virus stocks do not contain non-structural viral proteins, so a combination test for antibody to both to structural and non-structural proteins can provide full DIVA capability and detect circulating virus in vaccinated populations.

Genome editing technologies have opened an exciting new approach to vaccine development, providing scientists with the ability to genetically engineer pathogens with benign or reduced virulence, or to generate specific proteins known to induce protective immunity to the pathogen itself. These may be presented via their incorporation within benign vectors. And by incorporating sequences from multiple genotypes, cross-serotype protection can be induced via these novel methods. More recently, synthetic DNA and RNA vaccines have been developed, which directly induce synthesis of specific pathogen proteins within the recipient animals’ cells, so inducing immunity to the pathogen. These genome editing technologies can also facilitate DIVA capability.

In parallel, there are a number of new generic areas of research also underway, to improve the thermostability of vaccines and to explore different methods of delivery, such as by the intradermal, aerosol or oral route, in order to make vaccination easier and improve vaccine effectiveness.

2.4. Addressing risks associated with vaccine development

For vaccines under development for a pathogen which presents a high risk to animals, laboratory staff or the wider environment, it is extremely important to ensure that laboratory biosecurity risks are fully assessed and effectively mitigated.

Novel gene technologies present a number of novel risks. Engineering of viruses may result in increased virulence, adaptation to new hosts or might compromise the ability to detect the agent or antibody to it by existing methods. These are all examples of “gain of function” and such work should only be carried out if there is no other means of achieving the desired result. If it is to proceed, the risks need to be carefully assessed, also ensuring that they can be effectively mitigated and that the benefits are clear.

During field trials of candidate vaccines, measures should be put in place to address the potential risks of spread of the vaccine itself, also of novel recombinant strains being generated following infection of vaccinated animals with field strains.

Clearly, such developmental work requires specialist facilities and knowledge. WOAH Reference Laboratories can assist with providing guidance in this area, also supported by supply of controls and standards to validate laboratory capability. In all cases, candidate vaccines should fully meet the criteria set out in the TPP before progressing to clinical trials.

2.5. Vaccine quality

Quality control (QC) is an essential element of vaccine production and its importance cannot be over-emphasised. Many cases of vaccine failure can be traced back to poor QC. It operates at all levels of production, in order to ensure safety, efficacy, and potency. This is achieved through stringent monitoring of starting materials, the manufacturing processes and on the finished product itself. This involves applying Good Manufacturing Practices (GMP), rigorous in-process testing and monitoring, along with final product release tests at batch level. This is essential in order to guarantee consistent and reliable vaccine batches that meet strict regulatory standards. The EUFMD Commission has recently launched a scheme for prequalification of FMD vaccines, to make sure that vaccines of appropriate quality and characteristics are available whenever they are needed and in sufficient quantity to meet demand [2] (EUFMD, 2025).

Key aspects include validating processes, ensuring suitability of facilities and equipment, maintaining skilled staff, and utilizing quality assurance systems to uphold the high standards required for veterinary vaccines.

As with the development stage, vaccines should fully meet the performance specifications set out in the TPP. As well as performance in providing the target level of protection and safety, the robustness and shelf-life of a candidate vaccine should be assessed during the validation process, to ensure it fully meets the requirements set out in the TPP.

There may be a situation where a TPP was subsequently found to be too aspirational, in which case it may be reviewed. In such case, a modification of the risk assessment, incorporating any new mitigations to address any changed risks, also a revision of use will also be required.

2.6. Vaccine efficacy vs effectiveness

In the early stages of development of a candidate vaccine, animal experiments are conducted, in order to determine an optimal vaccination regime, involving variables such as dose, route of administration and timing of any multiple vaccination regime.

Once an optimal regime is identified, a final measure of vaccine efficacy is determined in a clinical trial setting, where animals are pre-screened and assigned to different groups, receiving different vaccine regimens and challenge, along with controls. The animals are also maintained during the experiment in a way that minimises or negates other factors that could influence the results.

The objective of such studies is to determine the level of protection from infection, clinical disease and/or spread among vaccinated animals, compared to a control group. The results are usually expressed as a percentage efficacy in achieving the desired outcome.

In contrast, vaccine effectiveness is a measure of how well vaccines perform in the real world, outside the strict controls of clinical trials. Such assessments will accommodate the diverse variables and other factors that occur a broader animal population such as age, breed, past exposure and potential future exposure to other pathogens etc, as well as environmental factors, which may differ significantly from those in the clinical trial.

A study of effectiveness can also be influenced by factors, such as the prevalence of circulating variants, the timing of vaccine administration, variations in individual immune responses. These, along with external factors such as adherence to recommended schedules concerning transport and storage, can all affect “real world” vaccine effectiveness.

2.7. Current challenges

For two newly emerged or newly introduced diseases in Asia, African swine fever (ASF) and lumpy skin disease (LSD), vaccines are either absent or less well established manufacture and/or supply. This has created significant opportunity for local manufacture, along with the development of new vaccines for these diseases. But it has also resulted in significantly increased risks, through import of poor quality vaccines and the unregulated use of unauthorised vaccines, which has led to increased threat due to emergence of novel virus strains. This has resulted in changes in the epidemiology of these diseases in the region, leading to greatly increased challenges in their control and eradication. In the longer term, this is also likely to result in changed pathways of evolution of these viruses, with differing disease manifestation, vaccine inefficacy and possible spread to other species.

For highly pathogenic avian influenza, vaccines for use in poultry are gaining in profile, particularly as part of a DIVA strategy, where they have been shown to reduce the risk of introduction and spread, also reducing the threat of zoonotic emergence. The most common approaches to DIVA vaccine development has been in the form of vectored vaccines, usually constructed to express a different hemagglutinin (H) or neuraminidase (N) subtype than the circulating HPAI virus. Novel approaches include a new trivalent vaccine, offering protection against Marek's disease, Infectious bursal disease and H5 avian influenza in a single injection.

Our understanding of the use of vaccines in aquaculture is also increasing, with new technologies providing significant advances. They are now increasingly deployed to prevent bacterial, viral and even parasitic diseases and can be administered not only via injection, but also via solution in the water, making them an increasingly valuable tool that contributes not only in improving the health, welfare and productivity of the farmed species themselves, but also aquatic wildlife, by reducing disease incidence and thereby reducing risks of spillover.

Harmonising technical requirements for vaccine registration could provide significant benefits to the region and WOAH has been working with the EU, USA and Japan through the VICH programme to achieve this [11]

For all diseases, it is essential to continue to monitor vaccine efficacy and to send circulating strains to WOAH Reference Centres, so that pathogen diversity can be monitored

2.8. Impact of diseases on wildlife

HPAI is having a profound impact on many wild bird species at a global level and wildlife surveillance is essential in the face of its emergence and spread in the region.

The introduction of ASF into Asia has had a profound effect on many native pig species across the region. As well as wild boar, there were early reports of the devastating impact of this disease on the pigmy hog in Nepal and Assam. The disease was also reported in bearded pigs, following its introduction to Borneo, with a significant drop in activity monitored by camera traps. Reliable data on the impact of ASF on the other 10 species of wild pigs in the region are scant, however, which constrains disease control efforts, as well as impacting on pig conservation, pig husbandry interventions for local livelihoods. The cascading ecological

impacts, such as for apex carnivores, may also be profound, where they depend on wild pigs as a key prey resource [6, 7] (Luskin et al 2021; 2023)

2.9. Role of vaccines in reducing AMR

Whilst many bacterial diseases of domestic animals are routinely treated with antimicrobials, there is increasing concern around their continuing efficacy, due to development of resistance to these medicines.

WOAH continues to strongly align with WHO's Global Action Plan on Antimicrobial Resistance (AMR) [12](WHO, 2016) and has long argued that veterinary vaccines provide the single most cost-effective strategic action in addressing the increasing threat of AMR in humans, animals and the environment [13](WOAH, 2015).

The global initiative to reduce the use of antimicrobials has identified a number of priorities in the field of animal production [5](Lhermie et al 2017). Their use as a growth promoter is now banned in many counties and is seen as a priority area for continued action. A recent report [16](WOAH, 2025) has highlighted the role WOAH has played in identifying sectors with the highest antibiotic consumption, such as poultry, swine and aquaculture. WOAHs group of experts highlighted priority areas for improvement regarding existing vaccines and identified a number of gaps where vaccines could make the strongest impact through increased use and effectiveness.

But decisions on use of antimicrobials is often left to farmers themselves, which is often sub-optimal and is too often response-based, without a proper understanding of how disease might be prevented by other methods, such as vaccination. However, availability, cost and acceptance act as major obstacles to vaccine use. It is therefore increasingly seen as a priority to develop more proactive approaches to disease prevention through vaccination, which addresses these obstacles, in order to reduce the need for antimicrobial use.

The role of viral infections in predisposing to secondary bacterial infections is also increasingly acknowledged as a key driver in common infections which significantly impact on production. The WOAH Report [13](WOAH, 2015) identified priority diseases in different sectors of animal production, where vaccination could reduce antimicrobial use, whilst also highlighting constraints associated with current vaccines.

Not all important diseases in animal production are routinely controlled by use of vaccine, with bovine viral diarrhoea virus (BVDV) and its role in calf respiratory disease providing a good example. The key element to BVD eradication is detection and removal of persistently infected animals, which are immune-tolerant to the virus and therefore unresponsive to vaccine. Strict biosecurity and animal ID/movement controls are also critical to preventing re-introduction and spread, thereby maintaining freedom. Members with BVD control programmes have seen a significant drop in respiratory disease, with consequent reductions in antimicrobial usage of up to 50% being reported, as well as significant improvements in productivity and welfare. Of course, wider benefits also accrue in the context of one health, with AMR reduction also benefitting people and the wider environment. These benefits are well recognised, with many counties in Europe now implementing mandatory or voluntary schemes on BVD control and eradication, in order to realise these benefits [8](Metcalfe, 2019). However, it is also recognised that, in Members with less structured cattle production, BVD control using the current methodology may be unfeasible, so it is anticipated that this will initiate the development of improved vaccines, also with DIVA capability, in the near future, to realise the benefits of reduced AMR use through reduced BVD circulation, rather than full eradication.

3. Part 2 – Vaccination

3.1. From vaccine and vaccination

"Vaccines do not protect, vaccination does", says an old phrase that recently appeared similarly at Lancet Regional Health – Western Pacific editorial, stating: "vaccines don't save lives, vaccination does" [4] (Lancet Editorial 2021). Vaccination is the practical application of vaccines. It is based on the available vaccines and these, as described in the first part, vary a lot in technology, safety, efficacy, effectiveness and availability. This part discusses the pros, cons, challenges and gaps of vaccination.

3.2. Disease control policy

"To vaccinate or not to vaccinate, that is the question". Vaccination is costly, an effort, and in some diseases an obstacle to export, or complicates diagnosis. Disease-freedom, either historical or gained by control and elimination, is largely a preferred policy over control. Some Members are isolated enough, well-resourced and organised enough to successfully eliminate endemic or emerging animal diseases and prevent their re-entry. In many other Members disease freedom is practically unachievable or too difficult to maintain, making vaccination a feasible means of prevention and control of many diseases, or as a step on the way to disease eradication. Member's disease status may change in a quick and "surprising" way, and Members vary in their ability to eliminate a newly emerging disease. Members which are not free of a certain disease need a risk-based control and prevention policy and program, while free Members should be prepared and have a contingency plan which will often include vaccine selection, procurement, accessible stockpile and the capability to execute a vaccination campaign. Some Members have both free and non-free zones, or a zone of non-vaccination and a zone of vaccination for the same disease, such as Foot and Mouth Disease (FMD). Some Members are striving to gain freedom without vaccination, while others prefer to be free with vaccination.

3.3. Limited resources

Veterinary authorities of all Members are operating under the constraints of policy and economy. Richer and poorer Members have limited resources; funds, knowledge, technical capacity, human resources, training and management tools. Diversity of disease challenges vs scarcity of resources is a common phenomenon. Therefore, each Member needs to assess, decide, execute and monitor its activities in disease prevention and control within its unique framework, legislation, regulations, location, borders, geo-politics, socio-economy, culture, religion and other factors. In a fast-changing world of threats and challenges, dynamics of diseases and interaction with human health and environment, vaccination is one of the more effective tools Members have. Vaccination is not perfect, it's not as good as disease-freedom, but it is practical and economic when it is risk-based, properly executed, and not merely by long-term traditional routine.

3.4. Risk-based vaccination

WOAH has adopted and developed the useful management tool termed Risk Analysis (RA). It is useful both for national and international levels, for disease prevention, control, food safety and trade. [14](WOAH code 2.1). RA is a dynamic and on-going process, practical and useful. Members are advised to periodically categorize and prioritize all their animal diseases threats, based on epidemiology, objectives, resources and interactions with other Members via borders or trade. The same disease threat may be considered a negligible risk in one Member and a high risk in another, based on the probability of disease introduction and spread, and the potential impact on food security, public health, local economy, or export. Risk management strategy of prevention, control, vaccination, stamping-out and other mitigation tools can and should vary between Members and regions.

Due to the transboundary and "surprising" spreading nature of some diseases, it is useful to have a regional preparedness and control strategy. Due to the constant changes in epidemiology and challenges, "copy-paste" from one Member to another, from one disease to another, or from one year to the next, should be replaced by a periodic revision and RA per disease.

Risk assessment is affected by the quality of the data, the information and the capabilities of the RA task team and vet authority. RA is unfortunately not part of the curriculum in many vet schools or Members' continuing-education programs. Several international organizations offer training and assistance in general or disease-specific risk analysis process. Risk communication is an important component of RA, affecting vaccination coverage and compliance.

3.5. Vaccination approaches

Based on the Member policy, resources and risk assessment, if the disease is zoonotic or economic, endemic, emerging or re-emerging, different vaccination approaches can be used. The approach for the same disease can vary and shift according to changes in the pathogen, the environment, the risk and the control progress. Systematic, routine mass preventive vaccination of the entire or part of the population at risk to prevent disease, or emergency partial vaccination only in response to an outbreak, are approaches practiced with

some transboundary diseases. Suppressive vaccination is used to contain the outbreak, followed by culling infected herds and even vaccinated animals to regain freedom status.

Alternating vaccination approaches can be used, like with Brucellosis; initially a “Blanket” or mass vaccination of the entire population to lower the incidence to a level that will enable to use only targeted vaccination, of the young replacement females. “Ring” vaccination is used for outbreak control around infected foci, but this may become less effective when outbreak locations are numerous. “Barrier”, “block” and “zonal” vaccination of a defined area are used to limit the spread of some fast-spreading diseases, or to protect against their incursion across borders.

3.6. Vaccination protocol

The same vaccine may be used in various protocols and ways in an animal population. A Member, based on its updated periodic risk assessment, geography, borders, climate, size and value of animals, import and export, management types and available budget, should decide on its optimal vaccination protocol. Vaccination protocol describes where, when, which and when-again to vaccinate. Plans are required on who is vaccinating, payment for the vaccine, payment for the vaccination and related costs. There is a need to compromise between the allocated budget, personnel, management types and other factors. For example, some globally used FMD vaccines recommend vaccination every six months in high-risk areas, yet some endemic Members vaccinate only once a year, due to lack of budget, vaccinators, seasonality, experience, or acceptance of a certain low level of outbreak risk. Collaboration between the private and public stakeholders, including human-helath authorities in the case of zoonotic diseases,vets and farmers, and is useful to optimize vaccination efficiency.

3.7. Vaccination economics

“Prevention is better than cure”, yet vaccination campaigns are costly, and funding is always limited. The cost-benefit of vaccination in a single animal is clear by the ratio between the cost of vaccination vs the value of the animal. Yet the herd or national cumulative cost of preventive vaccination is sometimes viewed as an economic burden that can be reduced or spared, leading to an unjustified decision to reduce or stop vaccination. In the case of zoonoses the reduction of human health risk should be added to the contribution of vaccination of animals.

In some Members all mandatory vaccinations are performed and covered or subsidised by the public sector, while in other vaccinations are fully or partially performed by the privet sector vets or even the farmers. In some Members animal owners must pay for both the vaccines and the vaccination. Other Members combine government and farmers funding, use insurance policies to share the costs, increase collaboration and create incentives for all players. Some Members regulated charging for vaccination in large commercial farms, while fully cover vaccination costs for smallholdings and backyard herds. Each mechanism has pros and cons and may affects vaccination effectiveness.

3.8. Vaccination coverage

One of the common reasons for the inability of Members to better prevent, control or eliminate disease outbreaks, is insufficient vaccination of the susceptible population. Herd immunity is gained only if a sufficient fraction of the population has been vaccinated. The percentage that will lead to herd immunity and full suppression of an outbreak is disease specific, and depends also on the vaccine effectiveness. Partial coverage is caused by various reasons: the population to be vaccinated is not fully known, the census isn’t accurate, there aren’t enough competenet and motivated vaccinators, assisting staff, restraint facilities, animal are in pasture or remote areas, and lack of risk communication and compliance.

3.9. Vaccination compliance

The compliance of non-government stakeholders, like owners, farmers and herders is critical for a successful vaccination campaign. Animal holders may not collaborate or even oppose vaccination of their animals, due to lack of awareness, fear of production loss, lack of compensation for fatal adverse reactions, “anti-vaxxers” ideas among farmers and consumers, and various other reasons not to collaborate with the authority. Risk

communication is an important part of risk analysis aimed to increase vaccination compliance and coverage [9] (Morgenstern).

3.10. Vaccination vs stamping out

Vaccination should often be evaluated versus and compared to other outbreak control measures. Stamping-out (SO) is a common practice to eliminate disease from a Member or a region. SO can be combined with suppressive vaccination by initially vaccinating to contain the disease spread, followed by SO, for a faster regain of disease freedom. SO is a dramatic and costly measure and its use must be evaluated thoroughly based on to the spatial-temporal conditions of the outbreak, the ability of the Member to execute SO fast and effectively, having sufficient legislation and regulations, staff, funding, carcass disposal capability and sufficient farmers' compensation. Well-organized and exporting Members benefit from effective SO, while other Members may struggle with the consequences. Effective vaccine combined with sufficient vaccination coverage, can be an efficient substitute to SO, in LSD. [1] (EFSA AHAW). Animal welfare and the justification to cull healthy or recovered animals is often questioned or even objected by owners, parts of the public and media. In some Members LSD vaccination has fully replaced stamping out, while other used them combined. In HPAI, the changing ecology and epidemiology of the disease and its impact on economy and food security have challenged the global paradigm of eradication through mass-culling to consider vaccination as a complementary tool.,.

3.11. Vaccination implementation

Vaccination refers to the application of a vaccine. Most veterinary vaccines, especially of terrestrial are injectable. Each animal must be individually restrained and inoculated, once or more, according to the vaccine instructions. The principles and details of vaccination implementation are described in the WOAH terrestrial code chapter 4.18. dedicated to vaccination.

Vaccines showing high efficacy in controlled studies in "ideal" conditions, can be less effective "in practice", due to implementation of vaccination. Effectiveness failure can happen in individual animals or in an animal population due to many variables anywhere along the vaccination process; from storage to transport, handling, exposure to temperature and light, contamination of vial or needle, animal restraint, route and site of injection, vaccines mixing and other factors. Vaccination of unhealthy animals may reduce effectiveness, while, vaccinating of disease incubating or infected animals may be perceived as vaccine failure.

The global and continental spread of some diseases in recent decades, combined with strong scientific tools to monitor and evaluate control measures, gives us the opportunity to learn from field scenarios about the diversity in vaccination effectiveness. Lumpy Skin Disease (LSD) was limited to Africa until 2012, and in the following 13 years managed to spread into part of Europe and the entire of Asia. Some Members and regions, using the same Neethling strain vaccines, were successful in eliminating LSD, while neighbouring Members with similar geography, climate and epidemiology, struggled for years or even became endemic. Vaccination was the cause for this difference much more than the vaccines used.

3.12. Vaccination surveillance

"What you can't measure you can't manage". It is highly important to monitor and evaluate the proper execution of the vaccination plan. Whether it is preventive, responsive or suppressive vaccination, it must be planned, performed and evaluated. Comprehensive animal and herds identification and registration system, complete data bases and capable information technology (IT) tools are beneficial. Population dynamics like livestock movements, transactions, newborns, slaughter and death, must be updated routinely. If all vaccinations are recorded and reported by the relevant stakeholders, it generates a real and clear picture of vaccination compliance and coverage. Records analysis is a fast, economic and efficient means to monitor and survey vaccination levels.

Serological surveillance of vaccination must be initiated, planned and inspected by the vet authority, whether vaccination is performed by official staff or by the private sector. The major objective is to verify compliance and coverage, rather than verify the vaccine efficacy. Sero-surveillance is more complicated and costly to execute, and therefore scale-limited. Vaccination surveillance approach should be chosen based on the

specific disease, Member priorities, export requirements, laboratories capacity, animal population, and funding capability.

3.13. Vaccination agains non-WOAH notifiable and production diseases

Vaccination against diseases that are not WOAH-notifiable, or “classical” production diseases like mastitis, neonatal and respiratory diseases, are usually not dealt with by WOAH and in some Members are fully left to the private sector. However, vaccine registration, laboratory diagnosis, recommendations and risk communication, are often done fully or partially by the veterinary authority. Lack of effective vaccines and vaccination for these diseases may lead to an increased morbidity, mortality, use of antibiotics and other medications. These diseases impact animal welfare, food security and safety, livelihood and the environment. Veterinary authorities are advised to be involved and support the non-government sectors to improve husbandry, economy, health and welfare of livestock, in line with the One Health strategy.

Some diseases, like Bovine Ephemeral Fever (BEF) are not WOAH notifiable disease but are national notifiable diseases. BEF is causing severe losses in affected Members, while the available BEF vaccines are scarce and have inadequate efficacy [3](GLESER). Regional and global attention must be given to improve vaccines and vaccination against such diseases, and be prepared for the future, when so called “foreign” and “exotic” diseases become a real and meaningful risk.

3.14. Regional Collaboration

Due to the transboundary nature of some major current diseases, the mitigation tools and efforts of one Member are affecting and affected by the epidemiology and management capacity of its immediate, or even further neighbours. Knowledge, producing and sharing information , transparency and timely reporting and collaboration in risk-assessment, impact early detection and outbreak management. Outbreak management ought to consider vaccination as a pragmatic tool for disease control. Preventive barrier vaccination by a belt or a block shape area in high risk-zones, or of imported animals, can effectively protect the rest of the Member’s area.

4. Summary

The field of vaccine development is an exciting one, driven by novel technologies which offer solutions both to diseases for which vaccines have previously been unavailable or offering poor protection, along with the ability to rapidly respond to new and emerging diseases or new strains. When making the decision to develop and/or deploy a vaccine, it is essential to develop a Target Product Profile (TPP), to define the requirements of a vaccine in the context of the target population and resources available to monitor its use and effectiveness. Potential safety and ethical issues should also be taken fully into account when developing and using a vaccine.

Vaccination was and remains an important tool for disease prevention and control. Vaccination is an economic and cost-effective method, when properly combined with other control measures. Vaccination must be risk-based, updated and revised periodically. It requires commitment and persistency. Animal welfare, impact on the environment and public perception should be considered when deciding whether to vaccinate or to cull animals. Risk communication and training should be used to reduce animal owners and keepers perception of vaccination as a cost and a burden. WOAH, other organizations, commercial and public vaccine producers should collaborate in their efforts to innovate, produce and use new vaccines and new vaccination methods as a future tool to eliminate and globally eradicate of animal diseases.

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