MUCOSAL VACCINE DELIVERY SYSTEMS:

THE FUTURE OF IMMUNIZATION

PART 2

Editors:
Shaweta Sharma
Aftab Alam
Akhil Sharma

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Mucosal Vaccine Delivery Systems: The Future of Immunization

(Part 2)

Edited by

Shaweta Sharma
School of Medical and Allied Sciences
Galgotias University, Yamuna Expressway
Gautam Buddha Nagar, Uttar Pradesh-201310
India

Aftab Alam
School of Pharmacy Katihar Medical College
Campus Alkarim University Katihar-854106 Katihar
India

&

Akhil Sharma
R.J. College of Pharmacy, Raipur, Gharbara
Tappal, Khair Uttar Pradesh, India

Mucosal Vaccine Delivery Systems: The Future of Immunization *(Part 2)*

Editors: Shaweta Sharma, Aftab Alam, and Akhil Sharma

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FOREWORD

Vaccination has long been a cornerstone of public health, and mucosal vaccine delivery systems represent a transformative step toward safer, more effective immunization strategies. Mucosal Vaccine Delivery Systems: The Future of Immunization – Part II delves into key advancements shaping this field, offering a comprehensive exploration of scientific, regulatory, economic, and clinical perspectives. This volume addresses critical topics, including regulatory considerations, economic implications, and applications in both human and veterinary medicine. Special focus is given to mucosal vaccination's role in combating emerging infectious diseases and cancer immunotherapy, alongside innovations in adjuvants and bioprocessing challenges in large-scale production. By bridging fundamental research with real-world applications, this book serves as an essential resource for researchers, healthcare professionals, and policymakers dedicated to advancing immunization strategies. As mucosal vaccines continue to evolve, their potential to revolutionize global health remains unparalleled.

Shivkanya Fuloria
Pharmaceutical Chemistry Unit
Faculty of Pharmacy, AIMST University
Kedah 08100 Malaysia

PREFACE

The field of mucosal vaccination continues to revolutionize immunization strategies, offering innovative approaches to disease prevention across human and veterinary medicine. As research advances, addressing regulatory, economic, and manufacturing challenges is crucial to ensuring the widespread adoption and success of these vaccines. Mucosal Vaccine Delivery Systems: The Future of Immunization – Part II delves into these critical aspects while exploring groundbreaking applications in emerging diseases and cancer immunotherapy.

This volume begins with an in-depth discussion of regulatory considerations, outlining the frameworks that govern mucosal vaccine approval and distribution. It then examines the economic impacts of mucosal vaccination programs, highlighting cost-effectiveness and public health benefits. The book further explores the role of mucosal vaccines in emerging and pandemic infectious diseases, emphasizing their potential to offer rapid, scalable solutions during global health crises.

Beyond human medicine, mucosal vaccination in veterinary science is addressed, showcasing its significance in controlling zoonotic diseases. Advances in adjuvant technology for mucosal vaccines are explored, focusing on innovations that enhance immune response and vaccine stability. Additionally, challenges in bioprocessing and large-scale production are examined, ensuring that these vaccines can be manufactured efficiently and affordably. Finally, the book highlights the promising role of mucosal vaccines in cancer immunotherapy, paving the way for novel, non-invasive cancer treatments.

By addressing these key topics, this volume serves as a valuable resource for researchers, policymakers, and industry professionals. We hope it inspires further innovation and collaboration to shape the future of mucosal immunization.

Shaweta Sharma
School of Medical and Allied Sciences
Galgotias University, Yamuna Expressway
Gautam Buddha Nagar, Uttar Pradesh-201310
India

Aftab Alam
School of Pharmacy Katihar Medical College
Campus Alkarim University Katihar-854106 Katihar
India

&

Akhil Sharma
R.J. College of Pharmacy, Raipur, Gharbara
Tappal, Khair Uttar Pradesh, India

List of Contributors

Ashish	Mangalmay Pharmacy College, Plot No. 9, Knowledge Park II, Greater Noida, Uttar Pradesh 201306, India
Akhil Sharma	R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India
Akanksha Sharma	R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India
Alok Bhardwaj	Lloyd Institute of Management & Technology, Plot No.-11, Knowledge Park-II, Greater Noida, Uttar Pradesh-201306, India
Koushal Dhamija	Lloyd Institute of Management & Technology, Plot No.-11, Knowledge Park-II, Greater Noida, Uttar Pradesh-201306, India
Md Nasar Mallick	School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India
Neeraj Kumar Fuloria	Department of Pharmaceutical Chemistry, Faculty of Pharmacy, AIMST University, Semeling Campus, Jalan Bedong-Semeling, Bedong, Kedah Darul Aman, Malaysia
Rupali Sharma	Amity University Haryana, Manesar, Gurugram, India
Shivkanya Fuloria	Faculty of Pharmacy, AIMST University, Semeling Campus, Bedong, Kedah, Malaysia
Sunita	Metro College of Health Sciences and Research, Greater Noida, India
Shaweta Sharma	School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India
Shekhar Singh	Babu Banarasi Das Northern India Institute of Technology, Faculty of Pharmacy, Lucknow, Uttar Pradesh, 226028, India
Sudhir Kumar	Faculty of Pharmaceutical Sciences, DAV University, Jalandhar, India
Shekhar Sharma	Lloyd Institute of Management & Technology, Plot No.-11, Knowledge Park-II, Greater Noida, Uttar Pradesh-201306, India

CHAPTER 1

Regulatory Considerations for Mucosal Vaccination

Shivkanya Fuloria[1], Sunita[2], Ashish[3], Shaweta Sharma[4] and **Akhil Sharma[5,*]**

[1] *Faculty of Pharmacy, AIMST University, Semeling Campus, Bedong, Kedah, Malaysia*

[2] *Metro College of Health Sciences and Research, Greater Noida, India*

[3] *Mangalmay Pharmacy College, Plot No. 9, Knowledge Park II, Greater Noida, Uttar Pradesh 201306, India*

[4] *School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India*

[5] *R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India*

Abstract: Mucosal vaccination has the potential to revolutionize immunization and has several benefits over other conventional parenteral vaccination routes, including enhanced mucosal immune responses and ease of administration. However, the regulatory environment for mucosal vaccines is complex and diverse, necessitating a detailed understanding of the requirements for their development, approval, and deployment. This section offers an in-depth examination of how a regulatory framework is constituted around mucosal vaccinations. This chapter starts with an overview of mucosal vaccination and its importance in the fight against infectious diseases. It proceeds to explore various regulatory policies provided by leading regulatory agencies, which include the Food and Drug Administration (FDA), European Medicines Agency (EMA), and World Health Organization (WHO). It gives a comprehensive look into what makes the control of mucosal vaccines different from others, such as immunological mechanisms, administration routes that are best, formulation stability, and safety assessment. The chapter presents critical insights and best practices for navigating the regulatory landscape effectively through analysis of diverse case studies representing successful regulatory approval processes for mucosal vaccines. Also, it talks about future perspectives on emerging technologies, regulatory adaptations to accommodate evolving scientific advancements, and the necessity for global collaboration to accelerate the development and regulatory approval of mucosal vaccination strategies. The main purpose of synthesizing contemporary regulatory knowledge and giving practical advice in this chapter was to create a useful tool for investigators, producers, and regulatory officials who are working on mucosal vaccines. In the long run, this work will help advance global public health programs.

[*] **Corresponding author Akhil Sharma:** R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India; E-mail: xs2akhil@gmail.com

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Keywords: Emerging technologies, European Medicines Agency (EMA), Food and Drug Administration (FDA), Global collaboration, Immunological considerations, Public health initiatives, Safety assessment, World Health Organization (WHO).

INTRODUCTION

Mucosal immunization is a novel form of vaccination that has numerous advantages over traditional injectable vaccines. It induces potent immune responses at the same sites on the mucosa, such as respiratory, gastrointestinal, and genitourinary tracts, where pathogens commonly invade the system. This affords an emergency response to infection-targeting pathogens before they become systematic [1].

An important advantage of mucosal immunization is its potential to result in local and systemic immune responses. Consequently, these immunizations not only prevent initial infections but also confer systemic protection, thus improving the overall efficacy of vaccines. For microbes that can invade both mucosal and systemic tissues, such double immunity guarantees total protection against numerous infectious agents [2].

Furthermore, mucosal vaccines provide additional benefits that can help to increase immunization coverage and public health outcomes. Patients with needle aversion or fear of needles are more likely to be interested in this method of injection without a needle or painful one. As a result, higher rates of vaccination and improved neighborhood security against the spread of infectious diseases may occur. Again, ease of administration and the possibility for self-administration in certain instances make mucosal vaccines the ideal means of reaching remote regions or areas with limited healthcare services [3].

Moreover, the adaptability of mucosal vaccine systems enables the creation of vaccines for an array of pathogens, including parasites, bacteria, and viruses. These vaccines can be given through several noninvasive alternatives, such as oral tablets, nasal sprays, or aerosols, that do away with the use of needles and syringes, hence minimizing needlestick injuries. This also promotes safety in addition to making possible mass immunization campaigns and hastening world-wide immunization initiatives [4].

On the other hand, the use of mucosal vaccination faces a number of challenges that should be considered and studied continuously. Among the major issues researchers in this area have to deal with are working towards overcoming mucosal barriers, formulating vaccines for stability and effectiveness, and

ensuring safety and tolerability. In addition, unlike systemic responses, mucosal immune responses might require tailored approaches to vaccine design and evaluation [5].

Mucosal vaccination has great potential for stopping infectious diseases and for improving public health. Because they use mucosal immunity, these vaccines are a new, effective strategy to keep populations immune from many pathogens. To fully benefit from this aspect of health in the world we are facing today, further research on mucosal immunization and development should be conducted [6].

Importance of Regulatory Considerations

Regulatory considerations are paramount in the development, approval, and deployment of any vaccine, including mucosal vaccines.

Safety

Safeguarding public health, regulatory agencies play a crucial role by ensuring that vaccines, which include mucosal vaccines, meet strict safety standards during their development and deployment. Mucosal vaccines often require extensive evaluation to tackle dangers like local irritation or systemic adverse reactions through innovative delivery modalities or formulations. Regulatory oversight is necessary throughout the preclinical and clinical developmental cycle in order to effectively identify and counteract safety issues [7]. In the preclinical stage, regulatory authorities demand a lot of laboratory testing so as to evaluate the safety profiles of various mucosal vaccine candidates. Such works include determining their potential toxicity, immunogenicity, and pharmacokinetics. There are also experiments carried out on animals in order to examine the biological effects of vaccines and confirm if they would lead to an appropriate immune response without causing harm [8].

When mucosal vaccines are advanced to clinical trials, regulatory oversight becomes even more imperative. Phase I trials are aimed at establishing the safety profile of the virus in a small number of people who will get it for experimental purposes; following this, it is given to them in different doses so that they can determine which dose is the best. In phase II, the number of individuals being studied rises so as to evaluate safety and immunogenicity within a bigger cohort, thereby providing more information about risks and benefits [9]. In phase III trials, the regulatory body looks at the safety data collected from a large and diverse population to confirm that the vaccine is safe as well as effective. Adverse events are reported and analyzed in considerable detail in order to identify unexpected reactions or patterns. Besides, regulators evaluate if the vaccine

CHAPTER 2

Economic Impacts of Mucosal Vaccination Programs

Neeraj Kumar Fuloria[1], Akhil Sharma[2], Sunita[3], Akanksha Sharma[2] and **Shaweta Sharma[4,*]**

[1] *Department of Pharmaceutical Chemistry, Faculty of Pharmacy, AIMST University, Semeling Campus, Jalan Bedong-Semeling, Bedong, Kedah Darul Aman, Malaysia*

[2] *R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India*

[3] *Metro College of Health Sciences and Research, Greater Noida, India*

[4] *School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India*

Abstract: Mucosal vaccination is a new method of immunization with the potential to revolutionize strategies in the prevention of diseases. Although more attention has been paid to its ability to generate strong immunity, its economic implications have not been adequately discussed. This abstract gives an inclusive summary of the economic effects of disease prevention programs with their possible advantages and drawbacks. There are various advantages of mucosal vaccination compared to traditional injection approaches, including improved immunity at the mucosal level, lesser rates of transmission, and faster acquisition of herd immunity. Consequently, all these benefits lead to substantial economic gains across different sectors. In the health system, a considerable amount of money can be saved if there are fewer ill people due to reduced disease burden, which would lower the costs of treatment and strain on healthcare infrastructure. Mucosal vaccination, apart from better healthcare, can have various economic implications on society and industries. A healthy labor force translates to higher productivity levels, reduced absenteeism rates as well as improved living standards for people and their families. In addition, the production and distribution of mucosal vaccines promote pharmaceutical growth as well as biotechnological sectors by encouraging research and development activities while expanding vaccine manufacturing capacities. However, the advantages of mucosal immunization initiatives in economic terms must be counterbalanced with their challenges. Some of the major things to consider in this case are high development and deployment costs, accessibility and distribution issues as well as public perception and acceptance. However, such problems are surmountable as the use of mucosal vaccination has been shown to be cost-effective and economically beneficial in the future. Eventually, vaccination programs targeting the mucosal surfaces provide a potential solution for

* **Corresponding author Shaweta Sharma:** School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India;
E-mail: shawetasharma@galgotiasuniversity.edu.in

Shaweta Sharma, Aftab Alam & Akhil Sharma (Eds.)

not only effective healthcare delivery but also considerable economic growth. Policymakers, healthcare providers, and industries should understand the economic consequences of vaccination through the mucosal route and should work together to overcome hindrances that might come their way in order to prevent disease and make the economy prosperous.

Keywords: Biotech sensors, Economic impact, Disease,, Healthcare, Industry, Immunization, Mucosal vaccination, Prevention, Treatment, Transmission, Vaccination programs.

INTRODUCTION

Mucosal vaccination is a new approach to immunization that focuses on the mucosal surfaces of the body, mainly in the respiratory, gastrointestinal, and genitourinary systems, instead of following traditional injection procedures. Mucosal vaccines do not act like regular vaccines that stimulate a systemic immune response through intramuscular or subcutaneous injection; rather, they elicit both mucosal and systemic immunity. Mucosal surfaces are the main entry points for many pathogens, such as respiratory viruses, sexually transmitted infections, and gastrointestinal pathogens [1].

By precisely aiming at such sites, mucosal immunization intensifies the body's ability to prevent infections better and control disease transmission. Most importantly, though, mucosal vaccines can also induce mucosal IgA antibodies that serve as a first line of defense against invading pathogens at portals of entry, thus partly filling the gap between systemic immune responses induced by conventional vaccines. These two aspects of immunity work together to not only improve protection against infection but also lead to herd immunity, reducing the overall incidence of a particular disease within a population [2].

Preventing infectious diseases from spreading and reducing disease rates is the way vaccination programs contribute to public health. Vaccination, in history, has been one of the most cost-effective interventions in public health, leading to the elimination or near eradication of a number of fatal diseases such as smallpox, polio, and measles, among others. Not only have vaccines saved millions of lives, but they have also had significant economic benefits through saving costs for healthcare, increasing productivity, and avoiding economic impacts triggered by outbreaks of disease [3].

Vaccination programs have a direct effect on individual health; they also contribute to better social equity, minimize healthcare discrepancies, and improve global health security. Besides that, immunization is a critical part of sustainable development as it facilitates economic growth, promotes the attainment of

education, and enhances social integration among people. That is why investment in vaccination programs can be considered an allocation of resources that can bring about substantial public health results alongside economic prosperity [4].

The economic impacts of mucosal vaccination programs go beyond public health and affect various sectors of the economy and society. From a health perspective, mucosal immunization can potentially result in significant cost savings by reducing the burden of infectious diseases. Prevention of illness and complications due to mucosal vaccines can reduce healthcare costs associated with treatment, hospitalizations, and long-term care, thus relieving healthcare systems and resources [5].

Moreover, immunizing staff against contagious illnesses makes them stronger and more prepared to contribute towards economic expansion. Furthermore, societies as a whole profit economically from mucosal vaccinations since healthier communities mean higher productivity levels as well as lower rates of absenteeism coupled with enhanced living standards. Industries, including biotechnology and pharmaceuticals, may benefit from mucosal vaccination initiatives in a variety of ways that can lead to innovation, research, and development. There are always new markets to be created when making or using vaccines through the mucosa, which also prompt investments into this type of infrastructure while at the same time fostering partnerships among different governments as well as with businesses across various industries [6].

Mucosal vaccination also promotes global health security by reducing the likelihood of pandemics and epidemics, which can cause severe economic damage on national or global scale. Therefore, multiple economic effects of mucosal vaccination programs exist, including those that reduce healthcare costs, improve societies, and foster sustainable development, global health equity, and the overall growth of various economies.

ECONOMIC IMPACTS ON HEALTHCARE SYSTEM

The economic impacts of mucosal vaccination programs on the healthcare system are presented in Fig. (**1**) and discussed below.

Cost Savings

Mucosal vaccination programs are cost-effective for healthcare systems by alleviating the burden of infectious diseases. These programs decrease the demand for treatment, hospitalization, and medication by preventing infections or lowering their severity. Consequently, fewer individuals become sick, thus cutting down on health spending linked to infectious disease management. In particular,

CHAPTER 3

Mucosal Vaccination for Emerging and Pandemic Infectious Diseases

Md Nasar Mallick[1], Akhil Sharma[2], Akanksha Sharma[2], Sunita[3] and **Shaweta Sharma[1,*]**

[1] *School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India*

[2] *R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India*

[3] *Metro College of Health Sciences and Research, Greater Noida, India*

Abstract: Mucosal vaccination is a revolutionary method for controlling epidemic and pandemic infectious ailments. The technique has an exclusive feature that makes it produce very strong immune responses to pathogens at the entry point. This section gives detailed information on mucosal immunity and its importance in protection against different diseases. It starts by probing into how mucosal immune responses work before presenting arguments that support mucosal vaccination choices over other options. In addition, the chapter provides a contrast between traditional systemic inoculation ways. It shows the superiority and wider range of action of mucosal vaccines when compared with traditional systemic vaccination routes. Detailed scrutiny of manifold mucosal vaccine delivery systems comprising oral, nasal, and pulmonary routes discloses various ways to overcome mucosal barriers and improve the uptake and efficiency of vaccines. The chapter presents success stories of preventing infectious diseases, including influenza, rotavirus, and cholera, through mucosal vaccination, as seen in preclinical and clinical studies. It also identifies complexities within the regulatory environment for a better understanding of those unique obstacles, which ought to be considered when seeking approval for a new type of vaccine, like one that is administered through mucosal routes. The chapter underscores the real-world impact of mucosal vaccination on the disease burden and the shaping of public health outcomes with insightful case studies. However, despite considerable progress made in this field, it is still confronted by various difficulties in the selection of antigens and optimization of formulations, as well as scaling up production. This paper also describes essential scientific tracks for future research along with some technological advancements that are considered to overcome these impediments and open a gateway for a new generation of mucosal vaccines. In summary, this chapter emphasizes the long-term investments and partnerships that are needed to optimize

* **Corresponding author Shaweta Sharma:** School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India;
E-mail: shawetasharma@galgotiasuniversity.edu.in

Shaweta Sharma, Aftab Alam & Akhil Sharma (Eds.)

mucosal vaccination as a major approach to addressing emerging and pandemic infectious diseases. This way, we can build up our ability to protect ourselves by encouraging prevention measures at the mucosal level.

Keywords: Emerging diseases, Mucosal immunity, Pandemic, Regulatory approval, Vaccine delivery systems, Vaccination.

INTRODUCTION

A specialized immunization technique known as mucosal vaccination entails giving vaccines directly into the body's mucosal surfaces, like respiratory, gastrointestinal, and genitourinary tracts. Its main objective is to promote a protective immunity against infectious diseases. Mucosal vaccination differs from the traditional systemic routes of vaccination that often consist of putting vaccines in the bloodstream or muscle tissues since it uses unique traits of mucosal tissues to stimulate immune responses through the spots where pathogens enter [1].

In mucosal vaccination, the vaccine's antigens are brought to the mucosal surfaces *via* several ways, like the oral, nasal, pulmonary, rectal, vaginal, and ocular route of administration. When these antigens reach the surface of the mucus membrane, for example, certain types of immune cells, such as dendritic cells, macrophages, and lymphocytes, play a role in capturing and initiating immune response towards them [2].

One of the most important characteristics of mucosal vaccination is its capacity to elicit both local and systemic immune responses. Mucosal vaccines used for this purpose so often result in the production of secretory immunoglobulin A (sIgA) antibodies, which provide a first line of defense against pathogens at mucosal surfaces through means such as neutralization and prevention of their passage into the body. Moreover, mucosal vaccination also activates systemic immune responses that produce circulating antibodies and activate T cells responsible for long-term immune protection against pathogens that breach the mucosal barrier into the blood stream [3].

Mucosal vaccination has various advantages over traditional systemic vaccination approaches. First, it mimics the natural infection path of several pathogens, leading to the elicitation of immune responses at the site where most likely they would be entering into the body. This is capable of bringing about an increase in mucosal and systemic immunity compared to systemic vaccination. Secondly, mucosal vaccinations can also cause immune reactions at numerous mucosal locations, hence providing a wide range of protection against different types of pathogens. Thirdly, most mucosal vaccines do not require needles and are admin-

istered without much strain, making them suitable for mass immunization programs as well as limited-resource settings [4].

Thus, because the vaccines are administered at the mucosal surface of the body, they have several benefits and limitations that need to be considered, such as bypassing immune responses. Nonetheless, the challenges can be overcome by the continued search for answers and swinging of mucosal immunization back into its potentially powerful applications in fighting infectious diseases, from pandemics to emerging ones [5, 6].

Importance in Combating Emerging and Pandemic Infectious Diseases

As a global strategy for the prevention of emerging and pandemic infectious diseases, mucosal vaccination is increasingly important. This is because it can utilize multiple defense tactics at mucosal surfaces, which are the main entry points for various types of pathogens. Mucosal vaccination prevents systemic distribution by directly activating the immune system near the site of infection. This enables the immune response to attack pathogens at their entry point and stops them from spreading further into the body. In addition to stopping infections from developing, this approach also reduces the likelihood of passing on diseases, thus blocking their wide-scale diffusion, which could lead to pandemics [7].

Apart from reacting fast, mucosal vaccination also provides a wide range of guards against different kinds of pathogens. Unlike traditional systematic vaccines that aim at one type of bacterium or virus, this category can activate various defenders, such as sIgA antibodies, mucosal T cells, and innate immune mediators. These many weapons not only destroy the intruders but also make the body resist closely related strains or completely different bugs, thereby increasing its resistance to constantly changing infectious hazards [8].

The strategic advantage of mucosal vaccination, in addition to this, is its ability to prevent mass transmission in crowded areas or impoverished regions. In fact, it can reduce the shedding of pathogens and their spread by breaking the continuous sequence between outbreaks that may otherwise lead to global pandemics. Also, these features make it ideal for large-scale immunization campaigns because there are no needles involved, which makes logistics simpler and faster while ensuring wide-reaching protection necessary during such explosive outbreaks with potential catastrophic health implications [9].

Even though mucosal vaccination has this unmatched beneficial side, it still has its share of difficulties. It is very challenging to design and optimize formulations for mucosal vaccines, which include selecting an antigen, incorporating an adjuvant, and developing a delivery system. Also, the regulatory pathways

CHAPTER 4

Mucosal Vaccination in Veterinary Medicine

Shekhar Singh[1], Akanksha Sharma[2], Shaweta Sharma[3] and **Akhil Sharma[2,*]**

[1] *Babu Banarasi Das Northern India Institute of Technology, Faculty of Pharmacy, Lucknow, Uttar Pradesh, 226028, India*

[2] *R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India*

[3] *School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India*

Abstract: Mucosal vaccination is emerging as a paradigm shift in veterinary medicine that gives a non-traumatic and efficient way to immunize animals against different infections. Unlike traditional injectable vaccines, mucosal vaccines focus on the mucosal surfaces, which are the preferred entry points for several pathogens. This chapter explains how mucosal immunity works and highlights some ways mucosal vaccination can be done, such as orally, nasally, and sublingually administered routes. All these routes have benefits, such as easy administration, a high chance of compliance, and strong immune responses without injection-related anxieties. The chapter also discusses the contemporary uses of mucosal vaccines in veterinary medicine, emphasizing their successful application in poultry, cattle, and pigs (livestock) and companion animals such as dogs and cats. Mucosal vaccines have several limitations, however, including the need to maintain formulation stability, develop effective delivery systems, and manage immune response variations across various animal species. Furthermore, utmost care is needed to ensure safety, and the possibility of side effects needs to be ensured. Such innovative technologies in vaccine production, such as nanotechnology-based delivery systems, genetic/recombinant vaccines, and new adjuvants, have improved mucosal vaccine efficacy and their range. To address emerging infectious diseases and improve animal health, researchers continue to generate new knowledge through ongoing studies and clinical trials. In conclusion, vaccination *via* the mucosal route represents an important breakthrough in veterinary medicine that could revolutionize animal healthcare with less invasive and highly effective immunization strategies. There is a chance for future advances in this area where integrated vaccination programs or individualized animal healthcare systems would lead to better global welfare of animals.

[*] **Corresponding author Akhil Sharma:** R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India; E-mail: xs2akhil@gmail.com

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Keywords: Animal, Biotechnology, Clinical trial, Gut-associated lymphoid tissue, Genetic, Health, Immunity, Livestock, Personalized medicine, Mucosal vaccine, Nasopharynx-associated lymphoid tissue, Oral vaccine, Recombinant, Technology, Veterinary medicine.

INTRODUCTION

Mucosal immunization refers to delivering vaccines through mucosa such as the respiratory, gastrointestinal, and genitourinary tracts. These vaccines are designed to generate immunity at the site of pathogen entry, providing local protection against infections. The mucosal immune system has a key role in protecting the body from pathogens; it includes tissues like Gut Associated Lymphoid Tissues (GALT) and Nasopharynx Associated Lymphoid Tissue (NALT) [1]. They may be delivered by mouth, nose, rectum, or vagina and work by stimulating the mucosal immune response that is characterized by the production of secretory immunoglobulin A (sIgA) antibodies that neutralize pathogens before they can reach deeper tissues [2, 3].

Importance in Veterinary Medicine

Mucosal vaccination is significant in veterinary medicine due to several unique advantages and its critical role in animal health management [4], which is discussed below in detail and summarized in Fig. (**1**).

Enhanced Immune Response

The main advantage of mucosal vaccines is their ability to promote both mucosal and systemic immunity. In contrast, injectable vaccines are designed to promote only systemic immunity. Mucosal vaccines, on the other hand, elicit a strong immune response at the site of infection, unlike traditional injected vaccines, which induce systemic immunity only. This dual effect is especially useful in preventing infections that invade through the respiratory or gastrointestinal systems. For example, oral vaccination against rotavirus can control severe diarrheal outbreaks, reducing animal morbidity and mortality rates [5].

Ease of Administration

It is easier to administer mucosal vaccines than injectable ones, especially in big animals. Oral vaccines can be mixed with feed or water, allowing for a less labor-intensive and more feasible mass vaccination drive. The result is that, in this way, the ease of administration reduces stress for animals and handlers while at the same time increasing compliance and guaranteeing a more uniform vaccine coverage. For instance, nasal vaccines used against respiratory diseases found

among cattle and swine have been administered without using needles, hence reducing handling time and related stress [6].

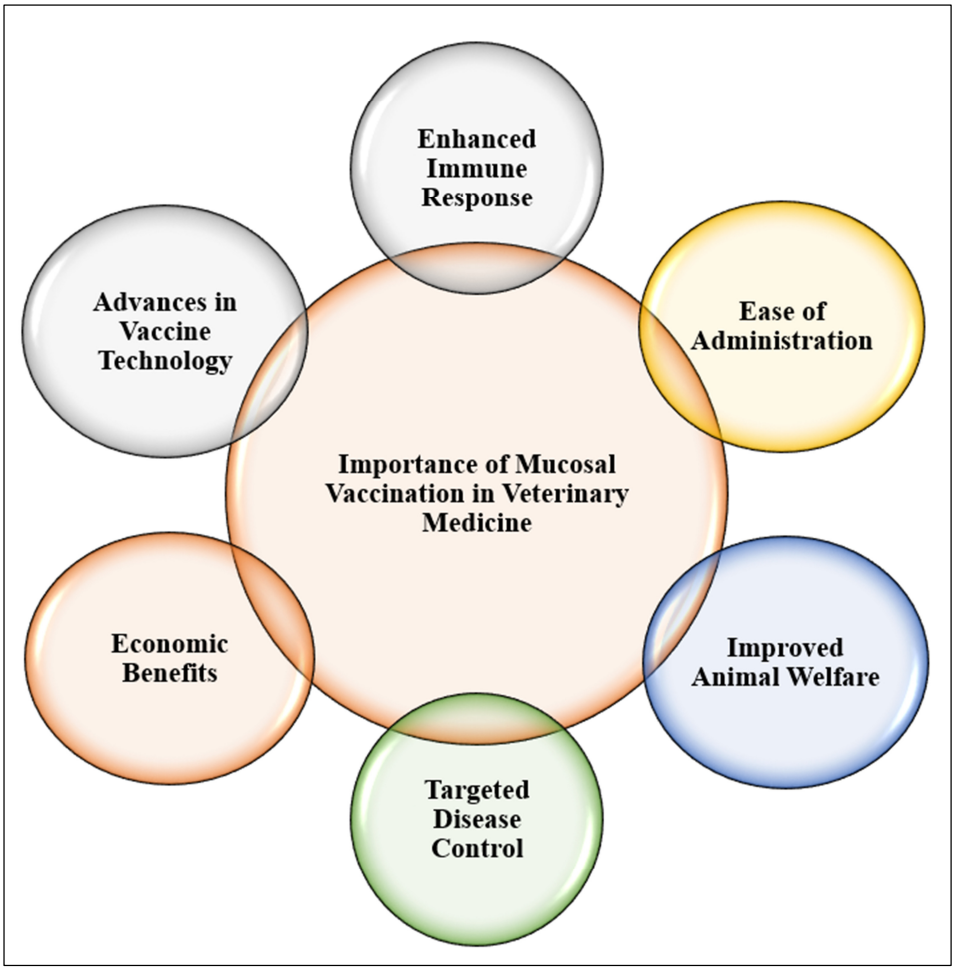

Fig. (1). Importance of mucosal vaccination in veterinary medicine.

Improved Animal Welfare

Mucosal vaccination avoids the use of needles and, therefore, improves animal welfare by eliminating the painful and stressful aspects of injection. This is especially crucial in pets and wild animals, where injecting them is tough and stressful. Unlike restraining the animal for injections, mucosal vaccines are given without it, thus reducing both discomfort and chances of injury to animals or human beings taking care of them. Besides, there are no dangers involved with needle-related diseases such as abscesses or infections [7].

CHAPTER 5

Innovation in Adjuvants for Mucosal Vaccine Enhancement

Akanksha Sharma[1], Sunita[2], Ashish[3], Shaweta Sharma[4] and **Akhil Sharma[1,*]**

[1] *R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India*

[2] *Metro College of Health Sciences and Research, Greater Noida, India*

[3] *Mangalmay Pharmacy College, Plot No. 9, Knowledge Park II, Greater Noida, Uttar Pradesh, 201306, India*

[4] *School of Medical and Allied Sciences, Galgotias University, Yamuna Expressway, Gautam Buddha Nagar, Uttar Pradesh-201310, India*

Abstract: The growth of efficacious mucosal vaccines delivered through mucosal surfaces like oral and nasal routes is a major improvement in immunization strategies. These agents provide the possibility for non-invasive administration, ease of giving them out, and the capability to induce systemic and local immune responses. Nevertheless, the body's natural barriers and the necessity of potent adjuvants to trigger immune responses have historically hindered the mucosal vaccines' effectiveness. This abstract will discuss new developments in adjuvants that can transform mucosal vaccine adoption's effectiveness. Traditional adjuvants like aluminum salts and MF59 have proved ineffective in mucosal contexts because they cannot penetrate the mucosal barriers to elicit strong mucosal immunity. This led to the development of new adjuvants such as nanoparticles, liposomes, and Toll-like receptor (TLR) agonists that could address these challenges. An example of such adjuvants is nanoparticle-based ones, which aid in stabilizing antigens and enable targeted delivery, thus ensuring they reach correct immune cells. Adjuvants commonly used in adjuvant development, such as aluminum salts and MF59, have proved less effective in mucosal contexts due to their inability to penetrate the mucosal barriers and elicit strong mucosal immunity. For this reason, scientists have created new adjuvants, including nanoparticles, liposomes, and Toll-like receptor (TLR) agonists, which can potentially address these deficiencies. Nanoparticle-based adjuvants, for example, may improve antigen stability while promoting delivery to specific immune cells that require them. Additionally, the development of recombinant proteins and synthetic peptides with strong functions as mucosal adjuvants has been made possible through improvements in bioengineering. To study these new adjuvants that are under trial progressively in medical practice, it is essential to perform clinical trials and research continuously. The future of mucosal

* **Corresponding author Akhil Sharma:** R. J. College of Pharmacy, 2HVJ+567, Raipur, Gharbara, Tappal, Khair, Uttar Pradesh 202165, India; E-mail: xs2akhil@gmail.com

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vaccines is bright, and this could be achieved by employing novel materials and technologies to make more efficient vaccines that can be easily accessed by everyone, thereby enhancing global health outcomes.

Keywords: Adjuvant, Antigen, Health, Immunization, Immune cells, Liposomes, Mucosal-associated lymphoid tissue, Mucosal vaccine, Mucosal surfaces, Non-invasive delivery, Nanoparticles, Toll-like receptor agonists, Targeted delivery.

INTRODUCTION

In this case, mucosal vaccines are administered *via* the gastrointestinal (oral) and respiratory (nasal) tracts. These types of vaccines do not require a needle injection like most traditional injectable vaccines but aim to create immunity at the point of pathogen entry to generate both local mucosal and systemic immune responses. They guard against infections that breach the body *via* its mucosal surfaces, including influenza, rotavirus, and certain types of pneumonia [1].

Mucosal vaccines can be delivered in several forms, such as liquids, powders, or oral vaccines packaged as tablets and nasal vaccines as sprays or drops. This kind of delivery is less invasive and more user-friendly, not to mention better suited to the elderly and children; it also has the potential to elicit stronger and more specific immune responses at numerous infectious agent portals of entry [2].

Mucosal immunity describes the immune defenses on mucosal membranes like the gastrointestinal, respiratory, and urogenital tracts, eyes, and oral cavities. These interfaces are the primary window between our bodies and the external environment. It is crucial to understand that entry points are quite frequent for pathogens; hence, this type of immunity plays a very important role. The innermost linings of the mucosa have epithelial cells that serve as a barrier and are reinforced by mucus; this is a slimy fluid that entraps germs and also contains antimicrobial peptides and enzymes. In MALT, such as the tonsils, Peyer's patches in the intestines and lymphoid tissues in the respiratory tract are found. It comprises immune cells primed to detect and react against any infecting pathogen [3].

Secretory IgA, the primary antibody class in these areas, represents a fundamental aspect of mucosal immunity. The chief role played by IgA is neutralization of pathogens and preventing them from getting attached to or penetrating the epithelial cells. Additionally, various specialized immune cells are found in the mucosal immune system. Antigen-presenting cells, namely dendritic cells (DCs), are the ones that capture antigens from pathogens and then travel to the lymphoid tissues where they display these antigens to T and B cells to initiate adaptive immune responses. Th17 cells are among the mucosal T-cells that participate in

maintaining mucosal barriers and responding to infections, whereas IgA-secreting B-cells transudate into the lumen of the epithelium at mucosa [4].

The mechanisms of the mucosal immune responses begin with sampling and presentation of antigens. M cells, specialized epithelial cells, sample antigens from the mucosal surface and transport them to underlying immune cells. Dendritic cells process these antigens and present them to T and B cells in the MALT. As a result of this interaction, secretory IgA is induced, and activated B cells turn into plasma cells that make IgA. The latter gets transferred *via* the epithelial layer to the mucosal surface, where it can attach to and deactivate pathogens. Furthermore, cell-mediated immunity is important, with MALT-activated T cells migrating to the mucosal surface for the direct killing of infected cells or coordinating other immune responses [5].

The significance of mucosal immunity in vaccination is that it can direct the immune response to the site of pathogen entry, thus providing local and systemic protection. Mucosal vaccines are modeled after natural infection routes, which trigger a powerful localized immune response leading to preventing pathogen entry and replication. In addition, their ability to cause systemic immunity offers all-inclusive security against pathogens. These vaccines can be taken through the mucosal route without any invasion; they can be given orally or nasally, and this is an alternative to needle administration that can help increase vaccine acceptance and compliance, especially among those who are afraid of needles. The immune system has a complicated aspect known as mucosal immunity that gives critical cover to the areas where our body easily gets infections. The potential to improve immunization strategies and public health outcomes through these vaccines depends on how best one utilizes their parts and functions from the immunological perspective [6].

Importance of Adjuvants

To improve the effectiveness and potency of vaccines, they are boosted with adjuvants that enhance their immuno-potency, leading to better immune responses. Adjuvants are designed to enhance immunity so as to make vaccines more effective in protecting against diseases with fewer antigens, which is important, especially in new or difficult-to-treat diseases [7].

Adjuvants are mainly used to boost the body's immune response to a vaccine antigen. Hence, adjuvants help stimulate innate immunity, which is usually the first line against infections. This includes the inducement of dendritic cells and macrophages necessary for antigen presentation before T and B cells. Antigen presentation carries out this purpose, and it is vital in starting adaptive immunity for long-term protection [8].

CHAPTER 6

Bioprocessing and Scale-up Challenges in Mucosal Vaccine Production

Rupali Sharma[1,*], Koushal Dhamija[2], Sudhir Kumar[3], Shekhar Sharma[2] and **Alok Bhardwaj[2]**

[1] *Amity University Haryana, Manesar, Gurugram, India*

[2] *Lloyd Institute of Management & Technology, Plot No.-11, Knowledge Park-II, Greater Noida, Uttar Pradesh-201306, India*

[3] *Faculty of Pharmaceutical Sciences, DAV University, Jalandhar, India*

Abstract: Mucosal vaccination stimulates strong systemic and mucosal immune responses and presents a viable path for the fight against infectious diseases. To reach their full potential, mucosal vaccine production does, however, present major bioprocessing and scale-up hurdles. An outline of these difficulties and possible solutions is given in this abstract. The primary source of bioprocessing problems is the intricate structure of mucosal delivery channels. Specific needs relate to adjuvant selection, antigen stability, and formulation for the nasal, oral, and pulmonary routes. Moreover, maintaining sterility and controlling contamination present significant challenges for manufacturing mucosal vaccines. To overcome these obstacles, new strategies for adjuvant and antigen optimization are required, together with developments in formulation technologies. The difficulties associated with scaling up mucosal vaccination production add to its complexity. When moving from laboratory-scale to industrial-scale production, it is important to carefully handle equipment considerations, regulatory requirements, and process scalability issues. Economic issues are also significant, necessitating cost-effective measures that maintain the efficacy and quality of vaccines. Collaborative efforts between academia, industry, and regulatory bodies are frequently essential to successful scale-up plans. Emerging technologies, including advanced bioprocessing methods, computational modeling, and omics technologies, present viable ways to address these issues. Integrating nanotechnology and synthetic biology, along with the principles of Quality by Design (QbD), offers prospects for optimizing vaccine efficacy and production processes. Nonetheless, regulatory issues need to be properly taken into account to guarantee the security and effectiveness of innovative technologies. In conclusion, improving the production of mucosal vaccines requires tackling the issues of bioprocessing and scale-up. These challenges can be addressed, and the full potential of mucosal vaccination in

[*] **Corresponding author Rupali Sharma:** Amity University Haryana, Manesar, Gurugram, India; E-mail: rsharma9@ggn.amity.edu

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the prevention of infectious diseases can be unlocked by utilizing cutting-edge technologies and collaborative methods.

Keywords: Adjuvant, Antigen, Bioprocessing, Immunity, Infectious diseases, Mucosal vaccine, Nasal delivery, Oral delivery, Pulmonary delivery, Quality by Design, Sterility.

INTRODUCTION

A class of vaccinations known as “mucosal vaccines” aims to produce protective immune responses at mucosal surfaces, including those lining the gastrointestinal, respiratory, and genitourinary tracts. Mucosal vaccines elicit both local mucosal and systemic immune responses, in contrast to traditional vaccines that are injected and mainly cause systemic immunity. This special characteristic is crucial to preventive medicine because mucosal surfaces are the main entry sites for various pathogens, such as viruses, bacteria, and parasites. These vaccines can stop infection at the point of entry, preventing pathogens from spreading throughout the host and the population. They do this by focusing on mucosal immunity [1, 2].

Mucosal vaccinations have a role in preventive medicine that goes beyond their capacity to offer targeted protection. Secretory IgA antibodies, which are essential for neutralizing toxins and preventing pathogen adherence to mucosal surfaces, can be induced by mucosal immunization. It has been demonstrated that mucosal vaccinations increase the host's capacity to fight invasive pathogens by inducing cellular immune responses, such as T lymphocyte activation. Because traditional vaccines may be less successful in preventing colonization and transmission in the context of mucosal infections, this multifaceted immune response is particularly advantageous [3, 4].

Mucosal vaccine development and production present substantial bioprocessing and scale-up challenges. To ensure stability and efficacy, mucosal vaccines need specialized formulation and delivery systems, unlike parenteral vaccines, which can be produced using tried-and-true methods. The optimization of antigen and adjuvant formulations for mucosal delivery, considering variables like mucosal adhesion properties, adjuvant toxicity, and antigen stability, presents bioprocessing challenges. Furthermore, producing mucosal vaccines poses special challenges because some formulations or delivery systems may not be compatible with conventional sterilization techniques. These include maintaining sterility and controlling contamination [5, 6].

Manufacturing process complexity increases with mucosal vaccine production scale-up, necessitating careful consideration of equipment needs, regulatory compliance, and process scalability. The development of affordable manufacturing processes that can fulfill the demands of large-scale vaccine production without sacrificing product quality or safety is imperative as the production moves from the laboratory to the industrial scale. Moreover, to guarantee the security, effectiveness, and uniformity of mucosal vaccinations commercially, regulatory bodies demand thorough documentation of manufacturing procedures and quality control methods. Mucosal vaccines can potentially transform mucosal infection prevention and enhance public health outcomes globally if these obstacles are overcome [7, 8].

TYPES OF MUCOSAL VACCINES

Mucosal vaccines are a broad category of vaccination approaches that aim to produce protective immune responses against pathogens by focusing on mucosal surfaces. Because of their simplicity of administration, capacity to elicit strong immune responses, and suitability for widespread vaccination campaigns, oral, nasal, and pulmonary vaccines stand out among the various types of mucosal vaccines as promising approaches, which are summarized in Fig. (**1**).

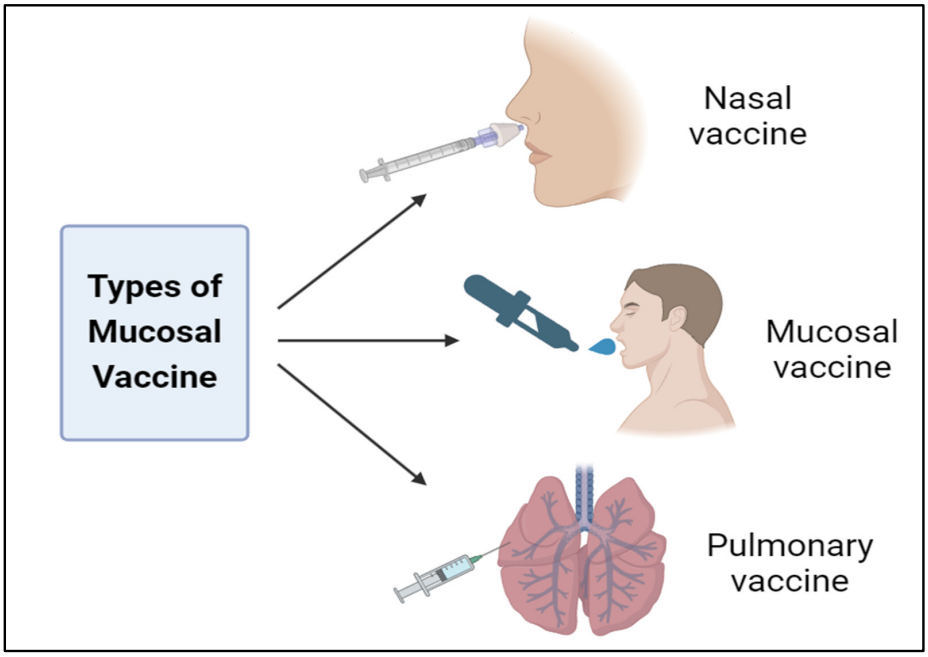

Fig. (1). Types of mucosal vaccines.

CHAPTER 7

Mucosal Vaccines in Cancer Immunotherapy

Koushal Dhamija[1,*], Alok Bhardwaj[1], Sudhir Kumar[2], Shekhar Sharma[1] and **Rupali Sharma[3]**

[1] *Lloyd Institute of Management & Technology, Plot No.-11, Knowledge Park-II, Greater Noida, Uttar Pradesh-201306, India*

[2] *Faculty of Pharmaceutical Sciences, DAV University, Jalandhar, India*

[3] *Amity University Haryana, Manesar, Gurugram, India*

Abstract: Mucosal vaccines, which use the body's mucosal immune system to fight cancerous cells, represent a promising new avenue in cancer immunotherapy. This paper provides a thorough overview of the role of mucosal vaccines in cancer treatment, emphasizing their benefits, drawbacks, current research, and prospects for the future. There are many different kinds of vaccines for the mucosa, such as live attenuated, inactivated, subunit, DNA, and vector-based vaccines. They function by triggering a systemic immune response against particular cancer antigens by stimulating mucosal immunity at sites such as the respiratory, gastrointestinal, and genitourinary tracts. Enhanced mucosal immune response, needle-free administration, cost-effectiveness, and broad coverage against various cancer types are just a few benefits of this special mechanism. Mucosal vaccines have limitations despite their potential, including the requirement for adjuvants, immune responses specific to a given route, stability issues, and safety concerns. Promising outcomes are being shown by ongoing studies and clinical trials, some of which have assessed safety and efficacy in clinical settings and demonstrated efficacy in preclinical models. In cancer immunotherapy, mucosal vaccines have a wide range of uses, such as treating metastatic disease, preventing cancer from returning, and boosting the effectiveness of immunotherapeutic combinations. Moreover, customized treatment plans based on unique patient profiles may be possible by developing personalized vaccines. Mucosal vaccinations in cancer immunotherapy have a promising future. There is hope for better patient outcomes and worldwide cancer prevention strategies thanks to developments in vaccine technology, integration into standard treatment protocols, and personalized approaches. Finally, mucosal vaccines offer a novel strategy for cancer immunotherapy that has the power to alter patient survival rates and treatment paradigms drastically. Realizing the full potential of mucosal vaccines in the fight against cancer requires ongoing research and clinical development.

[*] **Corresponding author Koushal Dhamija:** Lloyd Institute of Management & Technology, Plot No.-11, Knowledge Park-II, Greater Noida, Uttar Pradesh-201306, India;
E-mail: drkoushaldhamija81@gmail.com

Shaweta Sharma, Aftab Alam & Akhil Sharma (Eds.)

Keywords: Adoptive cell therapy, Cancer, Cancer antigens, Immunotherapy, Immunity, Mucosal vaccine, Mucosal-associated lymphoid tissues, Systemic immune response.

INTRODUCTION

With a significant impact on people, families, and societies, cancer continues to be one of the most common and difficult diseases in the world. Even with major advances in medicine, the disease's treatment is still complicated and frequently combines several different modalities, including radiation, chemotherapy, and surgery. These traditional methods have increased the survival rates of many cancer types. Still, they are frequently linked to severe side effects and poor results, especially in cases of advanced or metastatic disease [1].

Immunotherapy has changed the landscape of cancer treatment in recent years. In contrast to conventional therapies that target cancer cells directly, immunotherapy uses the body's immune system to identify, attack, and destroy cancerous cells. This creative approach has begun a new era in oncology, which offers the possibility of long-lasting effects, better survival rates, and improved quality of life for cancer patients [2].

Immunotherapy is a collective term for treatment modalities that aim to enhance the immune system's capacity to identify and eliminate cancer cells. Several of these have become important tactics in the fight against cancer, including adoptive cell transfer, immune checkpoint inhibitors, monoclonal antibodies, and cancer vaccines. By disabling the barriers that prevent immune responses, these treatments enable the body to develop a stronger anti-tumor defense or stimulate the immune system to target cancer cells [3, 4].

Immunotherapy's effectiveness varies among patients and tumor types despite its impressive success in treating some cancer types, such as melanoma, lung cancer, and hematologic malignancies. Immune evasion strategies, tumor heterogeneity, and the emergence of treatment resistance are just a few of the difficulties that make this area of study and innovation imperative [5].

Mucosal vaccines are a state-of-the-art cancer immunotherapy method that uses the body's mucosal immune system to fight cancer. Mucosal vaccines are delivered through mucosal surfaces, such as the respiratory, gastrointestinal, and genitourinary tracts, as opposed to traditional vaccines administered *via* injection. This novel mode of delivery presents several benefits, such as increased mucosal immune response, systemic immunity induction, and needle-free delivery, making it a compelling choice for cancer treatment and prevention [6, 7].

Different types of mucosal vaccines exist, each with a unique mechanism of action and possible uses in cancer immunotherapy. Live attenuated vaccines, which contain weakened versions of the pathogen, elicit a strong immune response without actually causing disease. Subunit vaccines, conversely, provoke particular immune responses against cancer cells by containing antigens specific to the pathogen. Additionally, versatile and potentially enabling personalized treatment approaches are other types of mucosal vaccines, including vector-based and DNA vaccines [8, 9].

The ability of mucosal vaccines to stimulate mucosal immunity, a vital part of the body's defense against infections and cancerous cells, holds promise for treating cancer. Immune cells such as T, B, and antigen-presenting cells are abundant on mucosal surfaces. These cells help coordinate immune responses and aid in removing malignant cells. Vaccines against mucosal surfaces can prime the immune system to recognize and eliminate cancer cells at primary and metastatic sites by inducing local and systemic immune responses. The advantage of needle-free administration that mucosal vaccines provide makes them more convenient and accessible for patients, especially in settings with limited resources. Immunotherapy may become more widely used as a standard cancer treatment modality due to its ease of administration, which could improve patient compliance [10, 11]. Mucosal vaccines differ from other cancer vaccine types, as shown in Table **1**.

Table 1. Difference between mucosal vaccines and other types of cancer vaccines.

Feature	Mucosal Vaccines	Other Types of Cancer Vaccines
Route of Administration	Oral, nasal, intranasal, or other mucosal routes.	Intramuscular, subcutaneous, or intradermal injection [12].
Target Tissues	Mucosal-associated lymphoid tissues (MALT).	Systemic lymphoid tissues [13].
Mechanism of Action	Induce mucosal and systemic immune responses.	Primarily stimulate systemic immune responses [14].
Immunogenicity	It may require potent adjuvants to overcome mucosal tolerance.	Often rely on adjuvants to enhance immune responses [15].
Antigen Stability	The formulation must protect antigens from degradation in the mucosal environment.	Stability is less of a concern due to systemic delivery [16].
Target Antigens	Tumor-specific or tumor-associated antigens.	Tumor-specific or tumor-associated antigens [17].
Delivery Considerations	Requires formulation optimization for mucosal adhesion and penetration.	Formulation optimization focused on antigen stability and immune response [18].

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Shaweta Sharma

Dr. Shaweta Sharma, M. Pharm., Ph.D., is currently employed as a Professor at Galgotias University, Greater Noida. She completed her Ph.D. in 2017 from Teerthanker Mahaveer University, Moradabad, U.P., India. She has been contributing to academics for more than 15 years and has published articles in numerous peer-reviewed national and international journals.

Aftab Alam

Dr. Aftab Alam is the Dean-cum-Principal at the School of Pharmacy, Katihar Medical College, Al-Karim University. He previously held key positions at Galgotias University and earned his Ph.D. from Jamia Hamdard. With research experience at the National Institute of Immunology (NII), numerous awards, and international presentations, his expertise spans cancer nanotechnology, drug delivery, and biomedical research. He has published over 50 papers and currently supervises multiple Ph.D. and M.Pharm. students.

Akhil Sharma

Dr. Akhil Sharma, M. Pharm., Ph.D., is currently working as Professor and Principal at R.J. College of Pharmacy, Raipur, Aligarh, U.P., India. He completed his Ph.D. in 2016 from Teerthanker Mahaveer University, Moradabad, U.P., India. He has been serving the pharmacy profession for more than 15 years and has published numerous articles in peer-reviewed national and international journals.