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Review Article

Importance and barriers to hepatitis A immunization and the clinical relevance of inactivated hepatitis A vaccine (TZ84 strain): insights from the pediatric experts

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ABSTRACT

The epidemiology of hepatitis A in India is shifting from high to intermediate endemicity, leading to a growing number of predisposed adolescents and adults who are at greater risk of symptomatic illness and sequelae. Vaccination is an efficacious preventative measure; yet, certain obstacles persist that hinder optimum vaccine use. This expert review aimed to explore the challenges associated with hepatitis A vaccination in India and to gather insights from pediatricians on the clinical relevance and factors influencing their choice of inactivated hepatitis A vaccines, with particular reference to the TZ84 strain. A focused group discussion (FGD) was conducted with 11 practicing pediatricians from various regions of India. The discussion examined opinions related to the epidemiological aspects of hepatitis A, immunization methodologies, obstacles to vaccine adoption, and determinants affecting vaccine choice. Pediatricians identified multiple challenges, such as financial obstacles, gaps in caregiver awareness, and a lack of hepatitis A vaccination in UIP. Participants highlighted the necessity for enhanced public health education and more robust policy initiatives aimed at increasing vaccination coverage. The inactivated hepatitis A vaccine (TZ84 strain) was considered clinically significant, given its demonstrated ability to elicit strong and durable immune responses and its potential for long-term protection against hepatitis A infection. The changing epidemiology of hepatitis A in India underscores the importance of strengthening vaccination strategies. Addressing policy, awareness, and accessibility barriers may improve vaccine uptake and reduce disease burden. Adoption of inactivated hepatitis A vaccines may help reduce disease burden, with TZ84 strain–based vaccine representing a reliable option for sustained protection.

Keywords: Hepatitis A, Vaccination, Pediatricians, Focus group discussion, India

INTRODUCTION

Hepatitis A is an acute viral infection of the liver that is caused by the hepatitis A virus (HAV), a non-enveloped, single-stranded ribonucleic acid (RNA) virus belonging to the *Picornaviridae* family. The infection is predominantly transmitted via the fecal–oral route through the consumption of contaminated food or water or intimate interpersonnel contact.[1] While infection is typically self-limiting, it can result in substantial morbidity, particularly in adolescents and adults, where symptoms are more severe. The clinical manifestations range from asymptomatic infection, commonly observed in young children, to symptomatic disease characterized by fever, anorexia, nausea, abdominal distress, jaundice, and, rarely, fulminant hepatic failure.[2,3]

India has been historically categorized as a high-endemic region for hepatitis A, where infection commonly occurs during early childhood, resulting in lifelong immunity. Studies have shown that seroprevalence among Indian children is nearly 90% in rural regions and 70% in urban areas.[4] However, socioeconomic development, improved sanitation, and improved access to pure water in specific

regions have led to a gradual epidemiological transition. Recent studies from different regions of India have reported declining seroprevalence among younger children and a growing pool of susceptible adolescents and adults. Recent studies have suggested a transition to high-intermediate endemicity in India, resulting in HAV infection acquisition at an advanced age, which is more likely to result in severe complications and symptomatic disease.[3]

Despite advancements in health care infrastructure, hepatitis A continues to present a significant disease burden in India. The infection remains one of the major causes of acute viral hepatitis and contributes significantly to pediatric liver disease in the country.[3] Epidemiological data indicate that a significant percentage of children and young adults continue to be vulnerable to HAV infection, with research showing that around 55% of individuals aged 5 to 15 years may still be without protective antibodies.[5] The occurrence of these epidemics leads to heightened demand for healthcare services and simultaneously places significant economic and social strains on impacted families and healthcare systems.

The administration of vaccines is recognized as the most efficacious preventive measure against hepatitis A infection. In India, the Indian Academy of Pediatrics (IAP) advocates the administration of hepatitis A vaccination to children beginning at 12 months of age.[6] Administering vaccinations at an early age not only mitigates the occurrence of symptomatic disease during childhood but also diminishes the likelihood of infection in later life, when the clinical severity tends to be more pronounced.[7]

Both inactivated and live-attenuated hepatitis A vaccines are available, and both elicit robust immunogenic responses. A single dose of live attenuated vaccines usually results in a robust, long-lasting, and comprehensive immune response involving both cellular and humoral immunity; however, there is a risk of adverse reactions, especially in immunocompromised individuals. In contrast, inactivated vaccines offer a favorable safety profile, can be administered to all population groups, including immunocompromised individuals, and typically show greater thermal stability.[8] Among the available inactivated hepatitis A vaccines, the inactivated TZ84 strain vaccine demonstrated superior immunogenicity compared with both the H2 live attenuated vaccine and the inactivated HM-175 strain vaccine. This enhanced response may be attributed to a higher viral antigen content in the TZ84 formulation relative to the HM-175–based vaccine, which could explain its greater immunogenic potential.[9]

Despite the availability of safe and effective vaccines, several gaps and challenges continue to impede optimal hepatitis A vaccination coverage in India. To address these issues, a focused group discussion (FGD) was conducted to explore the challenges associated with hepatitis A vaccination and to capture real world clinical perspectives. Insights were gathered from pediatricians across India regarding their vaccination practices, clinical experiences, and the factors influencing vaccine selection for hepatitis A prevention. This review aimed to explore aimed to explore the challenges associated with hepatitis A vaccination in India and to gather insights from pediatricians on the clinical relevance and factors influencing their choice of inactivated hepatitis A vaccines, with particular reference to the TZ84 strain.

METHODS

FGD was conducted with 11 Indian experts in the field of pediatrics. For the purpose of this discussion, experts were defined as senior pediatricians with extensive clinical experience in managing vaccine preventable diseases, active involvement in routine immunization practices, and a minimum of 15 years of professional experience in pediatric care.

The FGD explored key aspects of hepatitis A, including disease burden, evolving epidemiology, the need for vaccination, challenges to hepatitis A immunization, and factors influencing vaccine selection for hepatitis A prevention. In parallel, a comprehensive literature review was undertaken using databases such as PubMed, the Cochrane Library, and Google Scholar. Search terms included India, hepatitis A, epidemiology, hepatitis A vaccination, live vaccines, and inactivated vaccines. Current clinical practices related to hepatitis A vaccine selection were critically reviewed, with particular emphasis on the importance of inactivated vaccines, including vaccine with TZ84 strain.

BURDEN OF HEPATITIS A IN INDIA

Hepatitis A remains an important contributor to the burden of acute viral hepatitis in India. In regions with poor sanitation and limited access to safe drinking water, the transmission of HAV remains common, making hepatitis A a persistent public health challenge. Overcrowded housing environments, insufficient water supply infrastructure, and substandard community sanitation persist in promoting the spread of HAV across various regions of the nation. Outbreaks are frequently linked to the presence of contaminated drinking water or food sources, with children often serving as reservoirs of infection within communities.

Furthermore, the rise in urban development and environmental influences, including fluctuations in climate, could play a role in the onset and dissemination of outbreaks by impacting water accessibility and sanitation systems.[10]

Although hepatitis A is generally self-limiting, it can occasionally lead to severe complications such as fulminant hepatitis, which is associated with significant morbidity and mortality.[11]

CHANGING EPIDEMIOLOGY OF HEPATITIS A IN INDIA

In the past few years, India has experienced substantial socioeconomic progress. As a result of the economic transition and improvements in the standard of living and hygiene, the epidemiological pattern of the disease has changed.[12]

As a result, the age of primary infection has shifted from early childhood to adolescence and adulthood. This transition has increased the proportion of susceptible individuals who are more likely to develop symptomatic diseases. These changes underscore the need to strengthen public awareness of hepatitis A and to improve vaccination coverage, particularly among populations in lower- and middle-income groups, where significant gaps in vaccination coverage persist.[13]

Recent seroepidemiological studies indicate declining anti-HAV seroprevalence among younger age groups in urban and semi-urban populations. This shift has resulted in a growing pool of susceptible individuals who may experience symptomatic infection later in life.[14] In individuals under the age of 6, the condition presents without observable symptoms, whereas the likelihood of symptom manifestation and the severity of the condition escalate with advancing age.[15]

The World Health Organization (WHO) position paper published in 2012 indicates that the transition from high to intermediate endemicity of hepatitis A is associated with an elevated risk of clinically significant hepatitis.[16] In summary, the available epidemiological data, challenges associated with diagnosing infections in young children due to their often asymptomatic presentation or non-specific symptoms, and the heightened risk of disease severity with advancing age emphasize the critical need for hepatitis A prevention within the community.

Expert insights on shifting the disease burden of hepatitis A in India

Experts have noted that this change in epidemiology has led to a rise in hospitalization rates and an increased burden on healthcare systems, especially during outbreaks. The existence of a substantial unvaccinated demographic significantly increases the likelihood of disease propagation and its associated severity. The panel highlighted that this evolving burden illustrates the necessity for proactive preventive measures, such as enhanced awareness and broader implementation of hepatitis A vaccination, to tackle the shifting risk landscape in India.

According to expert discussions, the periodic occurrence of hepatitis A outbreaks in India is closely associated with environmental and seasonal factors. Participants noted that outbreaks are frequently observed during the monsoon and post-monsoon periods, when the likelihood of contamination of drinking water sources increases due to flooding, inadequate drainage systems, and weakened sanitation infrastructure.

Experts indicated that localized clusters of cases frequently occur in educational institutions, hostels, and communal living environments, where proximity among individuals promotes swift transmission.

Hepatitis A continues to be a frequently observed viral infection in pediatric clinical settings, with its prevalence differing by geographic area. Several clinicians mentioned that they handle around 2–5 cases of hepatitis A each month, with certain reports indicating a seasonal clustering of cases, especially during the pre- and post-monsoon periods. Clinicians have also observed that children who rely exclusively on government immunization programs are more likely to remain unprotected against hepatitis A, as the vaccine is not currently included in the Universal Immunization Programme (UIP).

NEED FOR HEPATITIS A VACCINATION IN CHILDREN IN INDIA

In India, the coexistence of populations with early life exposure and those remaining unexposed across different socio economic strata and geographic regions has created pockets of susceptibility, increasing the risk of outbreaks. Improvements in hygiene and sanitation have paradoxically reduced early childhood exposure in many urban settings, leaving children susceptible until school age or later.[17] This epidemiological shift has important clinical implications, as HAV infection acquired at older ages is associated with higher rates of symptomatic illness, complications, and severe disease.[18]

HAV remains the most common cause of fulminant hepatic failure among children in India. Transmission continues to occur frequently in shared community environments such as schools, colleges, hostels, and restaurants, facilitating rapid spread among susceptible individuals. The growing number of non immune children, adolescents, and adults across socio economic groups highlights the limitations of relying solely on environmental improvements to control the disease.[18] Moreover, in the absence of specific antiviral treatment for hepatitis A, prevention remains the cornerstone of disease management.[19]

Vaccination serves as a highly effective preventive measure, with the currently available hepatitis A vaccines exhibiting a high efficacy rate of approximately 90–95% and offering prolonged protection.[20] These vaccines facilitate swift seroconversion and are applicable for both pre-exposure and post-exposure prophylaxis. The administration of these vaccines has the potential to markedly decrease the occurrence of symptomatic infections and avert outbreaks, which have been increasingly documented in various Indian states.[18]

Although global health organizations, including the WHO, advocate hepatitis A vaccination policies based on regional epidemiology and cost-effectiveness, routine vaccination coverage in India remains limited.[2,18]

In brief, enhancing hepatitis A vaccination coverage, especially among vulnerable populations and high-risk occupational groups, coupled with advancements in sanitation, food safety protocols, and public health education, may significantly contribute to lowering the incidence of hepatitis A and averting outbreaks in India.

Expert insights on risk factors of hepatitis A and need for vaccination

The panel delineated multiple significant environmental and demographic risk factors correlated with hepatitis A infection. Inadequate sanitation, contaminated drinking water, and insufficient hygiene practices continue to be significant factors in the spread of diseases. Individuals living in slum areas, densely populated environments, or regions with substandard water quality were identified as especially susceptible.

Experts have noted that individuals residing in hostels, students in dormitory settings, and those in communal living situations are at a heightened risk of infection as a result of proximity and the use of shared amenities.

The management approach primarily emphasizes supportive care, which includes ensuring sufficient nutrition, maintaining hydration, and vigilant observation for potential complications. Clinicians have recognized multiple treatment challenges, such as diminished appetite, nutritional deficiencies, and dietary restrictions influenced by misinformation, which may result in hypoproteinemia and prolonged recovery times.

CHALLENGES IN HEPATITIS A VACCINATION IN INDIA

Despite the availability of effective vaccines, several gaps and challenges continue to limit the optimal implementation of hepatitis A vaccination strategies in India. These challenges are related to awareness, surveillance, healthcare infrastructure, and policy-level factors.[21]

The key gaps identified from the literature are summarized in Table 1.

To address these shortcomings, it is essential to bolster public awareness initiatives, refine disease surveillance mechanisms, enhance the training of healthcare professionals, and establish more robust policy frameworks aimed at increasing hepatitis A vaccination coverage and mitigating the overall disease burden in India.

Experts insights on the barriers to hepatitis A vaccination in clinical practices

The focus group discussion revealed multiple barriers that limit the uptake of hepatitis A vaccination in routine clinical practice in India.

Low caregiver awareness

Parents frequently regard hepatitis A as a harmless, self-limiting condition and may not recognize its possible extent in older children.

Cost-related barriers

The substantial financial burden associated with two-dose inactivated vaccines significantly restricts their adoption among numerous families.

Reliance on governmental timelines

A significant number of families adhere exclusively to government immunization initiatives, presuming that all essential vaccines are addressed within these programs.

Logistical challenges

Challenges include the accessibility of vaccines, the organization of appointment scheduling, and the assurance of adherence to multi-dose treatment protocols.

Limited preventive counselling

Time limitations in high-traffic clinical environments diminish the chances for comprehensive vaccine education and advocacy efforts.

Access disparities

Unequal access to vaccination services between urban and rural populations.

Missed opportunities for catch-up vaccination

Older children and adolescents often remain unvaccinated due to a lack of systematic catch-up strategies.

Lack of policy prioritization

The hepatitis A vaccine is not yet included un Universal Immunization Programme, resulting in a dependence on vaccinations provided by the private sector.

HEPATITIS A VACCINES IN INDIA

In routine clinical practice in India, hepatitis A prevention relies on two types available vaccine options—live attenuated and inactivated hepatitis A vaccines, each with distinct advantages and limitations. While live attenuated

vaccines offer the convenience of a single dose schedule, accumulated clinical evidence shows that inactivated hepatitis A vaccines provide a more consistent and durable immune response. Inactivated vaccines achieve higher seroconversion rates (95–100%) and protective efficacy (95–100%) compared with live attenuated vaccines, which demonstrate seroconversion rates of 83–91% in clinical studies, with greater inter individual variability.[22] Long term follow up and immune persistence analyses further demonstrate that inactivated vaccines can maintain complete seroprotection for more than a decade, with antibody persistence and immune protection predicted to extend up to 35 years, an important consideration in the context of India's shifting epidemiology.[23,24]

From a practical perspective, inactivated hepatitis A vaccines also address several limitations associated with live attenuated formulations. Live vaccines are characterized by a slower antibody induction, with peak seroconversion occurring 2–3 months after vaccination and are associated with risk of vaccine virus shedding and the potential for horizontal transmission. These concerns are not observed with inactivated vaccines.[9,22,25] These differences gain particular significance during outbreaks and post exposure situations, where rapid and predictable immune protection is essential. Evidence from outbreak investigations and expert reviews supports the effectiveness of inactivated hepatitis A vaccines for both outbreak control and post exposure prophylaxis, whereas corresponding data for live attenuated vaccines in these settings remain limited.[26]

Expert insights on evidence of hepatitis A vaccination in children

Experts strongly emphasized that hepatitis A vaccination is essential for children, particularly in the context of the epidemiological shift toward intermediate endemicity in India. With decreasing seropositivity in childhood, vaccination plays a crucial role in preventing symptomatic disease and severe complications later in life.

Experts highlighted that live attenuated vaccines present the benefit of a single-dose regimen, potentially enhancing adherence and cost-effectiveness. On the other hand, they also highlighted several advantages of inactivated hepatitis A vaccines, including: rapid immune response, strong long-term immunogenicity, favorable safety profile, and suitability for post-exposure prophylaxis. However, the two-dose schedule and higher cost may affect compliance.

Table 1: Challenges in hepatitis A vaccination in India.

Challenge	Description
Limited public awareness	The lack of sufficient understanding within the general populace regarding the transmission, prevention, and accessibility of vaccination for hepatitis A contributes to a decrease in vaccine uptake.
Limited awareness among healthcare workers	The lack of sufficient understanding within the wider community regarding the transmission, prevention, and accessibility of vaccination for hepatitis A contributes to a decrease in vaccine uptake.
Limited epidemiological data	The scarcity of epidemiological data and insufficient surveillance hinder precise estimation of the burden of hepatitis A and the formulation of targeted vaccination strategies.
Limited policy prioritization	The integration of hepatitis A vaccination into national immunization strategies is limited, thereby constraining its widespread implementation.
Resource constraints	The proliferation of hepatitis vaccination programs is influenced by competing public health priorities and constraints in funding.
Weak monitoring and reporting systems	Insufficient documentation, recording of information, and follow-up diminish the efficacy of vaccination initiatives and disease control strategies.

INACTIVATED HEPATITIS A VACCINE (TZ84 STRAIN)

The inactivated TZ84 strain hepatitis A vaccine is a domestically produced immunization solution in India, derived from the Asian hepatitis A virus strain. The vaccine development process involved importation of the bulk vaccine material from China, with subsequent fill–finish operations conducted in India. It is a formalin-inactivated, cell culture–based vaccine, specifically designed to provide effective protection against hepatitis A while addressing the unique epidemiological and economic needs of the Indian population.

The vaccine has been formulated to meet the demand for an economically viable and contextually appropriate preventive approach, where hepatitis A continues to pose a significant public health challenge.[26,27]

The inactivated TZ84 strain hepatitis A vaccine is administered intramuscularly in a two-dose schedule and is available in both vials and prefilled syringes (PFS). PFS offer advantages such as ease of use, accurate premeasured dosing, reduced risk of dosing errors, and improved safety. They are also less prone to breakage and enhance overall administration efficiency. An Indian study demonstrated that the use of PFS doubled the rate of vaccine administration and reduced handling errors and associated

health hazard risks by threefold compared to conventional vials.[28]

A randomized, single blind phase 3 study in India evaluated the safety and immunogenicity of an inactivated hepatitis A vaccine based on the TZ84 strain in 520 hepatitis A vaccine naïve children aged 1–15 years. Two intramuscular doses administered six months apart achieved 100% seroconversion by day 210, meeting non inferiority criteria versus the HM175 based vaccine. The TZ84 vaccine induced stronger immune responses, with higher geometric mean antibody concentrations and greater antibody rise.[29]

Evidence from long term follow up studies, comparative analyses, and immune persistence modeling demonstrates that inactivated hepatitis A vaccines provide durable and sustained protection. Comparative clinical data show that vaccines based on the TZ84 strain consistently elicit higher geometric mean antibody concentrations (GMCs) than HM175 based vaccines at multiple time points, including 6, 66, and 138 months post vaccination, reflecting a stronger and more durable immune response.[9,24] Eleven year follow up data confirm sustained seroprotection following inactivated vaccination, and mathematical modeling of antibody kinetics further predicts that protective anti HAV antibody levels are likely to persist for up to 35 years after completion of a two dose schedule, with more than 90% of vaccinated children remaining seroprotected; TZ84 based vaccines demonstrated slightly higher long term antibody trajectories in these models. These modeling approaches, which incorporate memory B cell dynamics and antibody plateau formation, strengthen confidence in the long term clinical relevance of inactivated hepatitis A vaccination.[24,25]

In addition, interchangeability studies show that different inactivated hepatitis A vaccines can be safely used within a two dose schedule, achieving 100% seroconversion across all vaccine combinations, with higher GMCs observed when TZ84 based vaccines are included as part of the primary or booster dose. Consistent with World Health Organization guidance, these findings support both the interchangeability of inactivated hepatitis A vaccines and the advantage of formulations associated with higher and sustained immunogenicity.[30,31]

The TZ84 strain vaccine presents a significant benefit due to its cost-effectiveness relative to other imported vaccines, thereby enhancing accessibility in resource-constrained environments. This cost advantage has the potential to enhance vaccine uptake, especially in populations where financial limitations pose a significant obstacle.[31]

Overall, the inactivated TZ84 strain hepatitis A vaccine is an effective, safe, and economically viable option for the prevention of hepatitis A in India. It has the capacity to significantly enhance vaccination coverage and mitigate the disease load.

Expert opinion

Experts highlighted that hepatitis A vaccines exhibit robust long-term immunogenicity and an advantageous safety profile, establishing them as an effective preventive measure. Inactivated vaccines have been observed to facilitate quicker seroconversion and sustained immune protection, which proves advantageous in outbreak scenarios.

Vaccination is regarded as a crucial method for managing outbreaks, especially in areas that face repeated occurrences of hepatitis A. Through the enhancement of population immunity, vaccination serves to disrupt transmission pathways and alleviate the burden of disease.

Experts further expressed a positive opinion on hepatitis A vaccines developed using the TZ84 strain, emphasizing that this well-characterized inactivated strain has demonstrated consistent immunogenicity and an established safety profile. Vaccines based on the TZ84 strain were considered reliable for both routine immunization and outbreak response, contributing meaningfully to hepatitis A prevention efforts. Although the overall evidence supports the effectiveness and safety of inactivated hepatitis A vaccines, experts noted certain limitations within the existing literature. A substantial proportion of immunogenicity and effectiveness data originates from studies conducted in China. Some participants expressed caution regarding the variability in study quality, limited availability of independently replicated data, and the restricted access to fully translated publications, which may constrain comprehensive critical appraisal

CONCLUSION

Hepatitis A is a clinically relevant and preventable cause of acute viral hepatitis, especially in view of the ongoing epidemiological shift from high to intermediate endemicity in India. Improvements in sanitation and living conditions, while beneficial, have paradoxically increased susceptibility among older age groups in which hepatitis A is more likely to be symptomatic, severe, and occasionally life threatening. Despite the availability of effective vaccines, hepatitis A immunization coverage remains suboptimal, limited by barriers such as low disease awareness, vaccine hesitancy.

Within this evolving landscape, vaccination assumes critical importance as the most reliable strategy for long term disease prevention. Both live attenuated and inactivated hepatitis A vaccines play a role; however, accumulating clinical evidence underscores the particular clinical relevance of inactivated hepatitis A vaccines. Inactivated vaccines, including those based on the TZ84 strain, offer consistently high immunogenicity, rapid and predictable antibody responses, an acceptable safety profile, and applicability across a broad range of populations, including individuals with chronic illnesses

or immunocompromised states. Robust long term follow-up and modelling data further indicate sustained immune protection lasting up to three decades or more, supporting their value for lifelong disease prevention and public health impact.

Expert insights highlight the need to move beyond short term considerations of convenience and cost toward evidence based vaccine selection that aligns with India's changing epidemiology and long term prevention goals. Integrating scientifically robust options such as inactivated hepatitis A vaccines, into routine and catch up immunization strategies can play a pivotal role in reducing disease burden, preventing outbreaks, and protecting vulnerable populations in the years ahead.

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