COMMENTARY

Importance of Vaccine Trials in Medical Curriculum

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In today's time,The infections are increasing at an alarming rate.The new treatment modalities are being introduced to deal with them.Out of which,Vaccines play a crucial role in preventing infectious diseases by stimulating the immune system to recognize and combat pathogens. They have significantly reduced the incidence of many diseases and even eradicated some, like smallpox.However, the development and application of vaccines come with challenges and considerations.

Key Benefits of Vaccines :-

Disease Eradication and Control: Vaccines have led to the eradication of smallpox and have significantly reduced diseases like polio, measles, and diphtheria.Thereby, reducing morbidity and mortality of the diseases.

Global Health Impact: Vaccines are essential for global health, especially in preventing pandemics and managing emerging infections.

Focus of Prevention: Vaccine become pioneer in the prevention of the diseases where specific treatment is not available, and the symptomatic treatment is given.

Non-Specific Benefits: Some vaccines, like the measles vaccine, have been shown to reduce mortality from infections other than their target disease, indicating broader immune benefits.

Challenges and Considerations

Vaccine-Induced Enhancement: In some cases, vaccines can enhance susceptibility to infections, as seen with certain viral infections like Dengue and HIV, due to mechanisms like antibody-dependent enhancement (ADE).

Age-Related Efficacy: The efficacy of vaccines can decrease in older populations due to age-related changes in the immune system, necessitating tailored vaccine strategies.

Adjuvant Use: Adjuvants are critical in enhancing vaccine efficacy by boosting immune responses. New adjuvants and technologies are being developed to improve vaccine performance and safety.

Innovations in Vaccine Development :-

New Technologies: Advances in nucleic acid and viral vector vaccines are promising for rapid development and large-scale production, crucial for addressing pandemics.

Noninvasive Vaccination: Methods like oral and intranasal vaccines offer advantages in safety and accessibility, particularly in resource-limited settings.

Process of Vaccine Development: Development of Vaccine is implementation of scientifically woven ideas dealing with bioengineering of particles endogenous or exogenous. After which the developed vaccine tool is brought into human system through phase trials. These trials are part of a

structured process aimed at ensuring safety, efficacy, and immunogenicity before they are approved for public use. The process traditionally involves three distinct phases, but recent innovations have introduced more efficient designs.

Each phase of clinical trials plays a distinct role in this process.

Importance of Phase Trials in Vaccine Development

Phase 1 Trials: These are the initial trials conducted on a small group of healthy volunteers to assess the safety and determine the appropriate dosage of the vaccine. They primarily focus on identifying any adverse reactions and establishing a safe dosage range.

Phase 2 Trials: These trials involve a larger group of participants and aim to evaluate the immunogenicity and further assess the safety of the vaccine. They help in determining the optimal dose and schedule for the vaccine.

Phase 3 Trials: These are large-scale trials that confirm the vaccine's efficacy and monitor adverse reactions in a diverse population. They are critical for demonstrating the vaccine's effectiveness in preventing the disease and are often the basis for regulatory approval.

Adaptive and Seamless Designs: Modern approaches like adaptive trial designs allow for modifications based on interim results, which can lead to early termination if the vaccine is highly effective or ineffective. Seamless phase designs can expedite the development process by combining phases, thus saving time and resources.

Infrastructure and Coordination: The rapid development of COVID-19 vaccines highlighted the importance of robust clinical trial infrastructure and coordination, as seen with the establishment of networks like the COVID-19 Prevention Network (CoVPN) to streamline phase trial,whereby it helped to tackle the pandemic.

Role of Medical students in Vaccine Trials: There is the dire need for implementation of phase trial education to the Undergraduate MBBS students. Teaching phase trials to medical students is crucial for equipping them with the necessary skills and knowledge to conduct and understand clinical research effectively. This training is essential for fostering a comprehensive understanding of the drug development process and the ethical considerations involved.

Importance of Phase Trial Education:

Skill Development: Mock phrase I trials serve as an educational tool, allowing students to gain hands-on experience in trial design, execution, and reporting. This practical training is instrumental in preparing them for real-world clinical research scenarios.

Understanding Therapeutic Intent: Phase I trials, traditionally seen as toxicity trials, are now recognized for their potential therapeutic benefits, especially in oncology. Educating students about this shift helps them appreciate the evolving landscape of clinical trials and the importance of early-phase trials in drug development.

Ethical and Regulatory Knowledge: Knowledge of clinical trials, including ethical guidelines and regulatory requirements, is often lacking among medical students. Addressing these gaps through targeted educational interventions is necessary to ensure that future healthcare professionals can conduct trials ethically and effectively.

Scope of Understanding from perspective of different Departments:-

As the students are in touch of departments- Microbiology, Community Medicine, Pharmacology during their education period of MBBS.

They should be entitled to know the role of these departments in vaccine development, administration and studying its effects/side effects/acceptance/restrictions.

This as a whole helps them to deal and comply with the evidence based medicine for their present and future participation as healthcare providers.

Benefits of Phase Trial Education

Enhanced Research Quality: By understanding the intricacies of phase trials, medical students can contribute to higher-quality research, ultimately leading to better healthcare outcomes.

Informed Decision-Making: Educating students about patient values and decision-making processes in early-phase trials can improve their ability to support patients in making informed choices about trial participation.

Exposure to Methodology:

Medical students' exposure to vaccine trial methodologies is crucial for their future roles as healthcare providers. Understanding their attitudes and willingness to participate in such trials can inform educational strategies and improve vaccine uptake.

1.Willingness to Participate in Vaccine Trials

Learning to how make more and more people willing to participate in vaccine trial with dealing of their negative opinions. Also, finding out the pre-requisition of being part of vaccine trial and dealing with questionarries, counselling, consenting, health fears, etc. and learning the individual and community characteristics to make willingness to participate.

2 Educational Interventions

Effective educational interventions for medical students often involve hands-on, interactive methods that simulate real practice, which can improve their understanding and attitudes towards vaccines and vaccine trials . These interventions should focus on evidence-based approaches like motivational interviewing rather than deficit-based models .

3.Vaccine Hesitancy and Acceptance

In general population have positive attitudes towards vaccines, but there is a notable level of hesitancy regarding participation in vaccine trials .Concerns about side effects and the speed of vaccine development can influence their willingness to participate .

4.Importance of Innovative Trial Designs

Innovative trial designs, such as adaptive designs and the use of real-world data, are becoming increasingly important in vaccine development. These methods can make trials more efficient and less resource-intensive, which is crucial in the context of emerging infectious diseases. The documentation about the physical, biological characteristics of participants ,side effects, failure or acceptance of vaccines helps in the future for better development of vaccine or similar oriented trials.Additionally, innovative trial designs can streamline the process, making it more appealing and feasible for student involvement.

Conclusion

The Vaccine play a crucial role in preventing infectious disease significantly reducing incidence, morbidity and mortality.

They come into market after undergoing phase trials. The MBBS students are not well known to the methodology of Vaccine trials whereas Vaccine trials are integral to medical education, providing a foundation for understanding immunization, improving communication skills, and addressing vaccine hesitancy. By incorporating structured vaccine education, ethical considerations, and effective communication strategies, medical education can better prepare future healthcare providers to promote vaccine acceptance. They should be known to the role of the different departments of MBBS curriculum in vaccine development to better practice the Evidence based medicine for their future.

Authors Contribution

Both authors have contributed equally.

Conflict of Interest

There are no conflicts of interest.

Declaration Of Generative Ai And Ai Assisted Technologies In The Writing Process

The authors haven’t used any generative AI/AI assisted technologies in the writing process.