



HOW TO INCREASE
**ANIMAL
VACCINATION**

*80 Recommendations to
Overcome Existing Barriers*

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HealthforAnimals represents the animal health sector: manufacturers of veterinary pharmaceuticals, vaccines and other animal health products throughout the world, as well as the associations that represent companies at national and regional levels.

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Introduction

For over 200 years, vaccines have been used to control and prevent disease. Vaccines have helped eradicate smallpox and rinderpest, while contributing to global reductions of diseases such as polio, rabies, and foot and mouth disease. Countless human and animal lives have been saved by timely, effective vaccination. These medicines are a cornerstone of health.

In the future, a growing world population will require increasing livestock production, while our pet population will be larger than ever. This brings with it a greater risk of disease outbreaks. Global movement of people, animals and food means a reduction in geographical barriers to disease, while a changing climate allows disease to thrive in new areas.

Animal vaccines are needed more than ever, but global uptake remains below optimal levels. The reasons why are complex, but primarily linked to six barriers.



Economic Barriers

Vaccine users, manufacturers and governments are all facing growing financial constraints. Costs of regulation are rising, funding for public animal health/veterinary departments is falling, and farms may choose not to invest in preventative medicine.



Political Barriers

Animal health decisions are often affected by political actors, influence and pressure. Issues such as trade, protectionism, and bureaucracy can dictate if vaccines are viewed as a critical tool within a regional or national animal health sector.



Technical & Scientific Barriers

New technologies such as genomic vaccines, platform concepts, and DIVA vaccines can strengthen animal care. Applying such innovations requires more research into mechanisms of protection against certain pathogens and clear paths to market.



Regulatory Barriers

As innovation advances, regulatory systems must keep pace. Inexperienced or outdated systems, non-existent frameworks, and lack of harmonization in certain regions means farmers cannot access many safe, effective vaccines, which can create black markets.



Field Use Barriers

Although highly effective, some vaccines can be difficult to administer without training. Improving ease of use alongside training of veterinarians, paraprofessionals and other vaccine handlers is necessary to improve use during the 'last mile'.



Social & Perception Barriers

After decades of vaccine success, there is a risk of complacency. 'Vaccine hesitancy' and 'anti-vaccination' attitudes are real, growing phenomena in both pets and livestock that puts everything vaccines have achieved at risk.

This report explores each of these barriers in-depth and provides clear steps everyone can take – industry, policymakers, regulators, IGOs, donor community, and others – to improve animal vaccination.



Current Veterinary Vaccines Market & Vaccination Rates

The demand for vaccines is growing and this is reflected in the market. In 2017, the veterinary vaccine market was valued at approximately USD\$7 billion and is predicted to reach USD\$9 billion by 2024¹.

Companion animal vaccines have the largest market share and highest growth rate. The preferences of pet owners for targeted vaccination supported by monitoring has resulted in an increase in the companion animal diagnostics sector as well².

There are around 10 established global companies and many more regional companies producing animal vaccines. Regional players (e.g. South American, Asian and Chinese companies) are also beginning to compete on the global market, often through partnerships with other companies.

Multinational companies are investing in increased production capacity; expanding sites in Asia and China; and building more partnerships. Small-to-medium size (SME) companies view emerging countries with growing economies as high-potential markets.

But, despite the obvious benefits of vaccination, global rates of animal vaccination are less than optimal. Unlike in human health, there is no centralised data source for global animal vaccination rates. No organisation has a central role like the WHO and not all governments collect data. Instead, a variety of sources must be consulted, such as:

- World Organisation for Animals (OIE) provides self-reported Member State data through their WAHIS database.
- Surveys by academics, charities and others provide some information about sectors, such as the UK's Agriculture and Horticulture Development Board report 2018 on use of vaccines in dairy and beef cattle production, the 2007-2008 APHIS survey of US beef operations, or the annual People's Dispensary for Sick Animals (PDSA) Animal Wellbeing (PAW) Report.
- Company sales figures provide a general understanding of markets but cannot be used for direct correlation and robust accuracy. In particular, autogenous vaccines for pigs, poultry and fish are common many parts of Europe and the US, meaning that analyses using commercial sales figures may not be entirely representative.

When these data sets are reviewed together, some common themes to rates of vaccination globally are observed:

- **Vaccination is extensively used in large operations** for pigs, poultry and fish globally. Rates are generally over 80% for Europe, USA, South Africa, Australasia, East Asia.
- **Backyard/smallholder producers have low-to-negligible rates**, particularly in Sub-Saharan Africa, Asia and South America, unless there are publicly financed campaigns. Rathod *et al* (2016) surveyed uptake of vaccines by Indian dairy farmers finding that 86% of farmers believed vaccination was relevant to production³, however, vaccine uptake was low unless the locality was visited by a vet carrying out sponsored vaccination. The Indian government finances vaccination schemes against foot and mouth disease (FMD), brucellosis, and peste des petit ruminants (PPR), which accounts for use of 219 million doses over 2 years but there is little evidence of sustained vaccination. A World Bank survey of livestock farming in Tanzania (2013) showed that less than one-third of all family-owned livestock are vaccinated⁴.



- Cattle vaccination is driven by financial prioritisation and risk assessments,** resulting in partial vaccination of herds and, in some regions, a focus only on life threatening diseases (e.g. Sub-Saharan Africa). A survey of 395 cattle farmers in Ireland and the UK showed that 65% of farmers did not vaccinate against calf pneumonia and only 20% vaccinated all stock⁵. In the UK, only half of all breeding cattle were vaccinated against BVD⁶. In addition, the US Department of Agriculture (USDA) surveyed beef operations in 24 states, finding 68.9% vaccinated some cattle/calves, however, when focused on adult cattle and young breeding cows, this fell below 40%⁷. In Australia, an analysis of Northern Territory cattle farmers found only 15-29% vaccinated against clostridial diseases in 2015⁸; similar patterns have been found in the EU.
- Pet vaccination in developed nations is high, but herd immunity may be at-risk.** Companion animal ownership is high in these regions and owners will invest in pet care. As a result, overall vaccination rates are reasonable-to-good, but warning signs are emerging. In the UK, 25% of dogs have never been vaccinated⁹ and in the US, 17% of owners thought vaccination was unnecessary¹⁰. There are concerns in Europe and the USA that the levels of vaccinated dogs and cats has fallen below levels necessary for herd immunity¹¹ (in the UK it has decreased by 7% since 2011¹²). The EU equine flu outbreak in revealed that only 48% of UK horses were vaccinated against equine flu¹³. In Finland, research found routine vaccination of competition horses declined in age and that 55-60% of all horses were not vaccinated against equine flu¹⁴.
- Pet vaccination in emerging economies, especially in Asia, is generally negligible.** Some vaccination of individually owned pet dogs happens in urban areas. Rabies vaccination campaigns for stray animals also occurs in areas of East Africa and South Asia.
- Official disease control programs can result in sporadic uptake,** but this is not always sustained. In India there is patchy vaccination against rabies despite the government signing up to a national control programme in 2014, and it is estimated that only 15% of dogs are vaccinated across India¹⁵. The state of Goa, however, has been successful in getting 70% coverage rates for rabies vaccination of dogs and halting deaths there¹⁶. In Saigon, 41% of dogs were vaccinated¹⁷. There is a worse picture in Sub-Saharan Africa with only 0.5% of dogs vaccinated against rabies in Malawi¹⁸. In South America there has been a large investment in sustained vaccination against rabies in dogs¹⁹ and FMD policies supporting sustained vaccination mean high rates of vaccination.

These themes provide valuable insights for vaccination policy development. But, more data collection on vaccination by governments and international organisations could help identify additional insights and lead to more informed decisions by policymakers.





Economic Barriers



Users

Generally, the cost of veterinary medicines is borne by animal owners across low- and high-income economies. Vaccination against diseases subject to control may receive some public funding and some insurance schemes for companion animals can mitigate costs, but these systems are not widespread. So, finances are a significant factor when deciding whether to vaccinate.

For example, rabies vaccination coverage in Malawi correlates with income²⁰, pet owners in India make vaccination decisions primarily based on cost, and 20% of UK pet owners cited expense of vaccines as a reason for not vaccinating their animals²¹.

For farmers in low-income countries, even small numbers of livestock represent significant investment, which is why these farmers are motivated to protect their animals' health to deliver greater profit.

However, it can be difficult for farmers to invest their limited resources against a disease which may not occur, especially in young animals that have not yet reached productivity. In addition, disease treatment options can often be cheaper, more readily available and easier to use than vaccines.

Direct contact and advocacy for vaccination from other farmers, local veterinary paraprofessionals and veterinarians increases vaccines use and positive personal experience leads to re-vaccination²².

Experience shows that providing free vaccine does not encourage sustained vaccination by farmers, but providing an affordable supply empowers local communities to take responsibility for vaccination.

The exception is areas where animals are community owned rather than individually (e.g. free roaming village dogs and pastoralist cattle herds). In this situation, good vaccination uptake requires free or subsidised programs. For example, evidence shows canine rabies vaccination in Africa requires provision of sponsored vaccination campaigns²³.

Studies show that farmers in developed regions are driven by cost when evaluating vaccines.

- Cattle farmers in the Northern Territory of Australia affected by lower export returns report not vaccinating against clostridial diseases due to cost²⁴.
- An analysis in the US of why cattle *E. coli* vaccines had low uptake²⁵ showed that farmers couldn't see a tangible economic benefit.
- Economics was found to be a primary motivator in the Netherlands²⁶, where provision of government subsidised vaccine for bluetongue motivated re-vaccination.
- UK sales figures show that cattle vaccines sales slumped when milk prices fell²⁷.



Larger, multi-site operations may trial a vaccine to inform final decisions. However, small-to-medium size operations cannot generate this data and therefore decision-making often relies on the farmer's subjective 'risk perception' versus data-based assessments. This can lead to conservative decision-making where treatment is often considered more cost-efficient than prevention since it provides a reliable backstop if disease occurs.

Veterinarians can play a role here by offering regular health plan consultations and incentivizing the uptake of vaccines. For example, some vets in the UK are promoting the BVD national campaign eradication campaign by offering reduced vaccines as an incentive to vaccinate²⁸.

Increased disease monitoring by governments, universities, and other organisations could also provide epidemiological data that helps farmers make better informed decisions, which could increase vaccination in times of high-risk and avoid overreliance on treatment.

Food suppliers and trading standards could also incentivise vaccination by giving higher return or special labels for products from vaccinated animals. This currently happens in beef from FMD vaccinated cattle in South America and for eggs from salmonella vaccinated hens in the UK. This can also improve public health as Liverpool University "attributes a dramatic fall in the number of [UK] salmonella cases in humans to mass vaccination programmes in poultry."²⁹

Governments could also incentivise farmers to adopt vaccines that offer public health benefits, but no direct economic benefit, with temporary subsidies. This could support initial adoption (and spur development by offering a reliable market) while allowing for programs like special labels to form, which offer a more sustainable, long-term economic benefit.

Pet owners also often make cost-benefit choices based on perceived risk of illness. For example, an owner may decide to vaccinate their dog since it plays with other dogs, but not vaccinate their cat because it only goes into the garden. They set this perceived risk against the cost of an annual vaccination.

In the UK, the British Small Animal Veterinary Association found approximately 25% of dogs and 35% of cats receive no primary vaccination course, the lowest level they have recorded and below herd immunity levels³⁰.

The 2019 equine flu outbreak in the UK revealed that approximately 50-60% of horses were partially or totally unvaccinated. Horse competitions have vaccination requirements; however, some are voluntary, and it is clear owners of occasional or non-competing horses make similar cost-benefit judgements.

Animal charities in the UK and US run subsidised 'pop-up' vaccination clinics in lower income areas which encourages uptake, but these may not be regular, sustained efforts.

Recommendations to overcome economic barriers related to users:

1. **Improve affordability of sustained vaccination.** In low-income regions, this could include subsidies or incentives from governments, NGOs, suppliers, etc. In high-income regions, governments or veterinarian practices could offer incentives (e.g. special prices) for priority diseases or repeat vaccinations.
2. **Systematic research** into the motivations of farmers to vaccinate, use of big data to support cost-benefit analyses and how to create accessible cost-benefit analyses.
3. **Increase disease monitoring** to provide more epidemiological data to farms and encourage vaccine adoption in higher-risk areas.
4. **Direct advocacy to farmers** with clear examples of economic benefits of vaccines in comparison to treatment.
5. **Offer incentives for adopting vaccines that deliver public health benefits** but do not provide economic benefits for producers. This could include short-term/temporary subsidies and, in the long-term, special labels or programs that provide higher return for products from the vaccinated animals.
6. **Train veterinarians, paraveterinarians** and, in more isolated areas, local community health workers to include vaccination as part of herd health plans.
7. **Free rabies vaccination programs** in developing nations to support eradication.
8. **Regular, subsidized pet 'pop-up' clinics** offering vaccinations and other pet health services in low-income neighbourhoods or regions.
9. **More information to pet owners** about the risks of non-vaccination and the promotion of proactive prevention and holistic health.
10. **Increased community work to promote pet health** by local veterinarians.





Manufacturers

Vaccine development is a long, complicated and expensive process.

Vaccines are manufactured using biological starting materials with the key ingredient often originating from infectious material. This carries risk that is mitigated by specialised handling, personnel and equipment. High standards must be applied from the start to maintain sterility throughout and some transmissible agents need specialized containment facilities.

Each vaccine active ingredient is unique, and its safety and fitness must be established before further development. In addition, developing genetically engineered vaccines requires additional levels of specialism and expertise.

Vaccines also require an extensive, secure cold chain network to reach point of sale, while variations in disease agents across regions mean local strains may require specially tailored vaccinations for effectiveness. Finally, before entering any market, products must be registered and approved by regulatory authorities (see 'Regulatory Barriers' section for more detail).

Altogether, this can make it quite expensive or simply financially impossible to enter certain vaccine markets. For example, in India there are very few authorized cat vaccines due to the very small market size and potential compared to high costs for product registration and importation.

For emerging diseases, the lack of a long-term market and clear regulatory pathway may inhibit the development of vaccines. Vaccines against diseases that are high-risk but not yet endemic or for minor use/minor species are financially unsustainable if the burden falls to industry alone.

During outbreaks, especially for an emerging disease, early communication between public and private sector can help deliver a more cost-effective control strategy for both sides. If governments prefer a control strategy through vaccination, companies can accelerate development or manufacturing efforts. If another control strategy is selected, companies avoid investing in vaccines that are unlikely to be used and can focus on other tools to help with control.

Even better is joint planning between public and private sectors for emergency scenarios, including vaccine bank agreements, before an outbreak occurs. This provides greater predictability for companies, enabling better investment in solutions.

Finally, emerging technologies, such as genomic vaccines, could offer ways to develop vaccines at a lower cost for manufacturers.

Recommendations to overcome economic barriers related to manufacturers:

11. **Mitigate research costs** by purchasing skills and/or completed research or creating partnerships with smaller companies and academic spinoffs.
12. **Contract specialist manufacturing** (e.g. clostridial, FMD vaccines) to existing firms that specialise in this area versus building in-house expertise.
13. **Form partnerships across regions.** Middle sized companies with regional portfolios have opportunities for expansion by working across regions e.g. South American companies with Asian and Chinese companies to fill market gaps and pick up smaller markets more attuned to their portfolios.
14. **Subsidies may be needed** to produce more affordable vaccination that recoups development costs.
15. **Vaccine banks can be a solution** for emergency products. There are regional banks (e.g. EU vaccine banks), but benefits are limited by the sustainability of the model which involves regional partners purchasing products with finite shelf life. Government/industry partners funding maintenance of banks of the starting actives (antigens) with options to use as the need arises or release products for purchase by countries outside the region on a need basis might be more sustainable.
16. **Early public-private sector communication on disease control measures** during an outbreak can help companies either accelerate vaccine development or avoid unnecessarily increasing efforts if vaccines will not be widely used. This ultimately helps companies focus on delivering the preferred tools for control.



Government

Livestock contributes up to 40% of the global agricultural GDP³¹, making animal health part of the foundation of economies worldwide.

Despite this, government budgets for animal health are universally a small fraction of the amount dedicated to human health.

This is true in both high- and low-income economies, but the impact is greater in the latter. Low-income nations face greater disease threats and may have limited capacity to implement preventative practices, which means authorities must constantly re-prioritize limited resources to address ongoing endemic diseases or epidemic outbreaks.

For example, the Indian government currently prioritises livestock vaccination over vaccination of dogs against rabies and centrally funds schemes against FMD, brucellosis, PPR, all while co-funding veterinary infrastructure alongside regional governments. This leads to poor central coordination and little evidence of sustained vaccination success³².

Cooperation programs with clear objectives and diverse, reliable funding can build sustainable models for not just disease control but possibly eradication.

The rinderpest eradication was funded not just by infected and at-risk countries but also the European Development Fund and EU countries. The FAO's Technical Cooperation Programme (TCP) then allowed countries to counter new outbreaks when the original funding was finished.

Co-funded or cooperative financial models are potential solutions for governments in high-income economies too. The EU fund model for animal health is co-funded by farmers and government. Contributions to the fund by stakeholders differ depending on disease status and risk control measures by stakeholder partners.

This acts as a positive incentive to farmers to maintain healthy animals by using good husbandry and disease control rather than giving a financial penalty for having infected animals.

Importing nations could also better safeguard food supplies and public health by co-funding vaccination programs in exporting nations that may not fully vaccinate. This could be done through development assistance programs and offer a 'win-win' of better animal health in the exporter and a better protected food supply in the importer.

Between nations or regions, tariffs can also raise the price of vaccines and make export markets unviable. Very few cat vaccines are available in India and a primary reason they are not supplied by global manufacturers is the import tariffs are high compared to the small nature of the market. The EU, recognising the importance of animal vaccines, allowed states to reduce tax on supply of animal medicines in 2018 and is working towards a zero rate³³.

In addition, countries/regions could allow vaccines from their banks to be provided to other countries or regions during times of need to improve disease control during outbreaks.

At an Inter-Governmental level, there is also a major disparity in funding between human and animal health. The OIE is a lean, centrally-organized entity working through national/regional networks with a budget of €30.3 million, as of 2017³⁴. The World Health Organisation's (WHO) 2018-2019 budget is \$4.42 billion³⁵.

Recommendations to overcome economic barriers related to government:

17. More recognition of the importance of animal health leading to greater flexibility in partnerships and resource sharing by governments and IGOs at the ground level.

18. More cooperative funding models drawn across a range of stakeholders. For example, high-income regions could contribute resources and experience in recognition of the value of growing markets, while international funds provide immediate short-term responses.

19. Cooperative funding can also support knowledge sharing. The database DISCONTTOOLS and the international research consortium, STAR-IDAZ both grew out of EU funded projects. Both are now funded by a range of stakeholders drawn from global industry, research bodies and NGOs. There are also various limited companies/trusts funded and commissioned by the farming industry groups to carry out research (e.g. Agrisearch Northern Ireland, Agri research Ireland/UK).

20. Removal/decrease in government taxes on vaccines leading to lower user cost.

21. Promotion of proactive disease management by providing financial benefits to farmers adopting vaccination and hygiene measures to manage flock/herd health rather than delivering financial compensation for flock/herd loss during disease eradication programmes.





Political Barriers



Trade

Vaccination can be an extremely effective way to counter an ongoing disease outbreak. However, it may often be regarded as an emergency measure instead of a front-line tool due to trade implications.

Vaccines cannot always provide 100%, guaranteed protection for every animal in a population. Even in vaccinated animals, there can be some risk of disease transmission.

As a result, countries may simply choose not to accept vaccinated animals or products from vaccinated animals to prevent an infection from entering their borders. This can push nations with infected animals to prioritise culling measures over vaccination during an outbreak, which creates serious welfare implications.

Selective eradication measures and animal movement restrictions in the short-term to reduce infection pressure followed by mass vaccination in the long-term can be a more welfare friendly measure.

This approach has been successful in South America for FMD eradication and trading of vaccinated animals is now possible (e.g. to the US). Such approaches need long-term coordination, constant risk evaluation and political agreements.

Europe is becoming more open to such approaches. The Netherlands allowed ring vaccination during the 2001 FMD outbreak (although “vaccinate to live” policies in the face of epidemics have yet to be deployed in Europe), and several EU nations (e.g. Germany and Netherlands) now allow vaccination alongside biosecurity and movement restrictions for BVD control. Canada also includes vaccination in its FMD contingency plans³⁶.

Internationally, the OIE and the FAO play key roles in coordinating information about disease status and measures being used and set rules around trade. However, some nations may exploit this information to raise trade barriers to vaccinated animals, which can put these important roles in jeopardy.

Recommendations to overcome political barriers related to trade:

22. **Provide enabling legislation** to encourage vaccination. For example, the new EU animal health legislation allows national flexibility to use vaccination alone, in combination, or not at all for many diseases.
23. **Offer a tiered approach to disease eradication** with an openness to implement vaccination as a first-line tool alongside biosecurity and movement restrictions.
24. **Provide positive incentives for disease reporting** and avoid punitive measures that may depress incident reports.
25. **Create innovative public facing communications** to promote and enable vaccination (e.g. visual presentation of disease incidence vs. vaccination rates).





Policies and Implementation

Depending on policies, structures and implementation, governments can act as an impetus or a hinderance to vaccine availability and uptake. For example:

- Implementing health and vaccination policies requires dedicated government departments, legislation, funding and veterinary service infrastructure. Without all these components, policies are often partially or minimally implemented.
- Poor remuneration and lack of career structure in some low-income areas, especially in Africa, means a lack of trained government veterinarians. As a result, often large areas won't have access to trained staff able to deliver vaccination.
- Official vaccination campaigns are well-intentioned, but often struggle with coordination; sustainability; and proper product sourcing and administration.
- In many nations, it is a legal requirement that only veterinarians procure and administer vaccinations. This limits access and may not be appropriate for products with low-risk profiles. One notable exception is the UK, whose risk-based system allows pharmacists and suitably qualified staff to supply directly.
- Globally, government animal health departments prioritise livestock health and rarely embrace companion animal health issues other than horses.

In emerging economies, contracting vaccination campaigns to NGOs or private groups could be effective, but officials are often reluctant to relinquish this responsibility. This hinders financing and efficient campaign coordination while limiting opportunities for private, non-government veterinarians to build stable, sustainable practices.

Good examples of NGO vaccination and disease management exists in Asia for rabies control. Mission Rabies, working with local officials in Goa, India, has successfully vaccinated local dogs to a level that, if sustained, could eliminate dog-mediated rabies in the area.

Rabies efforts also demonstrate how, although 'One Health' principles are encouraged globally, it still is rarely implemented at a ground level. Although safe, effective vaccines are available, dog vaccination is not prioritized. Reduction, and eventually eradication, of rabies in dogs would save on human rabies medicines, which are in short supply, and cost less than human treatments.

In the Philippines, government agencies have shifted funds across human and animal health agencies to support more dog vaccination. This is an encouraging move, but rarely seen in most other regions or countries.

Recommendations to overcome political barriers related to policies and implementation:

26. **Strengthen the veterinary career structure**, such as by outsourcing more official animal health activities to local private veterinarians.
27. **Use veterinary paraprofessionals and other trained professionals** to expand the amount of people who may legally supply and administer vaccines.

28. **Create more authentic 'One Health Initiatives'** by increasing cooperation across internal government departments as well as regional/global agencies. Also improve recognition of companion animal health in this space.

29. **Improve recognition of companion animal health** as an essential part of any One Health strategy and an important element of good public health.

30. **Increase interaction and resource sharing** between OIE, FAO and WHO. These organisations have the outreach, influence and technical know-how that, if combined, would support local governments in maintaining vaccination levels.

31. **Promote preventative medicine** as a first line of defence against animal disease at international, regional and domestic levels.



Manufacturing, Approvals, and Procurement

Manufacturing and procurement practices within a country or region can often be subject to various political influences.

Global companies seeking to establish good quality manufacturing may be pushed to select government facilities or laboratories as the local partner. NGOs seeking to undertake a vaccination campaign may be pressured to procure the medicine from a local producer instead of a multinational company, regardless of any quality or production differences. Likewise, vaccine research by government agencies can be subjected to political interference.

These types of pressures can discourage NGOs and companies from further engagement in that country or region.

Having an official, well-functioning regulatory system develops markets, ensures safe medicines, and stimulates competition. East Asia is an example where the growth of regulations has paralleled increasing standards and confidence of local producers and stimulated interest from global companies.

However, medicines regulations are also sometimes used to protect local markets. Political actors may push regulators to process applications from foreign companies more slowly or request information without a scientific basis. Tariffs and import rules may also be as a form of protectionism for local companies.

Strict, lengthy quarantine requirements also exist in some markets. These protect against the possible introduction of diseases but can impact supply as it limits the shelf life of products once they enter the market.

Recommendations to overcome political barriers related to manufacturing, approvals, and procurement:

32. **Promote 'arms-length' government control** of vaccine research, manufacturing and regulation, allowing a competitive market to develop.
33. **Discourage 'protectionism' in the vaccine market** that can hinder availability of products and distort markets.





Vaccine Research and Development

Vaccine research and development is a lengthy process requiring considerable investment. Just a few of the areas of complexity and expense include:

- Conventional vaccines are developed from disease isolates, and engineered vaccines by some degree of biological manipulation. All types require specialist researchers and facilities to mitigate biological risk.
- Any vaccine candidate must have quality characteristics which allow scale up of manufacturing and consistent production.
- The manufacturing process is about controlling biological growth (an inherently variable process) in a consistent way. Consistency of production is checked on each batch of the final product by testing for safety and potency. Measuring potency traditionally involved animal tests, but with non-animal tests now prioritized, this means development work on existing products must be done to revise potency test models.
- Safety and efficacy trials can involve expensive animal sourcing and housing costs, while developing relevant efficacy models is difficult and time-consuming.
- Vaccines based on live or genetically manipulated organisms require extensive technical packages to demonstrate safety and genetic stability.
- Many conventional vaccines are effective products, but often require tweaks in formulation, dosage, presentations, shelf life, temperature stability, transport, etc. to become relevant in different regions and markets.

These steps are all important processes to developing a beneficial vaccine, but highlight why it can be difficult to achieve.

On a more basic research level, the diseases for which vaccines do not exist are complex and multi-factorial and some disease strains constantly change (e.g. flu), which makes the vaccinology challenging.

Developers must also understand the disease agent at a molecular level and whether there are regional/species differences, otherwise vaccines developed in one region may not work in another region.

In the past, vaccine development used only basic understanding of the key immunogenic components, however, a more detailed understanding has enabled more technological advances:

- Platform or cassette technology: in which the key immunogen is slotted into a carrier which is usually a virus (vector). The safety of the carrier virus is established once. Different immunogens can be slotted in and, providing the insert is stable, this speeds up development.

Technical & Scientific Barriers



- DNA and RNA vaccine development: DNA/RNA vaccines could deliver targeted immunogenicity with fewer side effects although more examples and data are needed to judge this with absolute certainty.
- DIVA vaccines: Vaccinated animals raise an immune response similar to the response to the disease itself. This is a challenge for disease management since it is necessary to know if an animal has been exposed to the disease or simply vaccinated. Genetic manipulation of a non-critical immunogen in the vaccine changes the immune response so vaccinated animals can be distinguished from infected animals. These are called DIVA vaccines.

To target immunogenicity accurately it is also necessary to understand the disease agent at a molecular level and whether there are regional/species differences, otherwise vaccines developed in one region may not work in another region.

In addition, it is particularly important for eradication schemes to understand wildlife reservoirs of disease and how they interact with the target species and the environment. This was important in the eradication of Rinderpest and vaccination of wildlife reservoirs has been important in rabies control in the EU.

Wildlife vaccination can also support biodiversity. In the U.S., oral vaccination of prairie dogs protects a key food source for the black footed ferret, one of the most endangered mammals in the country³⁷.

But, designing wildlife vaccines is very challenging, particularly in relation to delivery mechanisms. The development of oral bait rabies vaccines advanced vaccination of foxes and racoon dogs. TB vaccination of badgers in the UK has been hampered by use of an injection vaccine.

Diagnostic agents and assays play key roles in achieving targeted vaccination, not only in eradication campaigns but also in pet animals. They can also play important roles in differentiating vaccinated animals from infected animals.

However, diagnostic agents/assays attract less interest than vaccines and are generally under resourced. Ideally, vaccine specialists would develop appropriate, complementary assays or provide information about suitable assays.

Combining antigens in one product (to protect against several diseases in one step) may also have huge benefits for field use but must contain the right mixes. Proving safety and efficacy of multi-component vaccines lengthens the development process and increases costs further.

Recommendations to overcome technical and scientific barriers:

- 34. Companies and government regulators should collaborate** from the early stages of development to give direction and focus on licensing requirements. This enables efficient targeted research to support successful licensing of the vaccine candidate.
- 35. Practicality in the field should be prioritized** early in development, potentially including customer surveys, to ensure a vaccine can be effectively administered and meets the intended purpose.
- 36. Continued innovation development** (e.g. DNA/RNA, platform technology, DIVA vaccines, etc.) can deliver more controllable, consistent products with greater value to users and governments.
- 37. Increase basic research** on molecular basis of infection agents as well as immunogenic characteristics to allow more targeted vaccines and field vaccination.
- 38. Greater coordination and knowledge sharing** will progress scientific research more quickly and efficiently. For example, STAR-IDAZ consortium coordinates ongoing research on vaccinology and diagnostics.



Regulatory Barriers



Non-existent or Inexperienced Systems

Both governments and industry benefit from a clear, predictable regulatory framework. It helps guide industry during vaccine development, ensures authorised products are safe, work consistently, and provides an official 'licence' for sale.

In developing regions, some nations have an inadequate or non-existent regulatory system for veterinary medicines. This prevents products from receiving an official licence and largely prevents global companies from engaging in the market. This then creates a large market for falsified, illegal and counterfeit medicines.

In some emerging economies, regulators may lack necessary expertise or experience, which means vaccines that use newer technologies are slow to be authorized.

Allowing companies to submit parts or all of the data package from authorizations by another trusted regulator could speed up the process and form the basis of official accelerated reviews. But it will be important to make sure the benefit/risk analysis is still appropriate under local conditions, particularly for efficacy where there may be different husbandry systems and disease patterns.

Recommendations to overcome regulatory barriers related to non-existent or inexperienced systems:

39. **Improve sharing of knowledge and best practices** between regulatory agencies, such as in forums like VICH or through secondments (e.g. newly formed agencies to existing ones).
40. **Allow companies to submit part or all of an authorized data package from another trusted regulatory authority** when seeking a license for novel products.





Risk-Adverse and Non-Collaborative Processes

Overly risk-averse primary medicines legislation not only increase the burden on industry, it leads to inflexible regulation that inhibits product development as well as products coming to market.

It can also prevent regulators from reacting quickly to emerging diseases and stifles innovative approaches to licensing novel products. It can even impact on how information is presented in product literature.

Requirements and guidance supporting primary legislation can be outdated, inaccurate and/or irrelevant if it is not produced in a timely way with consultation across industry and experts. This also inhibits development and can cause products in the pipeline to be abandoned. Distrust between regulators and industry leads to a lack of knowledge sharing, including exchanges with the human field, and joint problem solving.

Wide knowledge sharing requires trust, which can be built through regular meetings between industry and regulators, problem sharing and training. This happens within the EU network (e.g. interested party meetings and draft guideline consultation processes) and US, which helps produce science-based guidelines more quickly. Global technical networks such as VICH also involve industry/regulators and allow the development of internationally harmonised guidelines, but do not extend to training.

Recommendations to overcome regulatory barriers related to risk-adverse and non-collaborative processes:

41. **Primary legislation should be open and broad** supported by more detailed technical guidance put in place by experienced regulators.
42. **Guideline development should be done by experienced groups** of regulatory and industry experts in a timely, transparent manner.
43. **Promote widespread knowledge** sharing that utilizes all avenues such as one-on-one discussions, open forums (e.g. VICH), secondments, etc.
44. **Build an atmosphere of trust** between regulators in different regions as well as between regulators and industry. This will facilitate better knowledge sharing.
45. **Industry and regulators should host regular meetings** focused on problem sharing and training and flexibility towards labelling and product literature information.



Bureaucracy

Regulating a medicine covers its lifetime from development to authorisation, manufacture, batch release and market surveillance. For industry to serve the market, the regulator must have appropriate processes and routes enabling all these activities.

Good administrative processes and communication channels; up to date technology; flexible timelines; and specialist administrators and scientists are key to enable quick and efficient authorisation even in times of emergency.

Overly bureaucratic systems hinder communication, while slowing internal processes and adoption of decisions. In turn there is less industry engagement for advice and marketing of new products is slower.

Networks that enable regional mutual recognition of authorisations mean that companies acquire wide market access from one application process, while the burdens on national bureaucracy are lowered. GALVmed has supported the development of a similar system within East African countries while the Zazibona network is taking hold in South/West Africa. There are embryonic steps towards this in Asia/Thailand/Vietnam.

Recommendations to overcome regulatory barriers related to bureaucracy:

46. **Agencies need to be well-resourced** with administrators and specialists with continuing professional development.
47. **Promote open communication channels** to allow better access to administrators and specialists.
48. **Submission processes can be streamlined** using up to date IT, electronic submissions, issue of documentation.
49. **Provide support to emerging economic regions** to establish mutual recognition. These could also use accelerated reviews only re-evaluating all of the authorized data package from another trusted regulatory authority.
50. **International networks, (e.g. VICH) should work towards mutual recognition** across regions as well as within regions.





Staffing and Internal Knowledge

Vaccine regulation, like vaccine development, requires specialists with significant expertise, while responding to outbreaks with appropriate risk-benefit judgements requires experienced regulators. Staff retention and recruitment are essential for agencies.

However, both are continual challenges (as they are in all organisations) and can be hindered by hierarchy, culture, politics, budgets, etc. For example, the U.S. Center for Veterinary Biologics (CVB) has had a flat budget for over a decade and been subject to hiring freezes, leading to some positions going unfilled after staff departures. This can be a challenge since CVB must approve all vaccine batch releases, which means approvals can become backlogged.

Well-staffed agencies with robust expertise and flexible procedures will be well-positioned to assess the next generation of vaccine innovation such as new presentations (e.g. vaccine tablets), high-tech administration techniques, plant-based manufacturing, DNA/RNA technologies, etc. These agencies will have the scientific expertise and regulatory experience necessary to develop regulations, adapt to new technologies and assess the data packages. They will also have the personnel available to proactively speak with companies about novel products in the pipeline and prepare for submissions. Without these components, regulators could act as a bottleneck and slow these products coming to market.

Authorities that assess the capability of their regulatory body to respond to increased demand for medicines, especially newer technologies, can ensure it has adequate funding, staff and internal knowledge.

Recommendations to overcome regulatory barriers related to staffing and internal knowledge:

51. **Authorities should conduct internal audits** of staffing levels and their knowledge/capacities to ensure both are at adequate levels.
52. **Implement staff retention programs** to ensure relevant competencies and important institutional knowledge/experience are not lost.
53. **Proactively build frameworks to assess innovations in the pipeline** to ensure the technical and regulatory expertise and processes are in place for submission.



Submission and Assessment

Authorization routes allowing reduced data packages under specific conditions allow companies to provide products for emerging diseases, emergency situations, exotic diseases and therapeutic gaps more quickly.

Safety is paramount, particularly for the key animal categories (e.g. young animals or breeding animals). This safety data, alongside manufacturing information and short-term efficacy, is sufficient to allow a provisional marketing authorization, while long-term safety, efficacy and shelf-life data are provided later for a full marketing authorization.

The US and some EU countries have such routes allowing quick availability, such as the provisional marketing authorisations for bluetongue vaccines in the UK and France that preceded centralized EU exceptional authorisations. New U.S. legislation has also reduced lead times for vaccines in emergency situations.

The EU centralized system has accelerated procedures and exceptional authorisations as a mechanism, which was given a clearer legal basis in the new legislation, since in the past these could be overly bureaucratic and not as quick as national procedures, such as during the EU bluetongue emergency in the mid/late 2000s.

There are numerous cassette, platform, and engineered vaccines on the EU market, so regulators are experienced in the risk/benefit assessments. The new EU legislation could mean this is translated into a revision of requirements/processes.

Mechanisms such as antigen master files are needed for stand-alone data packages for cassettes/vectors to prevent repetition between submissions and assessments. Similar issues apply to updating vaccines with new strains and multi-component ranges. The EU has moved towards improvement, but more progress is needed.

Recommendations to overcome regulatory barriers related to submission and assessment:

54. **Create a more pragmatic approach** by EMA/EU committee and administrators using flexibility within EU legislation to provide a streamlined, case-by-case evaluation of need.
55. **Develop innovative solutions to reduce re-submission of data** such as the antigen master file concept.
56. **Consider revision or redevelopment** of requirement and guidelines based on risk evidence.



Harmonized Standards and Technical Requirements

The lack of a harmonized approach across Europe to regulating autogenous vaccine manufacturing and supply has led to an increase in the number and volume being supplied and this disincentivises commercial vaccine producers to invest in authorising minor use products.

Lack of harmonized technical requirements and manufacturing standards at the global level deters research and development, reduces availability of products and can be a form of protectionism. For example, master seeds cannot be easily moved outside the region of testing because the tests may not be globally recognized. This means re-testing or establishing new master seeds in other regions.

The manufacturing standards global organisation, PIC/S is a tool for mutual recognition of standards and inspections. Its technical equivalent, VICH includes industry and its guidelines supersede local guidelines in member countries. But the process can be slow, often due to the complexity of issues.

Recommendations to overcome regulatory barriers related to harmonized standards and technical requirements:

- 57. **Monitor volumes of autogenous vaccine production** and recommend conversion to a full market authorization after certain levels of production.
- 58. **Translate discussion into policy** in global networks like VICH and PIC/S. This needs transparent timetables and greater representation from experts.





Field Use Barriers



Availability

Currently there is more global demand than there is vaccine supply. The reasons for this are numerous and nuanced, but a few include:

- Niche vaccines (e.g. minor diseases and minor species such as turkeys and ducks) cannot turn a profit after cost of registration, manufacturing, delivery, and ongoing maintenance.
- Some vaccines are only produced by one or two companies.
- Assuring supply in emerging economies is difficult due to lack of quality local manufacturers and adequate cold chain transportation and storage after point of sale.
- Investment cannot be recouped in smaller markets after costs for registration, manufacturing.
- Local producers that have grown from government/academic institutes often lack the capacity, discipline and rigor of commercial production³⁸.

However, the situation is improving. Multinationals are now increasing their global production capacities, acquiring sites in expanding market areas such as Asia, India, China and Latin America but there is a lead time of 5-10 years given the complexity of biological production. Middle-sized companies with conventional vaccine portfolios covering ranges of diseases find it easier to break into these markets than large multinationals with high technology vaccine portfolios.

Partnerships of local producers with multinationals based on technology transfer and advice agreements are also leading to production of quality vaccine at local level. There are ongoing examples of this such as the Botswana Vaccine Institute and the GALVmed project with Hester Pharmaceuticals to develop a reliable supply chain of poultry vaccines for rural India³⁹.

Recommendations to overcome field use barriers related to availability:

59. **Create Public-Private Partnerships** where government receives a quality vaccine while the producer receives a guaranteed market. This provides sustainability for both parties.
60. **Build partnerships between local and global manufacturers**, particularly in emerging economies, to raise quality standards and built a more sustainable, lucrative commercial market that can attract more companies.
61. **Offer financial incentives and other support** from the government in smaller or minor markets in order to support a steady supply of vaccines.





Research and Development

It is no surprise that there are diseases without a suitable vaccine. The European Technology Platform for Global Animal Health (ETPGAH) in 2012 identified African Swine Fever, tuberculosis in cattle and brucellosis as primary examples. Each are unique and present specific, difficult challenges in vaccine development. Addressing these requires greater research coordination and knowledge sharing.

The 2012 ETPGAH work led to the creation of DISCONTTOOLS, which lists ongoing research into disease control including vaccines and diagnostics. It is an open access knowledge resource for international research funding bodies and is linked to International consortia such as STAR-IDAZ.

The 2012 survey showed that availability issues are complex as diseases can be caused by multiple strains and be present in many species. For example, mastitis and brucellosis have vaccines that give only partial coverage of species and strains.

Highlighting these gaps encourages development of new products, but there is no coordinated focus on the many vaccines already available. There are many sources of information on regional availability, but there is no central information site compiling availability of authorised products globally.

This can lead to inappropriate use (e.g. assuming local producers provide vaccines against local strains of disease) and inappropriate products remaining on the market.

Finally, significant effort is put into new vaccines or improving existing vaccines for “trans-boundary” diseases, but tropical zoonotic diseases with little effect on livestock economy and little direct risk to industrialised regions are currently underserved. Some form of official recognition of a neglected status could incentivise public/private funding for research based on the example created by the WHO’s official listing of human neglected diseases⁴⁰.

Recommendations to overcome field use barriers related to Research and Development:

62. **Create a global database**, similar to DISCONTTOOLS, covering all diseases and available vaccines, and diagnostics that is regularly updated based on input from industry, researchers and agencies.
63. **Improve accessibility of information** for funding bodies, researchers, industry, and international health policymakers.
64. **Create official listing of neglected diseases and minor markets** to incentivise more funding and research in these areas.
65. **Produce an official acknowledgement of diagnostic knowledge importance**, putting more emphasis on diagnostic agents in research and funding strategies.



Practical Use on the Ground

Getting a medicine to an animal and successfully administering it is the goal for vaccination. To be successful, the vaccine must be relevant to the local situation and still be stable and potent when it is administered.

Most vaccines need cold chain storage to be stable and potent at the point of use. Refrigerated transport and storage is expensive and requires electricity. Remoteness of farming communities and lack of practical infrastructure such as transport and refrigeration often mean vaccination is not an option for rural farmers in emerging economies.

When vaccination is an option in these rural, emerging areas, local producers are often favoured to shorten transport. This can lead to use of the wrong product for the situation.

In addition, proper vaccine use is not just an issue for emerging economies or the tropics. For example:

- Northern hemisphere fish farms are remote and the temperatures can fall below optimum temperatures for handling injection vaccines, which increases the risk of user error.
- Extensive, high-pasture farming systems involve traveling long distances to access flocks and herds while keeping vaccines held at a low temperature.
- A recent study in the UK showed that fridges on the farms surveyed didn’t meet specific vaccines storage requirements⁴¹.

It is important that veterinarians understand the principles of correct storage and the need to closely follow use instructions. University curriculums can emphasize these concepts in their veterinary education, but other vaccine handlers (e.g. paraprofessionals) must also receive this information through their training programs.

Vaccine administration can also be improved through new tools or modes of administration that makes the process easier. Currently, many vaccines are given by injection which requires trained operators injecting individual animals rather than dosing through food or water.

Easier-to-use injectors, chewable tablets, mass application through drinking water, and other methods could significantly improve uptake by reducing the amount of labour required.

However, there are legal requirements in many areas for vaccinations to be carried out under the supervision of a veterinarian. This makes the logistics of vaccination in remote communities complicated. It often results in the vaccine schedule not being completed and ultimately wastage of a product in short supply.

These issues are not limited to low-income countries. There are strict legal requirements around who is qualified to vaccinate in most regions. In some countries though, there is flexibility for vaccines administered through food and water or by trained vaccinators.

Giving vaccines at the right times is important to success and individual vaccines will have recommended schedules. Lack of compliance with these instructions is common in the field. Farmers in both low -and high- income countries value the advice of their veterinarian and compliance with schedules is improved by direct veterinarian advocacy⁴². Vaccines administered at the wrong site or by the wrong route can result in ineffective prevention and bad reactions such as abscesses at the site of injection which can lead to downgrading or refusal of animal products.

To be successful a mass vaccination campaign must achieve adequate coverage. This means keeping accurate real time records in the field that are centrally recorded for strategic planning of follow up vaccinations, all of which requires resources and infrastructure. A good example is the use of smart phones for field recording in rabies campaigns⁴³.

Recommendations to overcome field use barriers related to practical use on the ground:

- 66. **Develop more thermotolerant vaccine formulations** that remove the need for cold storage.
- 67. **Train community works or veterinary paraprofessionals** and adapt legal regimes to allow them to provide vaccine services.
- 68. **Train veterinarians and other vaccine handlers** in proper storage, correct use and transport as well as provide comprehensive use instructions and clear labels.
- 69. **Provide easy-to-use electronic recording** that can track vaccination in the field.
- 70. **Offer easier-to-use vaccine delivery systems** such as tablets, food/water administration, needleless injectors, etc. These can provide simpler, lower-risk vaccine administration and reduce training requirements for paraprofessionals, farmers or other vaccine handlers.



Social & Perception Barriers

Negative perceptions and social pressure against vaccination are not limited to one area or social group. It cuts across low- and high-income nations within rural, urban, farming, and other communities.

These negative sentiments typically manifest through general distrust, lack of knowledge, misconceptions, etc. and can be seen in organized anti-vaccination campaigns as well as spontaneous social media messaging.

Negative perceptions of vaccination are not new, but, had largely disappeared in the face of vaccination successes. However, there are signs that these are returning.



Pets

In the early 2000s, concerns about human vaccination alongside 'over-vaccination' of pets led to a re-emergence of anti-vaccination views in the US, Australia UK, followed by Europe.

Industry responded to concerns and developed vaccines with longer immunity thereby reducing the frequency of booster shots as well as vaccine ranges with different ingredients and combinations allowing the vet to vaccinate according to the individual circumstances of the animal.

Regulators, professional bodies and industry provided information to veterinarians and the public about the role of vaccination in protection, emphasising the need for a clinical assessment of the benefit/risk to the animal and global clinical guidelines for the vaccination of dogs and cats were developed by the World Small Animal Veterinary Association (WSAVA)⁴⁴.

These measures seemed to dampen campaigning and encouraged better clinical practice. But, the introduction of social media has created a new forum where one individual experience, often unverified or apocryphal, can spur a cascade of negative, self-reinforcing messages that creates a false image of widespread vaccine dangers.

Endorsement of 'vaccine hesitancy' or outright anti-vaccination by public figures has led to it being ranked by the WHO as a major threat to health and it has affected pet vaccination rates in America⁴⁵.

The Federation of European Companion Animal Veterinary Associations (FECAVA) noted in April 2019 that 25% of British dogs and 35% of cats do not receive or even complete their primary vaccinations schedules. For those that do, only 66% receive boosters. These are the lowest vaccination rates recorded in the UK and may be above the threshold figure necessary for herd immunity of the population⁴⁶.

Veterinarians in other developed nations like the U.S. and Australia also anecdotally report an increase in animal vaccine refusal due to 'hesitancy' or anti-vaccination attitudes^{47,48}.



Recommendations to overcome social and perception barriers in pets:

71. **Proactive rather than reactive communications** campaigns showing positive, real-world examples of vaccine use and success. Campaigns should use modern media and advertising coordinated across all stakeholders (industry, regulators, veterinarians, etc.).
72. **Greater public advocacy** for higher vaccination rates by major, respected figures such as high-level policymakers, Chief Veterinary Officers, NGO leaders, heads of major IGOs (e.g. WHO, UN, etc.), etc.
73. **Promote global and regional vaccination guidelines** from trusted organisations like the World Small Animal Veterinary Association (WSAVA) to encourage greater uptake and continued vaccination by pet owners.
74. **Increased professional and public education** on importance of herd immunity, risks of not vaccinating, and why continued vaccination, even with low disease levels, is critical.
75. **More science in media and journalism** that educates the public about the clear safety and track record of vaccinations.



Livestock

Distrust of vaccination is not limited to pets; it also has a presence in the livestock sector. For example:

- Rural communities in Asia and Africa are often influenced by traditional medicine practitioners who can foster distrust for modern treatments like vaccines.
- Farmers can become concerned about negative economic impacts of vaccines following reports of downgrading of meat from vaccinated animals.
- There may also be distrust of genetically engineered vaccines because of misconceptions and negative publicity about the impact on the food chain and the environment.

In addition, personal or reported bad experienced with vaccines can also build negative perceptions among farmers.

Cattle vaccination in Europe against BVD – a disease affecting productivity and fertility – dropped when there were severe adverse reactions to a specific BVD vaccine in 2010.

The vaccine was withdrawn from the market and the company sponsored investigatory research. There were communications at the time about the reasons for withdrawal and the outcomes of research are in the public domain, however, BVD vaccination rates are still depressed in certain areas.

Regulators and governments need to be transparent about risks and emphasise the role of post authorisation monitoring to overcome distrust in farming communities.

Among the public, awareness of the contribution of vaccination to food safety is low, despite vaccination's indisputable role in a safer food chain. As a result, consumers seeking more 'natural' foods could begin to shun produce from vaccinated animals.

Food suppliers could play a role here, as they are doing for welfare and environmental standards. In the UK, producers have successfully trademarked eggs from salmonella vaccinated chickens. This a lesson that could be taken to other parts of the supply chain to promote vaccine benefits.

Consumers increasing interest in animal welfare also offers an opportunity to build support for livestock vaccination. Campaigns, labels or other tools that can highlight that vaccines offer better welfare through disease prevention could make a significant difference.

The benefits of animal vaccination to the environment is also a relatively neglected area of promotion to the public and could be increased.

Recommendations to overcome social and perception barriers in livestock:

76. **Coordinated, transparent communications by all stakeholders** (regulators, industry, veterinarians, farming bodies, IGOs, etc.) of benefits of vaccines and risk management to counteract negative perceptions.
77. **Promotion of adverse reaction reporting** to livestock owners/farms.
78. **Greater use of personal stories** of vaccine benefits to livestock, farms, etc.
79. **Creation of food labels that promote vaccines** as a critical animal welfare tool and contributor to food safety.
80. **Communicate to consumers the importance of vaccination in animal welfare** to build support among the public.



Annexes



How Does Animal Vaccination Work?

Vaccination harnesses the body's natural defence system by stimulating a protective response without producing disease.

This response, known as the immune response, involves cells, fluids and specific proteins (antibodies) to create an immune "memory." This memory means the next time the body is exposed to the disease, it will be fully protected.

The first time this happens the defence system is "primed", and one or more vaccinations over weeks may be necessary for completion. Usually a re-vaccination is necessary at some point to boost the memory of the protective reaction. It is important that the correct intervals between primary vaccination steps are used to ensure that the primary response is fully "memorized".

It is also important that booster vaccinations are given at the right interval because even though some immune response may remain without the booster it may not be fully protective. The intervals will vary depending on the type of vaccine and the disease it protects against.

When sufficient numbers within a population have been protected by vaccination, disease spread can be slowed down or totally prevented. This is known as herd immunity. However, within any group of animals there will be some that do not respond to vaccination. This means it is important to vaccinate the full herd or flock of animals to maintain full protection of the population.

New-born animals don't have fully developed defences but receive a natural protection from their mothers before birth or, in some species, after birth (e.g. through milk feeding). This is called passive immunity and it will decline over a period of months as the animal's own defences develop.

Passive immunity can interfere with vaccination and this means animals should not be vaccinated until passive immunity has declined. Schedules will vary with individual vaccines, species, diseases, etc. For example, chickens can be vaccinated in the embryo or on the first day of life whereas puppies are not usually vaccinated until 6 weeks of age.

As well as producing an immune response, the body will react to vaccination in a similar but less extreme way as it would to the disease. This means that a mild temperature after vaccination, as well as redness and swelling at the vaccination site, are normal reactions. However, every individual will react differently and there is always a small risk that the reactions will be more severe. This must be set against the benefit of prevention or reduction of the disease itself by vaccination.





Benefits of Animal Vaccination

Preventing disease through vaccination not only protects the health of animals, it strengthens economies, improves farm sustainability, safeguards human health, and helps with responsible antimicrobial use.

Economic Benefits

Healthier livestock improve farmer livelihoods by reducing the economic burden of disease management (treatment costs, lower productivity due to illness, loss of animals, etc.) to farmers, consumers, trade and the wider economy. Greater productivity bringing more profit can lift farmers out of subsistence farming and deliver wider social benefits. For example, the extra income generated by vaccinating against East Coast Fever in Kenya meant farmers had spare income to educate more family members⁴⁹.

Environmental Benefits

Vaccines can help reduce the environmental footprint of a livestock operation. Healthy, disease-free animals process feed more efficiently and are more productive, which means fewer animals are needed to meet consumer demand. The United Nations Food and Agriculture Organisation recently identified vaccines as a technology with “a strong potential to reduce emissions⁵⁰”.

Livestock and pet vaccination also help limit spread of disease to wildlife, which means the wider ecosystem is better protected.

Human Health Benefits

Given that 60% of diseases that affect humans are zoonotic (meaning they spread from animals to people), preventing illness in animals helps protect people⁵¹.

Rabies still kills approximately 60,000 people each year following a dog bite⁵². Global, coordinated vaccine campaigns are working to end this by 2030. In Latin America, this work has reduced human infections from 25,000 in 1980 to 300 in 2010⁵³.

Antimicrobial Use Benefits

Vaccinating animals against infection can reduce the need for antimicrobials. For example, furunculosis was a common disease in Norwegian salmon in the 1980s. Antibiotics were used for treatment until the private sector delivered an effective vaccine. Nearly all fisheries now vaccinate against the disease and the need for antibiotics has fallen significantly.



Vaccine Success Stories

The role of vaccination in the global eradication of Rinderpest⁵⁴

Rinderpest, a devastating cattle disease, was the first animal disease to be globally eradicated and relied upon vaccination for success.

Mass vaccination campaigns began in the 1940s to reduce disease in Asia and Africa. By the 1960s eradication became a goal for Africa, leading to greater coordination and financing by regional and international agencies.

The disease had been largely eliminated by 1979 but complete eradication was not achieved. At the time there was a lack of appropriate diagnostic tests to support surveillance and monitor vaccination. As a result, campaigns struggled to target high-risk areas and evaluate success.

Unfortunately, these initial successes were undermined by complacency in official disease reporting, lack of official surveillance systems and undetected reservoirs of disease in wildlife.

In the '90s the OIE and FAO established systematic eradication plans and global eradication was declared in 2011. Well-coordinated international and regional activities which were key to this success.

These included establishing permanently staffed, centralised project coordination and sourcing funding from international public and private organisations to support gaps in national/regional budgets.

This management allowed global technical networks to support the development and transfer of diagnostic tools to regional laboratories followed by standardisation and commercialisation globally. It also enabled research to characterise the genetic profile of the virus, extending the understanding and modelling of the disease and allowing policymakers to use targeted vaccination.

The development of a highly immunogenic vaccine which could be produced in sufficient quantity and gave long lasting protection after only one shot with no adverse reactions was also a key success factor. Its temperature stability allowed easy transport and field use in remote areas without specialist storage.

The establishment of state official quality control laboratories ensuring local manufacturers sold batches of standard vaccine was also an important factor in the vaccine's success. A change in mindset of state animal health departments led to synergistic partnerships of state veterinarians with private veterinarians and trained community animal health workers which allowed flexibility in campaign logistics and facilitated vaccination in remote areas. This included pilot vaccination exercises, training community vaccinators, building up supply networks, and monitoring herd immunity before launching targeted full campaigns.

Finally, an accredited OIE scheme for surveillance allowed countries to robustly monitor progress towards true freedom of disease.

Vaccination and Reducing the Need for Antibiotics in the Norwegian Fish Industry^{55 56 57}

As fish farming became more intensive in the 1980s, wild salmon diseases became established in fish farms. Vaccines were unavailable, and antibiotics were extensively used to treat disease.

The Norwegian government recognised the need for vaccines and supported vaccine development leading to commercially available vaccines for the major salmon diseases by 1994. These were one shot vaccines for use in young fish with immunity covering the entire salmon growth period.

Specialist equipment was developed allowing individual fish to be vaccinated quickly and safely in large numbers. Nowadays vaccination campaigns are carried out by teams of specially trained fish vaccinators travelling to remote farm sites.

Antibiotic usage in farmed fish has been reduced by 99% since 1981 and in 2016 less than 2 tonnes were sold for fish use. Vaccination played a key role in reducing the disease burden in modern fish farming, in combination with good hygiene practices.

Norway has become one of the biggest global producers of farmed salmon while reducing their need for antibiotics by maintaining strict vaccination protocols and good hygiene practices on fish farms.

Eradication and Control of Aujeszky's Disease^{58 59}

Aujeszky's disease is a worldwide disease of pigs caused by a virus which is highly infectious and persistent once herds are infected. It has major economic consequences since infected herds are less productive.

Vaccines which protected against disease had been available for some time, but it was not possible to tell whether animals were vaccinated or infected. This meant that control programmes would cull vaccinated animals as well as infected animals.

In the 1990s 'DIVA Vaccines' were developed and provided immunity while allowing vaccinated animals to be differentiated from infected animals. These DIVA, or 'marker assisted' vaccinations were used to proactively protect herds against disease but also to control and eventually eradicate disease in infected herds.

This allowed vaccines to play a major role in the eradication of Aujeszky's disease from many European countries.

Control of Salmonella in Poultry in the UK^{60 61 62}

In the 1980s, Salmonella infections in humans, linked to the consumption of eggs and chicken meat, dramatically increased in the UK, prompting the government to introduce compulsory slaughter of Salmonella infected poultry.

When Salmonella vaccines became available, the poultry industry began to vaccinate breeding and laying flocks voluntarily. In 2001, an expert committee advised that widespread vaccination of laying flocks against Salmonella combined with improved flock hygiene measures had reduced the incidence of Salmonella in people.

The British Egg Industry Council developed a quality code of practice which requires mandatory vaccination of all layers against Salmonella, as well as other measures and the government removed the compulsory slaughter policy.

Producers operating under the quality code can use a trademark on their eggs and these now account for around 85% of the total market.

In addition, the number of laboratory-confirmed cases of salmonella illness dropped from more than 18,000 in 1993 to just 459 in 2010.

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