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Autogenous vaccines: an alternative approach to disease control in poultry

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Abstract

Autogenous vaccines are increasingly used to control poultry diseases not adequately managed by licensed vaccines. Tailored to flock-specific pathogens, they can improve performance by reducing mortality and morbidity during outbreaks and lowering antimicrobial use in herds with recurrent bacterial challenges. Their value extends to variant viral agents affected by antigenic drift. Despite benefits, variability in efficacy and limited standardized safety data remain challenges for broader adoption.

Keywords: autogenous vaccine, poultry, custom biologics, manufacture.

Introduction

Biosecurity and vaccination are the main prevention and control measures in poultry farming. Biosecurity measures help to reduce the likelihood of pathogens entry into the farm and decrease the environmental load of infectious agents through cleaning and disinfection. Vaccination prevents disease outbreaks and reduces susceptibility to pathogens that are likely to cause economic losses. Together, biosecurity and vaccination contribute to reducing the antimicrobials use while safeguarding animal welfare and production performance.

Poultry production represents one of the most rapidly expanding animal protein sectors worldwide, contributing more than 40% of the global meat supply and playing a central role in food security[1]. Infectious diseases such as *Escherichia coli*, Avian Influenza Virus, Infectious Bronchitis Virus, and Avian Reovirus continue to impose substantial economic burdens on the industry, with global losses from major viral diseases estimated in the billions of dollars annually due to mortality, reduced performance, and trade restrictions[2]. The recurring emergence of antigenic variants, particularly among rapidly evolving viruses, further compromises the effectiveness of existing licensed vaccines and reinforces the need for tailored immunization strategies.

Licensed vaccines are formulated to combat significant and persistent threats to the poultry industry, prevalent across various global markets. Consequently, they require the large-scale production of doses worldwide, which justifies the substantial investments in research, development, registration, commercialization, and testing of each master seed and subsequent production batches. Given the ongoing challenges within the sector and the similar obstacles faced by licensed vaccines, these products are expected to

remain relevant for decades. Nevertheless, if it is determined that the challenge agent exhibits antigenic variation from the classical strains included in licensed vaccines, the protection provided may be insufficient to prevent the economic consequences of infection. As a result, disease management may require the use of autogenous vaccines, formulated from isolates obtained from the affected animals[3]. Numerous licensed vaccines are employed in poultry farming, typically available as either inactivated or live formulations. Nonetheless, autogenous inactivated vaccines are gaining growing popularity.

Methodology

To obtain a broad overview of the main publications on autogenous vaccines in poultry production, we performed a literature search using key terms commonly employed in this field, including “autogenous vaccines”, “passive immunity”, and “antigenic dilution”. These terms were combined using the Boolean operator “AND” and searched across major scientific databases.

What are autogenous vaccines?

Autogenous (custom-made) vaccines have become a critical tool in poultry farming to address emerging and evolving diseases. These vaccines are designed to target pathogens prevalent within a particular flock or region, offering a targeted approach to disease control strategy. Autogenous vaccines are prepared using pathogens isolated directly from the same flock or from adjacent regions with confirmed epidemiological links. Autogenous vaccines are custom-made products prepared from pathogens isolated from

a specific flock, herd, or epidemiologically related group of animals; they are produced at the population level and used to control outbreaks caused by locally circulating strains. In contrast, autologous vaccines are prepared from materials (usually tumor cells or immune cells) collected from a single individual and intended exclusively for that same individual, a concept used almost entirely in human medicine, especially in cancer immunotherapy. Therefore, autologous vaccines do not apply to poultry production, whereas autogenous vaccines are widely used in animal health to target flock-specific pathogens. Their preparation and use may vary according to the normative instructions or specific regulatory guidelines for autogenous vaccines in each country. The inclusion of autogenous vaccines in the management of certain diseases is justified by the unavailability of licensed vaccines, by the evolution and diversity of antigens in the field that are not covered by licensed vaccines, or even due to a health emergency. Autogenous vaccines are commonly applied to control both bacterial and viral infections in poultry, such as Avian Reovirus, Avian Adenovirus, *Salmonella*, and *Escherichia coli*[3,4].

Autogenous vaccines are manufactured from isolated pathogens obtained from an animal or group of animals within a defined epidemiological unit and are intended for use to treat animals within the same epidemiological unit or in another unit with a confirmed epidemiological link[5]. These vaccines can be formulated as viral vaccines, bacterins, or a combination of both. They are especially valuable when licensed vaccines are unavailable or insufficient.

Autogenous viral vaccines are used to treat illnesses and syndromes produced by novel antigenic variations and ongoing viral evolution. For some viruses, particularly RNA viruses that mutate frequently and display substantial genotype diversity, licensed vaccines containing a “representative vaccine candidate” may not always provide

adequate protection. In such cases, autogenous vaccines may be employed. This method is commonly applied for viruses like Avian Reovirus, which comprises some viral subtypes and where vaccine efficacy is often attributed to antigenic similarity between the vaccine strain and the specific virus circulating on the farm.

Autogenous vaccines are prepared using farm-specific strains, which are isolated and propagated in specialized laboratories before the final vaccine formulation is returned to the farm of origin for administration. Although safety and efficacy testing are generally not mandatory or completed, laboratories are expected to maintain systems for prospective counter-testing and surveillance; that is, autogenous vaccines are subject to minimal purity and safety tests compared to the rigorous testing imposed on licensed vaccines.

Licensed vaccines are designed to address major and ongoing threats to the industry, which are common in several poultry markets around the world, and thus necessitate the large-scale production to justify the considerable investment in research, development, registration, commercialization, and testing of each master seed, as well as the serial launch of the final product. Given the enduring nature of these challenges and the widespread obstacles encountered in the field, such vaccines are expected to remain relevant for decades. However, if it is proved that the challenge agent is antigenically distinct (antigenic variations) from the classical strains found in ordinary licensed vaccinations, the immunity conferred by these licensed vaccines may be insufficient to avert the challenge's economic repercussions. In such cases, disease prevention may necessitate the use of autogenous "emergency", "tailored", "complex-specific", or "farm-specific" vaccines derived from isolates collected from affected animals.

Therefore, autogenous vaccines are developed by isolating the pathogen, inactivating it, and combining it with adjuvants to boost immune responses. These vaccines are controlled differently than licensed vaccines, with less licensing requirements, making them more readily available for field usage[3,6]. As a result, they can be manufactured within a few weeks and help address gaps left by licensed vaccines. Their production typically follows defined quality and safety standards but is exempt from full efficacy testing. Autogenous vaccines are especially useful in outbreaks and situations requiring precise antigenic matching to newly circulating pathogens, which is often not feasible with licensed vaccines. In the poultry industry, the use of autogenous vaccines mainly includes broiler and layer breeders, laying hens, turkeys, and ducks, while fewer autogenous vaccines are produced for other avian species, such as geese, quail, and gamebirds[3].

Autogenous vaccines may be monovalent or polyvalent, with a combination of relevant strains of one or more pathogens. Careful analysis must be taken to select the isolates, ensuring that only well-characterized, pure seed material is used[7]. Isolates should only be reused if they have been verified as still relevant to the locality or possess an epidemiological link, and such reuse must be supported by robust justification from the veterinarian[5]. Autogenous vaccines should be prescribed with the smallest possible number of antigenic fractions, as they are not subjected to efficacy studies that prove the absence of interference between each antigenic fraction in the target species.

Unlike licensed vaccines, autogenous vaccines are not subject to mandatory safety and efficacy studies, although they are produced and commercialized under defined rules to control potential risks. However, available data on the potency, efficacy and safety of

autogenous vaccines remains limited, typically based on clinical outcomes and herd performance data.

Good manufacturing practices (GMP) play a critical role in minimizing risks during the production of autogenous vaccines. These GMP principles ensure that products are manufactured and controlled according to established quality standards[5]. The manufacturer's authorization for the autogenous vaccines production must specify the microorganisms manipulated on site. In addition, manufacturing documentation must be established for each vaccine type. Additionally, it is also necessary to implement contamination and cross-contamination control measures, perform a risk assessment, and validate critical manufacturing steps as well as any significant process changes. Facilities, equipment and systems must be qualified, and analytical methods validated for their intended use[5].

Autogenous vaccines can be developed and deployed quickly, making them ideal for addressing emerging diseases. This rapid response capability is particularly valuable in the poultry industry, where disease outbreaks can lead to significant economic losses if not controlled promptly[3,6]. However, because these vaccines are typically effective only against the specific strain or serotype used in their preparation, frequent updates to the formulation are often required to keep pace with ongoing antigenic changes in pathogen populations[7,8].

Table 1 highlights the key differences between autogenous and licensed vaccines, emphasizing both the distinct advantages and the limitations of autogenous vaccines in poultry farming (Table 1). Table 2 compares the efficacy of licensed and autogenous vaccines against some important poultry diseases (Table 2).

Table 1. Comparison of autogenous and licensed poultry vaccines.

Aspect	Autogenous vaccines	Licensed vaccines	Reference
Specificity	Tailored to specific pathogens prevalent in a flock or region	Broad-spectrum protection against multiple strains	Putnam et al., 2024[3]; Sulejmanovic et al., 2024[7]
Protection duration	Requires frequent updates due to antigenic changes	Generally, provides longer-term protection against known strains	Fallah Mehrabadi et al., 2020[8]; Sulejmanovic et al., 2024[7]
Antibody response	Often induces higher antibody titers due to antigenic similarity	May induce lower titers against emerging or variant strains	Fallah Mehrabadi et al., 2020[8]; Hassan et al., 2024[9]
Regulatory requirements	Subject to specific regulations; manufacturing processes must comply with standards	Undergo rigorous licensing and regulatory approval processes	Sulejmanovic et al., 2024[7]; Tollis, 2004[10]
Antimicrobial use	Reduces reliance on antimicrobials by providing targeted disease control	May not address the root cause of disease, leading to continued antimicrobial use	Chase, 2023[6]; Lozica et al., 2022[11]

Table 2. Comparative efficacy of licensed and autogenous vaccines against poultry diseases.

Disease	Licensed vaccine efficacy	Autogenous vaccine efficacy	Reference
Avian Influenza (H9N2)	Faster innate and humoral immune responses	Better protection against recent isolates; reduced viral loads and improved clinical outcomes	Fallah Mehrabadi et al., 2020[8]; Raheel et al., 2024[12]
Newcastle Disease (ND)	Broad protection against multiple genotypes	Enhanced protection with genotype-matched isolates; up to 100% survival and reduced shedding	Sultan et al., 2022[13]; Barbour et al., 2017[14]
Infectious Bursal Disease (IBD)	Robust protection against multiple genotypes	Superior protection against local variants	Sedeik et al., 2019[15]
Infectious Bronchitis (IB)	Moderate protection against common strains	Better reduction in viral shedding and tissue damage	Hassan et al., 2024[9]
Escherichia coli	Effective in combination with autogenous vaccines	Significant reduction in disease incidence	Lozica et al., 2022[11]; Šenk et al., 2022[16]
Infectious Coryza	Variable or limited efficacy depending on serovar	Strong antibody responses and high clinical protection with farm-matched isolates	Chukiatsiri et al., 2009[17]; Wambura, 2010[18]
Campylobacter	No licensed poultry vaccine available	Genomic-tailored reduces pathogenic strains and improve food safety	Calland et al., 2024[19]

Production and development of autogenous vaccines

To produce autogenous vaccines, it is necessary to isolate, identify and characterize samples of bacteria and viruses collected on the farm. For bacteria, isolation and identification can be performed in just three days, but for viruses, it can take 3-4 weeks[3]. Manufacture and release of batches are carried out in a short time, usually only 3 to 8 weeks, depending on the growth characteristics of the pathogen[7].

Moreover, molecular characterization includes technologies such as real-time PCR and next-generation sequencing. Characterization of antigenicity and pathogenicity can be performed using classical laboratory and *in vivo* methods. Samples can be obtained from clinical cases, monitoring programs and sentinel chickens. Active surveillance in commercial production is important for the selection and maintenance of autogenous vaccines[3].

The defined and selected microorganisms are propagated according to quality control standards to ensure purity, following GMP guidelines for pharmaceutical products. After purity testing, the antigen is inactivated, usually by a chemical method, such as the addition of formaldehyde, β-propiolactone, or binary ethylenimine[20]. Testing and validation of inactivation procedures are commonly required, as the risk of incomplete inactivation is considered high and critical[7]. Residual levels of the inactivating agent must also be monitored, and in particular, the final product must be tested for residual formaldehyde whenever this compound is used in the manufacturing process.

The antigen is tested for inactivation, followed by batching and formulation with the selected adjuvant. The finished vaccine is bottled, subjected to sterility testing, labeled, and stored. Retention samples of each batch are archived for quality assurance[3]. In

addition to sterility testing, safety evaluation of the final product is required. This is performed by administering 0.5 mL of the vaccine intraperitoneally to at least eight young adult mice, or 2 mL subcutaneously to at least two guinea pigs, followed by observation for adverse reactions over seven days. The physicochemical quality of the product must also be verified: the final pH must fall between 6.8 and 7.4, unless otherwise justified by a duly substantiated technical specification. For autogenous vaccines, stability testing is not considered mandatory; therefore, a uniform shelf life of 12 months is proposed for the final product under appropriate conditions. Each batch must be certified by the person responsible for releasing the batch, declaring compliance with the specified manufacturing and testing requirements[5].

Autogenous inactivated vaccines must be combined with an adjuvant to enhance the immune response in poultry[21]. The appropriate adjuvant must meet a number of requirements, such as being approved for use in food-producing animals, being cost-effective, stable, and easy to process and inject, and inducing few adverse effects[22,23]. Combining the antigen with the most appropriate adjuvant can significantly improve the efficacy of autogenous vaccines (Figure 1)[5]. Depending on the viscosity, tissue reactivity of the adjuvant, and immunogenicity of the antigens, the ratio of antigen to adjuvant may vary for each vaccine. Aluminum hydroxide precipitated gels and mineral oils are commonly used as adjuvants in poultry[21]. Table 3 shows the mechanisms of action, advantages, and disadvantages of different types of adjuvants used in vaccines (Table 3).

Table 3. Mechanisms of action, advantages, and disadvantages of different types of adjuvants used in vaccines.

Type of adjuvant	Mechanism of action	Advantages	Disadvantages	Reference
Aluminum (aluminum hydroxide)	Induces local inflammation; stimulates Th2 response (antibodies)	Approved for use in production animals; low cost; easy to handle	Low induction of cellular response (Th1); may cause local reactions; less effective against certain viral pathogens	Collett et al., 2019[21]; Heegaard et al., 2011[23], 2016[22]
Mineral oil (oil emulsions)	Slow release of antigen; strong inflammatory stimulus; induces Th1 and Th2 responses	High immunogenic potency; prolongs the duration of the immune response; effective against inactivated bacteria and viruses	High viscosity; can cause severe reactions at the injection site; more difficult to administer	Collett et al., 2019[21]; Grein et al., 2022[5]; Heegaard et al., 2011[23]
Water/oil/water (w/o/w) emulsions	Sustained stimulation by multiple particles; blends cellular and humoral responses	Combines the benefits of oil and water emulsions; lower reactogenicity compared to pure mineral oil	More complex to formulate; higher production costs	Heegaard et al., 2016[22]
Polymeric adjuvants (carbomers)	Controlled release of antigen; stimulates Th2 response with reduced local inflammation	Low reactogenicity; good stability; suitable for subcutaneous and intramuscular injections	Less adjuvant effect compared to mineral oil; may require higher antigen doses	Heegaard et al., 2011[23]
Liposome-based adjuvants	Targeted delivery of antigen to antigen-presenting cells (APCs); activates cellular and humoral responses	Promotes a strong cellular response; can be combined with various immunomodulatory molecules	High cost; greater technological complexity; limited stability	Heegaard et al., 2016[22]

Although local reactions to these vaccines are uncommon, any adverse response should first prompt verification of potential handling or administration errors. Another possible source of reaction is endotoxin content, particularly in bacterins containing *Salmonella* spp., which may harbor high levels of lipopolysaccharide (LPS). In such cases, unknown or poorly characterized isolates may contribute to excessive LPS production. Laboratories with stringent quality control employ pyrogenicity testing to monitor and prevent this issue.

Autogenous vaccines are produced more quickly than licensed vaccines, because of regulatory processes. In addition, modern laboratory techniques accelerate the selection and characterization of isolates for vaccine production[3]. In general, autogenous vaccines must be produced in licensed facilities that hold specific manufacturing authorization and demonstrate appropriate laboratory equipment, expertise and

reliability[7]. Figure 2 shows a flowchart of the steps involved in autogenous vaccine production (Figure 2).

The typical vaccine development timeline is around 10 to 15 years. For many pathogens, there are no licensed commercial vaccines available. The reasons for this lack of availability include strain variation and insufficient economic incentives for developing a vaccine. Therefore, measures have been implemented to compensate for the partial waiver of data on the efficacy, safety and quality of autogenous vaccines. As a result, there are specific GMP requirements, standardized manufacturing processes, restrictions on their use, and limitations on inactivated autogenous vaccines[5].

The production of autogenous vaccines is subject to specific regulatory requirements, which vary by region. In general, autogenous vaccines are exclusively inactivated bacterial and viral vaccines, and their manufacturing processes must comply with regulatory standards[7,10]. Ideally, manufacturing establishments should only manufacture autogenous vaccines if they provide evidence that there are no registered vaccines or that existing registered vaccines for the same indication do not guarantee adequate protection against the disease, as duly documented by the manufacturing establishment. The production and use of autogenous vaccines are subject to regulatory constraints, which may limit their availability in certain regions[4,7]. Farmers should consult with veterinary professionals to determine the most appropriate vaccination strategy based on local disease conditions and economic factors. Furthermore, licensed vaccines are generally more cost-effective for large-scale operations, while autogenous vaccines may be more economical in the long term for farms facing persistent outbreaks of specific pathogens[4,7].

Antigenic dilution

According to the definition, "the more different antigens included in the vaccine, the more diluted each individual antigen is in the series". Autogenous vaccines are created from field strains that have not been chosen or optimized for the industrial propagation systems employed in the vaccine manufacturing business. A series may include bacterial or viral antigens. Both bacterins and autogenous viral vaccines contain at least one antigen; however, most include several antigens (~2-5). Examples of formulations for autogenous viral vaccines used in the field are: 2-4 antigens from various A virus groups, as well as 2-4 B virus serotypes. For autogenous bacterins, use 3-4 different serovars of the same bacteria or 1-2 separate serovars of two different bacteria. Users are particularly concerned about the restricted space available under the aqueous phase. The inclusion of more distinct antigens in the vaccine causes each particular antigen to become more "diluted" in the series. Furthermore, these antigens must be present in sufficient antigenic concentration to elicit a good immune response. It is unknown how many antigens can be successfully delivered simultaneously. However, preliminary findings reveal that individual antigenic vaccination has no significant negative effect on antibody levels when compared to polyvalent vaccines. Thus, research suggests that the antigenic level (potency) of an antigen is more important than the amount of antigens in a vaccine[24].

Potency concerns are associated with "antigenic dilution" and are more common in viral vaccines than in bacterins, as some field isolates replicate better in embryonated eggs or specialized differentiated tissues. Because of the different propagation capacity, or growth potential in media in the case of bacterial isolates, and the lack of potency

studies, it is common to see significant variability between different isolate harvest titers, which can translate into different antigenic levels of vaccine fractions within an autogenous series, potentially under stimulating immunity against some serotypes at the expense of others within the same vaccine. Thus, autogenous vaccinations, even while containing the same strain (from different seeds), may not be as effective. Other ramifications of this issue include limitations in monitoring across vaccine batches, as the same virus from the same group or bacteria of the same serotype can cause considerable changes in ELISA titers in the field[25].

Although large amounts of antigen in both viral and bacterial harvests can be diluted, only the bacterial antigen can be concentrated economically. The viral antigen is more difficult to concentrate since it requires an ultracentrifuge, which raises the expense of vaccine production. As a result, viral antigens are rarely concentrated, and in certain situations, these field viruses do not reproduce in large numbers in factory/laboratory production methods (Specific Pathogen Free – SPF embryonated eggs, cell culture) and are given undiluted to the vaccine. This amount of antigen may be insufficient to elicit the robust immunity required by the program, and using numerous antigens in the aqueous phase may further "dilute" the already low titers in a single dosage. Because vaccine producers rarely communicate production details with customers, such as the amount of antigen in each fraction in the series, the efficacy of the autogenous batch must be assessed indirectly in the field[26]. The most common approach is serological monitoring, performed for 2-3 weeks following vaccine completion. It is important to have a sampling strategy because the immune response can be influenced not only by the antigenic content of the autogenous vaccine, but also by factors such as live challenges in the field, vaccination errors, and immunosuppression in animals; this will only provide indirect and

subjective information about the antigenic content of the vaccine's fractions. Nucleic acids can be extracted from oil-based inactivated vaccines by separating the aqueous and oily phases; thus, molecular techniques (e.g., qPCR or RT-qPCR) can be investigated and developed as a tool for indirectly assessing the amount of antigen fraction included in the autogenous vaccine[27].

Application of autogenous vaccines against specific diseases

One of the primary advantages of autogenous vaccines is their specificity to the pathogens prevalent in a particular flock or region. This tailored approach ensures that the vaccine is highly effective against the circulating strains, unlike licensed vaccines, which may offer broader but less specific protection[3,7]. In vaccination programs for breeding stock and laying hens, autogenous vaccines are included in the prevention and control of viral and bacterial diseases, especially due to the constant evolution of viral antigenic variants and bacterial serovars[3]. Table 2 shows examples of the application of autogenous vaccines against poultry diseases.

New pathogens continue to emerge and cause economic losses in poultry farming. Furthermore, they are constantly evolving and continue to find ways to evade the immunity produced by licensed vaccines. For the control of emerging and evolving viruses and bacteria, autogenous vaccines are an alternative, especially when licensed vaccines are not available[3].

The Infectious Bursal Disease Virus (IBDV) has acquired the ability to escape the immune response induced by licensed vaccines by changing its antigenicity over time. In recent years, IBDV variants capable of evading the antibody response have been

detected[28,29]. By using recent isolates, autogenous vaccines minimize the risk of antigenic drift, ensuring that the vaccine antigens are closely matched to the circulating pathogens. This is particularly important for diseases like IBDV, where antigenic variation is a significant challenge[15,30]. For decades, disease associated with Avian Reovirus (ARV) was controlled by licensed vaccines. However, ARVs have undergone antigenic changes over time, making them antigenically different from vaccine strains. There are currently several ARV variants, and it is important to isolate and characterize them for identification and incorporation into autogenous vaccines[25,31,32]. Autogenous or locally tailored ARV vaccination programs were associated with major reductions in clinical incidence and isolations: national programs and breeder vaccination strategies (including use of locally adapted vaccines/controlled exposure) correlated with a marked decline in ARV-positive broiler flocks, underscoring the value of regionally matched vaccines for rapidly evolving viral pathogens[26].

For bacterial pathogens that have mutated or for which there are no licensed vaccines available, autogenous bacterins are a preventive strategy. Bacterins have been used to prevent several avian diseases, such as infectious colibacillosis, coryza, erysipelas, fowl cholera, and spotty liver disease, and to protect the food supply by reducing the prevalence of *Escherichia coli* and *Salmonella* in broilers[3].

Furthermore, autogenous vaccines can elicit more specific immune responses both humoral and cell-mediated, due to their antigenic similarity to the pathogens currently circulating in the field. Autogenous vaccines have been effectively used to manage Infectious Bronchitis Virus (IBV) in layer chickens. A study demonstrated that an autogenous IBV vaccine provided superior protection by reducing viral loads in renal and reproductive tissues compared to licensed vaccines[9]. Similarly, autogenous vaccines

have been employed to combat Avian Influenza (H9N2) in broilers. These vaccines, when formulated with recent isolates, induce higher hemagglutination inhibition (HI) titers and reduce viral shedding more effectively than licensed vaccines[8]. A possible reason for these findings is that autogenous vaccines are made to match the circulating local strains that are currently circulating in the target flock or area, while licensed vaccines are usually formulated based on more common or have been around for a long time[4]. If the licensed vaccine is based on a broader or older strain that does not perfectly match the current local viral variants, its cross-protection may be incomplete, especially for rapidly evolving viruses like IBV and H9N2 Avian Influenza[3,4]. In contrast, autogenous vaccines, produced from recent field isolates, have antigenic profiles that are very similar to the strains that are currently spreading. This makes the immune system recognize them better, raises antibody levels (like HI titers), and lowers viral loads and shedding more effectively. So, even though the licensed vaccine may protect against a wider range of strains, it is often less specific to the local outbreak strain[3]. This is why the autogenous vaccine can work better in those situations. This shows how important it is for vaccine strains and field strains to have the same antigens, especially when it comes to how viruses change and how they can avoid the immune system.

Autogenous vaccines have some advantages, particularly their specificity to local strains of pathogens. However, because they are designed using newly isolated local strains, their protective effect is usually limited to those specific strains and does not extend to the broader cross-protection offered by licensed vaccines, which are intentionally developed and characterized to cover multiple or widespread strains[3]. Autogenous vaccines, however, may exhibit some degree of cross-protection, but this effect is incidental rather than a goal of their formulation or characterization. This antigenic

focus means that autogenous vaccines may be ineffective against emerging or heterologous variants not included in the vaccine. Furthermore, autogenous vaccines are produced under partial regulatory exemptions, often without the comprehensive efficacy, safety, and stability data required for licensed vaccines, which can raise concerns about batch consistency and long-term safety[4]. Therefore, while the manufacturing process for autogenous vaccines is faster, it also requires more steps, such as isolating and characterizing pathogens, which can increase costs. Although autogenous vaccines are excellent tools in managing local outbreaks and rapidly evolving pathogens, these vaccines need to be part of a larger disease control plan that includes biosecurity, surveillance and, where appropriate, combination with licensed vaccines.

Similar to subunit vaccines and licensed inactivated vaccines, inactivated autogenous vaccines do not introduce exogenous genetic material and therefore do not directly induce recombination. Thus, even if the vaccine pathogen is inactivated and cannot replicate or directly contribute live genetic material to the viral or bacterial population, there is still an indirect risk of applying positive selective pressure on the circulating pathogen population[33]. This selective pressure may favor the survival and spread of escape mutants, which are variants with mutations or recombinations that allow them to evade vaccine-induced immunity[34]. The explanation is that the immunological pressure that vaccines create in the vaccinated population may indirectly increase the evolutionary advantage of strains that are better able to evade immune responses[33,35]. Over time, this may lead to the selection of more diverse or recombinant strains, especially in rapidly evolving viruses such as IBV or Avian Influenza, where recombination or reassortment occurs naturally. Therefore, autogenous vaccines are solutions for sporadic use and when animals are being affected by new variants. Therefore, although

autogenous vaccines are valuable tools in managing local outbreaks and rapidly evolving pathogens, they must be carefully integrated into a broader disease control strategy that includes biosecurity, surveillance, and, where appropriate, a combination with licensed vaccines.

One of the primary benefits of autogenous vaccines is their role in diminishing the necessity for antimicrobial usage in the field, especially by providing a targeted alternative to prophylactic therapies. For instance, in a case study on a layer hen farm, the application of an autogenous *Escherichia coli* vaccine significantly decreased morbidity, mortality, and the need for antimicrobial treatments. This approach not only improved egg production but also contributed to antimicrobial stewardship[11]. By reducing reliance on antimicrobials, autogenous vaccines play a crucial role in mitigating the rise of antimicrobial resistance. This aligns with global efforts to promote sustainable and responsible farming practices[6,11].

Autogenous vaccines have been successfully used to manage various poultry diseases. Vaccines prepared from local strains of *Avibacterium paragallinarum* have shown high efficacy in protecting layer chickens against clinical signs and mortality caused by infectious coryza[18]. Genomic tailoring of autogenous vaccines has been explored to target *Campylobacter* strains with genes associated to survival outside the host. This approach has led to a significant reduction in pathogenic strains on poultry farms[19]. Moreover, an autogenous vaccine developed against the predominant genotype VI of Newcastle Disease Virus (NDV) demonstrated 100% survival in challenged broilers, highlighting its potential as a targeted solution[14]. An aerogenous challenge model in broiler breeders vaccinated with an autogenous *Escherichia coli* bacterin showed significantly lower bacteriology scores and reduced air-sac lesion scores in vaccinated

birds (gross pathology score 1.95 vs 2.8 in unvaccinated controls), consistent with improved tissue pathology and reduced organ colonization[36].

The efficacy of autogenous vaccines is attributed to their ability to induce more specific immune responses. An autogenous *Escherichia coli* vaccine prepared from outer membrane proteins (OMP) elicited higher antibody titers and provided 92% protection against colibacillosis in chickens, outperforming licensed vaccines[37]. By targeting specific pathogens, autogenous vaccines help reduce the spread of disease within flocks, thereby minimizing economic losses. The use of an autogenous vaccine against *Salmonella enterica* in poultry farms has been associated with a significant reduction in bacterial shedding and disease incidence[4]. Autogenous *Salmonella* bacterins can induce rapid local inflammatory responses and robust *Salmonella Enteritidis*-specific antibody isotype switching (IgM → IgG/IgA) after primary exposure, supporting their use to reduce environmental contamination and shedding[38]. Vaccine regimens combining live and inactivated vaccines have also been shown to reduce caecal colonization in laying hens, illustrating that tailored vaccine strategies (including autogenous formulations where relevant) can reduce pathogen load and thereby food-safety risk[39].

While autogenous vaccines have shown promise in managing many poultry diseases, their efficacy can vary depending on the disease and the vaccine formulation. Autogenous *Escherichia coli* vaccines did not confer significant protection against heterologous challenges, highlighting the need for careful vaccine design[40]. Furthermore, the use of combination vaccines, which include both licensed and autogenous components, is being explored to enhance protection against multiple serotypes of a pathogen. A study on *Escherichia coli* vaccines demonstrated that combining licensed and autogenous vaccines expanded heterologous protection and reduced disease

incidence[16]. This combination is also associated with significant reductions in broiler chick mortality. In flocks whose parents received both vaccines, mortality in the first week fell to 0.91% (compared to 1.40% in unvaccinated flocks), and total mortality to slaughter fell to 3.14% (compared to 4.33% in the controls)[41].

The efficacy of autogenous vaccines can be further enhanced through the use of advanced adjuvant technologies. The inclusion of mineral oil adjuvants in autogenous vaccines against *Avibacterium paragallinarum* has been shown to induce faster and stronger immune responses compared to aluminum hydroxide gel adjuvants[17].

Passive immunity

Newborn chicks have an immature and underdeveloped immune system, which limits their ability to mount effective immune responses in the first days and weeks of life. Maternal antibodies play a critical role during this vulnerable period, providing early protection against pathogenic organisms[42,43]. These antibodies, primarily immunoglobulins, are transferred from vaccinated or naturally infected parent birds to their offspring through the egg yolk, conferring passive immunity that helps protect chicks until their adaptive immune system becomes fully functional. This passive immunity is relatively short-lived. Maternally derived antibody (MDA) levels typically peak 3 to 4 days after hatching. Consequently, chicks become increasingly vulnerable to infectious diseases, especially during the second week after hatching[42].

These MDAs offer temporary yet significant protection against several major poultry diseases, including Infectious Bursal Disease (IBD/Gumboro), Newcastle Disease, Avian Reovirus (viral arthritis), Infectious Bronchitis (IB), Marek's Disease, Avian

Encephalomyelitis (AE), and Chicken Anemia Virus (CAV). By conferring passive immunity, these antibodies help reduce early susceptibility to infection and support flock health until the chick's own immune system becomes fully functional.

Maternal immunity plays a crucial role in the protection of progeny chickens against various pathogens, particularly through the use of autogenous vaccines. Maternal antibodies, transferred through egg yolk, provide passive immunity to chicks, which is crucial during their early life when their immune systems are still developing. The transfer of maternal antibodies can enhance the immune response in offspring, but it can also interfere with the efficacy of subsequent vaccinations. The health and condition of the hen directly influence the quantity of antibodies transferred. Variability in these transfer levels has been observed, suggesting that maternal health plays a crucial role in shaping offspring immunity. The transfer rate of antibodies can vary significantly among hens, with a range of 9.2% to 38.4% of maternal circulating antibodies being transferred[44].

Table 4 shows the geometric mean titers (GMT) of MDAs transferred from breeder hens to their chicks and how these antibody levels decline during the first month of life (Table 4). At hatch, chicks possess relatively high antibody titers for several important poultry pathogens, reflecting the immune status of the parent flock. Pathogens such as IBDV, IBV, CAV, and reovirus exhibit especially high initial titers, while others such as NDV and *Mycoplasma* spp. begin at lower but still detectable levels. However, these maternal antibodies decrease rapidly as the chicks age. In most cases, a substantial decline is already evident by the fifth day of life, and by 10 to 15 days, titers for many pathogens approach zero. This pattern illustrates the short-lived nature of passive immunity, with a critical window of vulnerability emerging in the second week after

hatching, when antibody levels are no longer protective but the chick's own immune system remains immature.

The rate of antibody decline varies among pathogens. Antibodies against NDV, reovirus, and IBDV persist for a longer duration, remaining detectable up to 20 or even 30 days, while those against Avian Encephalomyelitis Virus (AEV), Avian Influenza Virus (AIV), IBV, Infectious Laryngotracheitis Virus (ILTV), *Mycoplasma gallisepticum* (MG), and *Mycoplasma synoviae* (MS) disappear much earlier, often between 15 and 20 days of age. These pathogen-specific differences reflect diverse immunological characteristics and directly influence the duration of maternal protection. Understanding these dynamics is essential for designing effective vaccination programs. If vaccination occurs when MDA levels are too high, maternal antibodies may neutralize vaccines and interfere with immune priming. Conversely, delaying vaccination excessively may leave chicks unprotected during periods of heightened susceptibility.

Table 4 also provides the average maternal antibody transfer percentages for each pathogen, based on a licensed vaccine. Although transfer efficiencies vary, these values are important for guiding decisions regarding which agents should be included in breeder vaccination programs. When a pathogen has a low average transfer rate, maternally derived antibodies may not provide adequate early protection to chicks, even though immunizing the breeder flock adds physiological stress and increases production costs. Recognizing both the decay patterns and transfer efficiency of MDAs is therefore crucial for optimizing maternal vaccination strategies, ensuring sufficient offspring protection, and making efficient use of resources. Together, these insights enable veterinarians and producers to refine vaccination schedules, reduce MDA interference, and promote timely development of active immunity.

Table 4. Geometric mean titers (GMT) of maternally derived antibodies (MDAs) against different pathogens from hatch to 30 days of age.

Pathogen	Parent Flock	Day 0	Day 5	Day 10	Day 15	Day 20	Day 25	Day 30	Mean Transfer (%)
AEV	3,839	405	29	2	0	0	0	0	4.3
AIV	1,910	668	37	2	1	0	0	0	19.5
CAV	9,283	1,985	108	18	1	1	0	0	25.5
IBDV	35,012	21,104	16,295	10,643	3,983	546	84	2	73.6
IBV	19,472	6,706	860	15	0	0	0	0	38.6
ILTV	3,146	209	10	2	2	1	0	0	6.9
MG	3,165	1,134	365	5	1	0	0	0	32.4
MS	4,881	828	21	3	1	0	0	0	22.4
NDV	8.5	5.9	4.9	3.5	3.5	3.1	2.4	1.1	29.2
Reo	2,761	790	41	4	0	0	0	0	32.8

Parent-flock titers correspond to the day eggs were laid by the breeders. Values represent geometric mean titers determined using ELISA, except NDV (hemagglutination inhibition assay). AEV = Avian encephalomyelitis virus; AIV = Avian influenza virus; CAV = Chicken anemia virus; IBDV = Infectious bursal disease virus; IBV = Infectious bronchitis virus; ILTV = Infectious laryngotracheitis virus; MG = *Mycoplasma gallisepticum*; MS = *Mycoplasma synoviae*; NDV = Newcastle disease virus; Reo = Reovirus. This table was adapted from Gharaibeh & Mahmoud, 2013[43].

High levels of maternal antibodies can offer some protection against infections, as seen in studies where progeny from vaccinated hens showed reduced both the incidence and severity of infectious diseases[45]. Transfer efficiency varies widely, however, as reflected in Table 4. Notably, IBDV demonstrates exceptionally high transfer (73.6%), providing substantial early protection. Moderate transfer levels are observed for pathogens such as IBV (38.6%), MG (32.4%), MS (22.4%), and reovirus (32.8%). External studies support these results: broiler breeders vaccinated against CAV

transferred approximately 63% of antibodies to their offspring[46], while NDV maternal antibody transfer reached around 41.5%[47], consistent with the moderate NDV transfer recorded in Table 4 (29.2%). Together, these data demonstrate that while maternal antibody transfer varies across pathogens, it remains a critical determinant of chick health and a key factor in shaping vaccination strategies during the first weeks of life.

While maternal antibodies confer initial protection, they can interfere with the chicks' immune response to vaccinations, potentially leading to reduced antibody production upon subsequent exposure to pathogens[47,48]. For instance, high maternal antibody levels significantly reduced the immune response to Avian Influenza vaccination in progeny. Therefore, due to interference with the effectiveness of subsequent vaccinations, careful timing and vaccines selection is required[49,50].

Autogenous vaccines, tailored to specific pathogens, can enhance the quality of maternal antibodies, thereby improving offspring immunity and reducing disease incidence[51]. Optimizing maternal immunization strategies could enhance the protective effects of vaccines in progeny. For example, maternal immunization with recombinant vaccines has shown promise in providing protection against necrotic enteritis[45]. Future vaccine strategies may need to consider the timing and type of maternal immunization to balance protection and vaccine efficacy in offspring. A study on avian pathogenic *Escherichia coli* (APEC) further demonstrated the potential of autogenous vaccines: breeder hens vaccinated with a bivalent APEC formulation generated maternal antibodies that reduced chick mortality from 80% to 40% after challenge with one homologous strain, though no protection was observed against another strain[52]. It is important to note that, because autogenous vaccines are inactivated, achieving robust antibody titers in breeder

hens generally requires the administration of at least one booster dose to ensure an adequate immune response.

Despite the benefits of autogenous vaccines in enhancing maternal immunity, challenges remain, such as the potential for maternal antibodies to hinder the effectiveness of active immunization in young chicks. This dual role of maternal antibodies necessitates a balanced approach in vaccination strategies to optimize both immediate and long-term immunity. In contrast, the variability in maternal antibody transfer suggests that not all offspring may receive adequate protection, highlighting the need for careful management of vaccination schedules to optimize both maternal and offspring immunity. This complexity underscores the importance of understanding maternal effects in poultry health management.

Conclusions

The choice between licensed and autogenous vaccines depends on the specific needs of the farm, including the prevalence of disease, antigenic variation, and economic considerations. Licensed vaccines offer broad protection, convenience, and regulatory assurance, while autogenous vaccines provide tailored immunity and enhanced efficacy against regionally prevalent strains. A combination of both strategies, where feasible, may offer the best protection against a wide range of pathogens.

Autogenous vaccines have proven to be a valuable tool in poultry farming, offering targeted and effective disease control. Their ability to reduce antimicrobial use, provide rapid protection against emerging strains, and contribute to sustainable farming practices makes them an essential component of modern poultry health management. However,

their effectiveness depends on careful formulation, adherence to regulatory standards, and ongoing research to address evolving pathogen challenges. The success of autogenous vaccines as a prevention strategy for affected flocks requires careful attention in the composition of the vaccine, and depends on the identification of circulating strains as well as serological and clinical monitoring[7].

Condemnation rates, mortality and antimicrobial use can be reduced with the help of autogenous vaccines, and overall flock performance can be improved. Implementing action plans on affected farms can mitigate the economic impact of infections. These action plans should incorporate all relevant measures, such as a well-designed vaccination program, regular updates of vaccine formulations based on continuous monitoring and robust biosecurity practice[7].

To improve vaccines or optimize treatment outcomes, collecting information on the effects of autogenous vaccines use is important for both veterinarians and manufacturers. This information can also contribute to the development of a licensed vaccine. In addition, innovative approaches to the production of autogenous vaccines, such as the use of mRNA platforms, should be explored for future applicability, recognizing that this will require updates in legislation[5].

Future directions

Future advances in autogenous vaccine technology are expected to focus on increasing precision, speed, and standardization. Emerging platforms such as mRNA, DNA, and recombinant vector-based systems hold promise for producing highly specific autogenous vaccines with shorter development timelines and greater adaptability to

rapidly evolving pathogens. Although these technologies are already transforming human and veterinary vaccinology, their use in flock-specific vaccine production will require substantial regulatory adaptation, as well as validation of safety, stability, and on-farm applicability.

A major challenge for the next decade will be the standardization of potency and quality across autogenous vaccine batches produced for different farms and under variable field conditions. Establishing harmonized guidelines for antigen quantification, adjuvant selection, and evaluation of immune responses will be essential to increase consistency and confidence among veterinarians and producers. Additionally, the creation of regional or global databases containing poultry pathogen genomes, antigenic profiles, and vaccine performance records would support more informed decision-making. Such databases could facilitate strain tracking, early identification of emerging variants, and more efficient updating of autogenous vaccine formulations.

These innovations, ranging from advanced vaccine platforms to improved surveillance networks, represent key opportunities to enhance the reliability, scalability, and strategic value of autogenous vaccines in poultry production.

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Authors contribution

VH contributed to the literature search, data curation, initial drafting of the manuscript, and preparation of figures and tables. KRDS assisted in the literature review, and consolidation of scientific evidence. APB conceptualized the review, supervised the analysis and interpretation of the literature, and critically revised the manuscript for important intellectual content. All authors reviewed and approved the final version of the manuscript.

Data availability statement

Not applicable.

Competing interests

The authors declare that they have no known competing financial or non-financial interests, nor any personal relationships that could have influenced the work reported in this paper.

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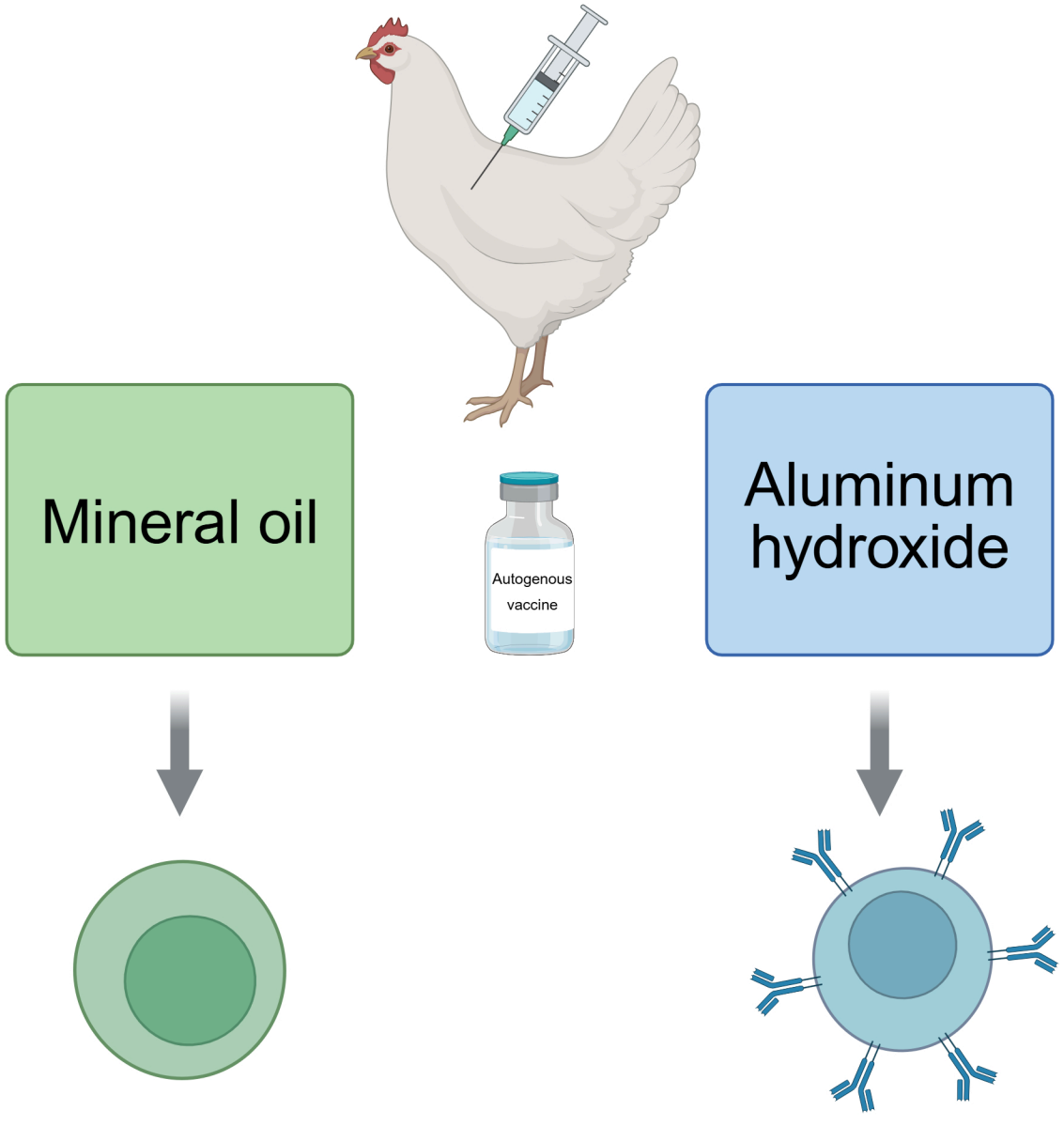
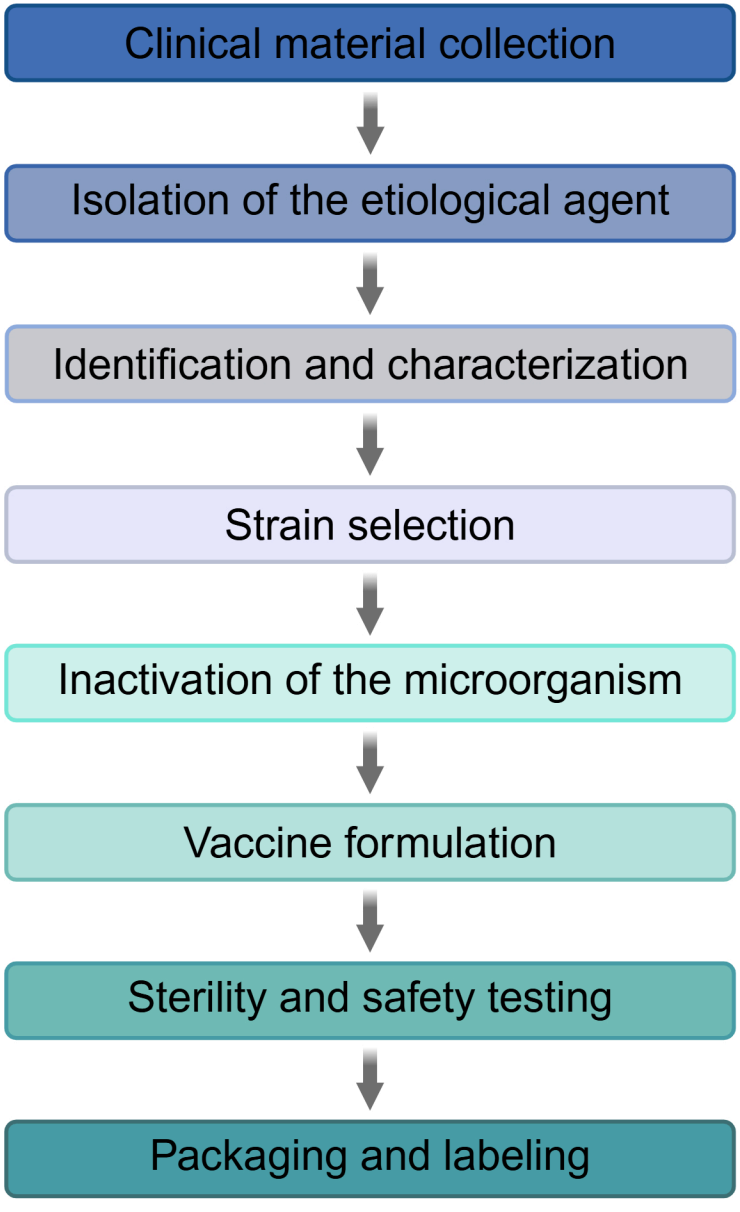
Figure Legends

Figure 1. Mechanism of action of autogenous vaccines with mineral oil and aluminum hydroxide adjuvants. Created in https://BioRender.com.

Figure 2. Autogenous vaccine production flowchart. Created in https://BioRender.com.


Mineral oil
Autogenous vaccine
Aluminum hydroxide


Clinical material collection
Isolation of the etiological agent
Identification and characterization
Strain selection
Inactivation of the microorganism
Vaccine formulation
Sterility and safety testing
Packaging and labeling