



Vaccine development; examining the advancements in vaccine technology for effective control and prevention of infectious diseases

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Article Info

Volume 2, Issue 2, July 2025

Received : 10 January 2025

Accepted : 25 May 2025

Published : 25 July 2025

doi: [10.62587/AFRJMS.2.2.2025.18-25](https://doi.org/10.62587/AFRJMS.2.2.2025.18-25)

Abstract

Background: The COVID-19 pandemic emphasized the urgent need for rapid and effective vaccine development. Recent innovations such as mRNA, viral vector, and protein subunit platforms have transformed the vaccine landscape, improving both efficacy and safety. **Methodology:** This paper reviews emerging vaccine technologies and highlights specific innovations like the Multi-Epitope Vaccine (MEV) developed by Man *et al.* (2021) for schistosomiasis. It also explores the role of immunoinformatic in accelerating the identification of vaccine candidates. **Results:** Evidence shows that while traditional childhood vaccines have greatly reduced mortality (CDC, 1999), the cost-benefit balance of newer vaccines targeting chronic or rare diseases (e.g., cancer) remains debatable. Nevertheless, advances in microbiology and immunology are contributing to more targeted and efficient vaccine development. **Conclusion:** Technological advancements in vaccine development are crucial to reducing the global disease burden. These innovations may also enhance public trust by improving vaccine safety and efficacy, thereby addressing vaccine hesitancy and supporting global health goals.

Keywords: Vaccine technology, Infectious diseases, Vaccine development, Public health, Vaccine efficacy, Vaccine hesitancy

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1. Introduction

Vaccines represent one of the most significant public health advancements of the past century, with estimates suggesting they save between 2 to 3 million lives annually. Currently, licensed vaccines are available to prevent over 30 different infectious diseases, many of which can be combined into single vaccines or administered during a single vaccination session (Delany *et al.*, 2014). The pathogens responsible for these diseases have long been recognized, and it was after the introduction of the first vaccine that it became clear humans could be protected from these threats (Khare and Sahu, 2022). Vaccines are a key benefit of contemporary medicine (Khare and Sahu, 2022). Without them, the global population, particularly children, would face widespread infections from diseases such as smallpox, diphtheria, hepatitis, polio, and measles (Khare and Sahu, 2022). Numerous vaccines are currently available to provide immunity against bacterial, viral, fungal, and parasitic infections (Khare and Sahu, 2022). However, effective vaccines for neglected infectious diseases like HIV, Hepatitis C, and Malaria remain unavailable (Khare and Sahu, 2022). Vaccines are considered one of the most cost-effective tools for controlling infectious diseases (Khare and Sahu, 2022). They have played a crucial role in reducing the morbidity and mortality associated with infectious diseases globally (Cable *et al.*, 2020). Nevertheless, effective vaccines for many serious and preventable infectious diseases are still lacking (Cable *et al.*, 2020). Innovations in vaccine technology such as new delivery systems and adjuvants along with advancements in systems biology and a deeper understanding of the human immune system, offer potential solutions to these challenges (Cable *et al.*, 2020). Vaccines consist of biological formulations designed to stimulate and prepare the immune system to combat infections or diseases (Saxena *et al.*, 2021; Ghattas *et al.*, 2021). They leverage the sophisticated capabilities of the mammalian immune system to identify, respond to, and remember pathogens (Saxena *et al.*, 2021; Ghattas *et al.*, 2021). The main ingredients in vaccines are antigens derived from the targeted pathogen or produced through biomanufacturing (Saxena *et al.*, 2021; Ghattas *et al.*, 2021). Other components may include preservatives, stabilizers, excipients, and trace substances from the manufacturing process (Saxena *et al.*, 2021; Ghattas *et al.*, 2021). Adjuvants are often included to enhance immunogenicity the ability to provoke an immune response – and effectiveness in certain populations such as infants, the elderly, and immunocompromised individuals. They can also help reduce the required antigen dose, thereby increasing global vaccine availability (Ghattas *et al.*, 2021). The goal of vaccination is to elicit a protective immune response against a specific pathogen without exposing individuals to the risk of contracting the disease or experiencing its complications (Saxena *et al.*, 2021; Ghattas *et al.*, 2021).

2. Types of vaccines

2.1. Live attenuated vaccines

Live attenuated vaccines contain pathogens that have been weakened, altered or selected to be less virulent than their wild-type counterparts (Vetter *et al.*, 2018). In their altered form, they cannot cause the actual disease (Vetter *et al.*, 2018). Live attenuated vaccines are generally produced from viruses rather than bacteria because viruses contain fewer genes and attenuation can be obtained and controlled more reliably (Vetter *et al.*, 2018). The most common method to obtain live attenuated vaccines is to pass the virus through a series of in vitro cell cultures (e.g., in chick embryo cells) (Clem, 2011). At each “passage”, the selected viruses become better at infecting and replicating in cell cultures but progressively lose their ability to infect and replicate in their original human host (Clem, 2011).

2.2. Inactivated vaccines

Vaccines based on inactivated pathogens are produced by inactivating preparations of whole pathogens by heat, radiation, or chemicals such as formalin or formaldehyde (Vetter *et al.*, 2018). Inactivation destroys the pathogen’s ability to replicate and cause the disease but maintains its immunogenicity, so that the immune system can still recognize the targeted pathogen (Vetter *et al.*, 2018). Examples include typhoid fever, cholera, Rabies, and hepatitis A vaccines (Delany *et al.*, 2014; Cunningham *et al.*, 2016).

2.3. Subunit vaccines

Subunit vaccines contain selected fragments of the pathogen as antigens instead of the whole pathogen (Vetter *et al.*, 2018). These fragments can be proteins, polysaccharides, or parts of a virus that may form Virus-Like

Particles (VLPs) (Vetter *et al.*, 2018). Subunit vaccines generally cause less adverse reactions than live or inactivated whole-organism vaccines, but they may be less immunogenic because they contain fewer antigens and the purification process often eliminates components that trigger innate immunity (Vetter *et al.*, 2018). Examples of subunit vaccines include tetanus toxoid, inactivated split and subunit seasonal influenza, acellular pertussis and pneumococcal polysaccharide vaccines (Rappuoli *et al.*, 2014).

2.4. Synthetic peptide vaccines

Synthetic Peptide Vaccines Immune responses to pathogens are dominated by effector cells that recognize either one or multiple epitopes on an antigen (Ghattas *et al.*, 2021). Identification and synthesis of these immunodominant peptide sequences are used to develop novel vaccine modalities (Ghattas *et al.*, 2021). The design of synthetic peptides involves extensive *in vitro* screening and modeling to identify appropriate immunodominant peptides with suitable manufacturing characteristics (Li *et al.*, 2014). Due to their small size, peptide vaccines are typically mixed with or conjugated to an adjuvant to enhance their immune response and uptake by APCs (Ghattas *et al.*, 2021). Adjuvants must be carefully chosen, since engineered epitopes are sensitive to denaturation or emulsification that might occur in the presence of specific adjuvants (Malonis *et al.*, 2020).

2.5. Toxoid vaccines

Some bacteria such as *Clostridium tetani*, *Clostridium difficile* or *Corynebacterium diphtheriae* cause disease by releasing pathogenic toxins (Vetter *et al.*, 2018). Vaccines against these diseases are produced by detoxifying the toxin using heat, chemicals (e.g., formaldehyde) or both (Vetter *et al.*, 2018). The inactivated toxins, called toxoids, are no longer pathogenic but retain their ability to induce toxin-neutralizing antibodies (Vetter *et al.*, 2018). Classical examples of toxoid vaccines are those against diphtheria and tetanus (Moloney, 1926; World Health Organization, 2006).

2.5.1. Proof of concept

In early stage of vaccine development researchers explore the idea for a potential vaccine (Centers for Disease Control and Prevention, 2023). Vaccine development often takes 10-15 years of laboratory research, usually at a company in private industry, but often involves collaboration with researchers at a university (Centers for Disease Control and Prevention, 2023). Before a vaccine can be tested in people, researchers study its ability to cause an immune response with small animals, like mice (Centers for Disease Control and Prevention, 2023). At this stage, researchers may adjust the vaccine to make it more effective (Centers for Disease Control and Prevention, 2023). Vaccine effectiveness is important because it measures how well vaccination protects people against outcomes such as infection, symptomatic illness, hospitalization, and death (Centers for Disease Control and Prevention, 2023). A vaccine-specific developmental plan should be clearly established to ensure the efficient and successful development before clinical evaluation (Han, 2015).

This includes the following contents:

1. Identification of the target population (mostly healthy people with particular demographic characteristics) and their sociocultural factors;
2. Risk assessment of the target disease and the vaccine itself;
3. Understanding of the incidence of the target disease and environmental factors;
4. Identification of the dose and route of administration;
5. Plans to induce herd immunity; and
6. Regulatory strategies.

3. Advancements in vaccine technology for effective control and prevention of infectious diseases

Entire viral genomes can now be cloned into bacterial or yeast vectors, allowing manipulation of genes prior to “rescue,” or regeneration of infectious organisms in culture (McCullers and Dunn, 2008). These techniques

enable the rapid custom design of organisms for use in vaccines, Influenza virus vaccines can serve as an example (McCullers and Dunn, 2008). The surface proteins from circulating strains can be cloned into plasmids and are co-expressed with a set of “backbone” genes responsible for high growth in eggs but attenuation in humans, allowing the production of safe, high-yield vaccines (Hoffmann *et al.*, 2002). Undesirable traits, such as the multi basic cleavage site found in the main attachment protein of highly pathogenic avian influenza viruses, can be “edited out” at the DNA level before rescue of the virus, further enhancing safety (Webby *et al.*, 2004). The use of plasmid-based methods also has the potential to hasten production of Reassortant vaccines (i.e., vaccines from viruses created by combining genes from more than one organism or strain) (McCullers and Dunn, 2008). The current process for making influenza vaccine relies on selecting appropriate vaccine strains from among many candidates generated by chance, whereas molecular methods allow complete control over the output, eliminating several steps in the generation of seed stocks (Hoffmann *et al.*, 2002). A variety of virus types, engineered by these methods to be safe in humans, are being used to express immunogenic foreign proteins outside of the context of the virulent parent organism (McCullers and Dunn, 2008). As an example, adenoviruses in which critical virulence genes are deleted have been used to express proteins from HIV19 (Liniger *et al.*, 2007). It may be possible to create vaccine cocktails directed against several different pathogens by inserting multiple proteins into a single vector or by mixing several vaccines made with the same viral vector but expressing different proteins (Schmidt *et al.*, 2002). It is also possible to deliver the immunogenic proteins without using a replication-competent, live virus (McCullers and Dunn, 2008). Virus-Like Particles (VLPs) are self-assembling constructs that express a viral antigen, but they do not contain the necessary material to replicate (McCullers and Dunn, 2008). This technology was used to develop Gardasil, Merck’s vaccine to protect against Human Papilloma Virus (HPV), approved in 2006 (Lowy and Schiller, 2006). In conjunction with new technology for vaccines, adjuvants are also needed (McCullers and Dunn, 2008). New compounds may enhance immunogenicity quantitatively, by increasing the levels of protective immune responses, and qualitatively, by eliciting responses from different arms of the immune system or by broadening the scope of covered immunogens (McCullers and Dunn, 2008). This advance has the potential to improve overall outcomes and achieve cost-savings by allowing lower doses to be used and, possibly, by eliminating or postponing the need for booster injections (McCullers and Dunn, 2008). In a clinical trial in humans, an oil-in-water emulsion from GlaxoSmithKline (GSK) enhanced the immunogenicity of a potential pandemic influenza vaccine (McCullers and Dunn, 2008). This vaccine enabled the dose to be reduced, and it induced responses that were cross-reactive in several clades (distinct virus groupings) (Leroux-Roels *et al.*, 2007). Clinical trials of GlaxoSmithKline (GSK’s) VLP-based HPV vaccine Cervarix have shown similar cross-protective responses to subtypes not included in the vaccine, which might be attributable to the novel adjuvant ASO4 (Lowy and Schiller, 2006; Harper *et al.*, 2006; Paavonen *et al.*, 2007). The ability of certain adjuvants to enhance the levels of memory B cells and antibodies, in some cases to numbers much higher than those seen with natural infection has implications for the longevity of the response as well (Giannini *et al.*, 2006). In one study comparing ASO4 plus alum with alum alone against HPV, significantly higher antibody titers were observed when ASO4 was included (Giannini *et al.*, 2006). This advantage was maintained during long-term follow-up (McCullers and Dunn, 2008). These dual benefits extending the time that antibody levels are maintained above the threshold required for neutralization of the organism and enhancing the capacity of the patient to respond to a booster immunization are important for future planning and estimating costs (McCullers and Dunn, 2008). Another desirable feature of adjuvants is their ability to be paired with multiple antigens so that they can be included in different vaccines (McCullers and Dunn, 2008). For example, ASO4 has been studied in conjunction with both hepatitis B and HPV vaccines (Giannini *et al.*, 2006). This capability can reduce the vaccine’s developmental costs and the time to market (McCullers and Dunn, 2008). With each new adjuvant and each new combination of adjuvant and vaccine, the advantages of increased immunogenicity, longevity, and perhaps broadened coverage of strains must be balanced with the potential for increased reactogenicity (McCullers and Dunn, 2008). In this context, reactogenicity refers to the generally undesirable effects of the vaccine, typically mediated by the immune response to the vaccine rather than by the product’s direct toxicological effects. Redness or swelling at an injection site are two common examples (McCullers and Dunn, 2008). In concert with the advances in vaccine engineering and adjuvantation, novel routes of delivery are also being investigated (McCullers and Dunn, 2008). Intradermal delivery directly to an environment rich in Antigen-Presenting Cells (APCs) is a dose-sparing measure for several vaccines, including those used for HIV and influenza (Belshe *et al.*, 2007). Needle-free variants of this route, such as transdermal patches and electroporation, are also being

tested for conditions as diverse as influenza, traveler's diarrhea, and melanoma (Yu *et al.*, 2002; Garg *et al.*, 2007; National Institutes of Health, 2007). Mucosal delivery, which has the advantage of not requiring a needle, is already being used for several vaccines (McCullers and Dunn, 2008). The live, attenuated influenza vaccine FluMist is given as a nasal spray (Belshe *et al.*, 2007; Dennehy, 2007). The mucosal route of delivery may contribute to the protection seen with both vaccines by inducing broader immunity, including mucosal immunoglobulin A (McCullers and Dunn, 2008). Mucosal delivery is also being studied for several other potential vaccines directed against diseases such as HIV infection and tuberculosis (National Institutes of Health, 2007). Recently, the great advances made in bioinformatic sciences have led to approaches for the development of novel and, potentially effective, vaccine candidates against different pathogens, such as viruses, bacteria and parasites (Kardani *et al.*, 2020). Thus, immunoinformatic methodologies, due to their reliability, safety, low cost, stability, precision and, above all, speed, have recently been used to progress Multiple Epitope Vaccines (MEVs) (Arora *et al.*, 2022). MEVs represent an interesting novel approach in designing vaccines (Cianci and Franza, 2022). It is sometimes difficult to identify a single antigen capable of determining an immune response and this has been a major problem in different occasions (Cianci and Franza, 2022). Moreover, immunoinformatics can help detect T-cell/B-cell epitopes, highlight antigenic immunodominant epitopes, reduce allergenicity and toxicity and enhance stability of a vaccine candidate (Sunita *et al.*, 2020). Yet, it is also worth noting that, after having designed MEVs, a subsequent strong validation in animal models is needed to confirm the real immunogenicity and safety of the vaccine (Cianci and Franza, 2022; Suleman *et al.*, 2021) for instance, have used bioinformatics to design a new multi-epitopes subunit vaccine candidate that could potentially determine a strong immune response against an emerging Tick-Borne Encephalitis Virus (TBEV), a member of the Flaviviridae family that has caught the attention of researchers, as it is the causative agent of a severe neurological disease, and transmitted by ticks (Rehman *et al.*, 2021) have designed a MEV as a new option for Schistosomiasis, which is the second most common tropical disease after malaria.

4. Conclusion

Vaccines exemplify the premise behind managed care to promote wellness and prevent disease while also avoiding unnecessary treatment related costs (McCullers and Dunn, 2008). Vaccines can elicit the production of an adequate acquired immunity (Cianci and Franza, 2022). The benefits of childhood vaccines in reducing mortality alone are undeniable (Centers for Disease Control and Prevention, 1999). However, the cost benefit relationship for the new generation of vaccines that can target reductions in morbidity or prevent rare and costly illnesses such as cancer is less clear, but the promise of a brighter future is motivation up to a point (McCullers and Dunn, 2008). Without doubt, the quantity and quality of clinical vaccine development will improve greatly in the future (Han, 2015). Simultaneously, the coverage of vaccines against diverse diseases will be broadened faster than ever (Han, 2015). Integration of knowledge about microbiology and immunology, establishment of efficient vaccine development strategies, and streamlining of regulatory approval processes may facilitate this trend (Han, 2015). Advancement in vaccine technology has the potential to prevent illness and reduce the economic burden of diseases (McCullers and Dunn, 2008). The recent advances in immunoinformatics have paved the way for rapid identification of novel vaccine candidates that could evoke a strong immune response (Cianci and Franza, 2022). Moreover, the technological advances that are taking place may allow us to target several infectious diseases that, at present, can be treated only through supportive care (Cianci and Franza, 2022). This is particularly interesting when considering multi-resistant pathogens, which represent a serious threat globally (Cianci and Franza, 2022). Furthermore, the progress that has been made may also allow us to make existing vaccines more efficient and even safer, which is particularly important given the present distrust towards vaccinations (Cianci and Franza, 2022).

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Cite this article as: Abubakar Babangida Usman, Hussaini Muhammad Alhassan, Mustapha Umar Kalgo, Abdulrahman Ibrahim Zagga and Kabir Magaji Hamid (2025). *Vaccine development; examining the advancements in vaccine technology for effective control and prevention of infectious diseases. African Research Journal of Medical Sciences*. 2(2), 18-25. doi: [10.62587/AFRJMS.2.2.2025.18-25](https://doi.org/10.62587/AFRJMS.2.2.2025.18-25).