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MEETING REPORT

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Expert consensus and recommendations on the live attenuated hepatitis A vaccine and immunization practices in India

Nitin Shah[a], M.M.A. Faridi[b], Sheila Bhave[c], Apurba Ghosh[d], S. Balasubramanian[e], Vidya Arankalle[f], Raju Shah[g], Amar Jeet Chitkara[h], Arun Wadhwa[i], Jaydeep Chaudhry[d], Ramesh Srinivasan[j], M. Surendranath[k], Amita Sapru[c], and Monjori Mitra[d]

[a]Department of Paediatrics, P. D. Hinduja Hospital & Medical Research Centre, Mumbai, India; [b]Department of Paediatrics and Neonatology, Era's Lucknow Medical College and Hospital, Lucknow, Uttar Pradesh, India; [c]Department of Paediatrics, KEM Hospital Research Centre, Pune, India; [d]Department of Paediatrics, Institute of Child Health, Kolkata, India; [e]Department of Pediatrics, Kanchi Kamakoti CHILDS Trust Hospital, Chennai, India; [f]Department of Communicable Diseases, Interactive Research School for Health Affairs (IRSHA), Bharati Vidyapeeth (Deemed to be University), Pune, India; [g]Department of Pediatrics, Ankur Children Hospital, Ahmedabad, Gujarat, India; [h]Department of Pediatrics, Max Super Specialty Hospital, Delhi, India; [i]Department of Pediatrics, Dr. Wadhwa's Clinic, New Delhi, India; [j]Department of Gastroenterology, Apollo Hospitals, Hyderabad, India; [k]Department of Pediatrics, Vijay Marie Hospital, Hyderabad, India

ABSTRACT

While Hepatitis A Virus (HAV) vaccination in global immunization programs has shown a virtual elimination of the disease within few years of the vaccination program, changing epidemiological landscape in India underscores the need for evidence-based, updated guidance on immunization practices. In May 2024, a panel of 15 distinguished opinion leaders and an organizing committee convened for an intensive, face-to-face advisory board meeting on high burden of HAV infection among adults, increased mortality rate in adolescents, symptomatic presentation in children, and evolving landscape globally and within India. Extensive comparable deliberations on long-term follow-up data from India and data from country of origin advocated immunogenicity, tolerability, and long-term protective effects of single-dose live attenuated HAV vaccine in children. Finally, a consensus was achieved on recognition of increased global attention toward HAV prevention through vaccination coverage. The need for a single dose of live attenuated HAV vaccine was an important outcome of this meeting.

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Hepatitis A; immunogenicity; live attenuated vaccine; tolerability; safety

Background and context

Viral hepatitis, with about 1.4 million deaths annually, is the seventh-leading cause of mortality and morbidity in low- and middle-income countries (LMICs) and other regions globally.[1–5] Among these, hepatitis A virus (HAV), a virus of the family *Picornaviridae*, genus *Hepatovirus*,[6] accounts for 15,000 to 30,000 deaths (*i.e.*, 0.5% of deaths from viral hepatitis), 100 million self-limited infections, and 1.5 million symptomatic cases annually worldwide.[6,7] The distribution of the HAV is closely related to hygiene and sanitation standards, as well as socio-economic status, with sporadic food-borne outbreaks reported in many endemic countries.[8,9] Recognizing the global burden of HAV (*i.e.*, 1.4 disability-adjusted life years (DALYs) and 2.5 DALYs in 2010 and 2023, respectively), the World Health Organization (WHO) developed a long-term goal of eliminating viral hepatitis, including hepatitis A, as a major public health threat by 2030.[10]

Although the HAV was first identified in 1973 and the vaccine has existed since 1992, viral hepatitis A infection remains a significant public health challenge in the world. The clinical cases afflicted by HAV increased 150% during 2018–2023 compared with 2016–2018 in the USA; endemicity persists and outbreaks continue to occur in Europe. Shifting patterns of anti-HAV positivity, with a transition from higher to lower seroprevalence, have been notable in various countries of the WHO Western Pacific Region. India is one of the most populous and heterogeneous countries in the Asia Pacific region and is primarily considered a hyper-endemic country; however, bulk pooled authentic national data on the prevalence of hepatitis A are still lacking due to the non-availability of suitable surveillance systems.[11–13,2,15] Serosurveys conducted between 1992 and 2010 showed decreased HAV seroprevalence in children but increased in older age groups, which perhaps reflected historical exposure in early childhood prior to this period of economic development. However, such studies were conducted in different geographical areas with consequent variation in development.[15–17] Given the attack rates in the adolescents and adults and the changing social and cultural behaviors in India, it is a reasonable assumption that with the shifting HAV endemicity in India, HAV infection could have a larger impact on the individual health, and families due to loss of income and productivity. HAV is also the most common cause of fulminant hepatic failure among children in India, which has been reported life-

CONTACT Monjori Mitra monjorimr@gmail.com Department of Paediatrics, Institute of Child Health, 11 Biresh Guha Street, Kolkata 700017, India.
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threatening. The coexistence of heterogeneous pockets of exposed and unexposed individuals in different social classes and regions within the country makes population prone to HAV outbreaks.

Need for consensus: perspectives from Indian subcontinent

According to the series of WHO position papers published in 2000, 2012, and 2022,[18] the transition from high to intermediate endemicity of hepatitis A leads to an increased risk of clinically significant hepatitis. In general, epidemiological data, difficulty in diagnosis of asymptomatic or nonspecific symptoms of infection in children, and risk of disease severity with increasing age underline the importance of prevention of hepatitis A in the community. Nonetheless, the evolving disease patterns within India, especially in cities, are a result of improved hygiene, sanitation, and living conditions among parents handling infants and very young kids of <5 y of age. This means that children are not exposed to natural infections until they reach school age. Should they contract the infection later in life, they are at a higher risk of developing serious illnesses, and there is also a greater likelihood of complications. Children, adolescents, and adults are prone to HAV infection within the external environmental conditions (schools, colleges, restaurants). The alarming increase in the number of susceptible children, adolescents, and adults and continuous reports of HAV outcomes in different parts of the country suggest a definite need for the hepatitis A vaccination, regardless of the socioeconomic status.[19–21]

Scope and objectives of the advisory board meeting

In May 2024, a panel of 15 distinguished experts and the organizing committee convened an intensive, face-to-face advisory board meeting. These key opinion leaders, selected for their outstanding reputations and expertise in the pediatrics, vaccinology, pediatric gastroenterology, hepatology, and virology, and all the principal investigators for the clinical trial of the live attenuated hepatitis A study in India over the last 15 y participated in the meeting. The meeting aimed to consolidate expert opinions on (i) independent review of research, particularly recent update on the sero-epidemiology of HAV in India and the complications of fulminant hepatitis A infections, and (ii) the long-term persistence of the immunogenicity of the live attenuated hepatitis A vaccine along with the understanding of the experience of the 20 y use of the vaccine in India.

After the confirmation of the participation, the experts were briefed on the agenda of the meeting in line with the above topics, and extensive research papers were circulated as pre-reads. Further, the key points were reviewed and approved by the KOLs who showed interest in participating in the meeting. The questions related to each topic were addressed by all the representatives and discussed in detail during the meeting (Figure 1). Their outputs were consolidated into a key consensus document.

Summarized description of sessions

Session 1: (a) Seroepidemiology of hepatitis A in India: changing scenario

During the session, an expert from the National Institute of Virology, Pune, and Interactive Research School for Health Affairs (IRSHA), Bharati Vidyapeeth University, Pune,

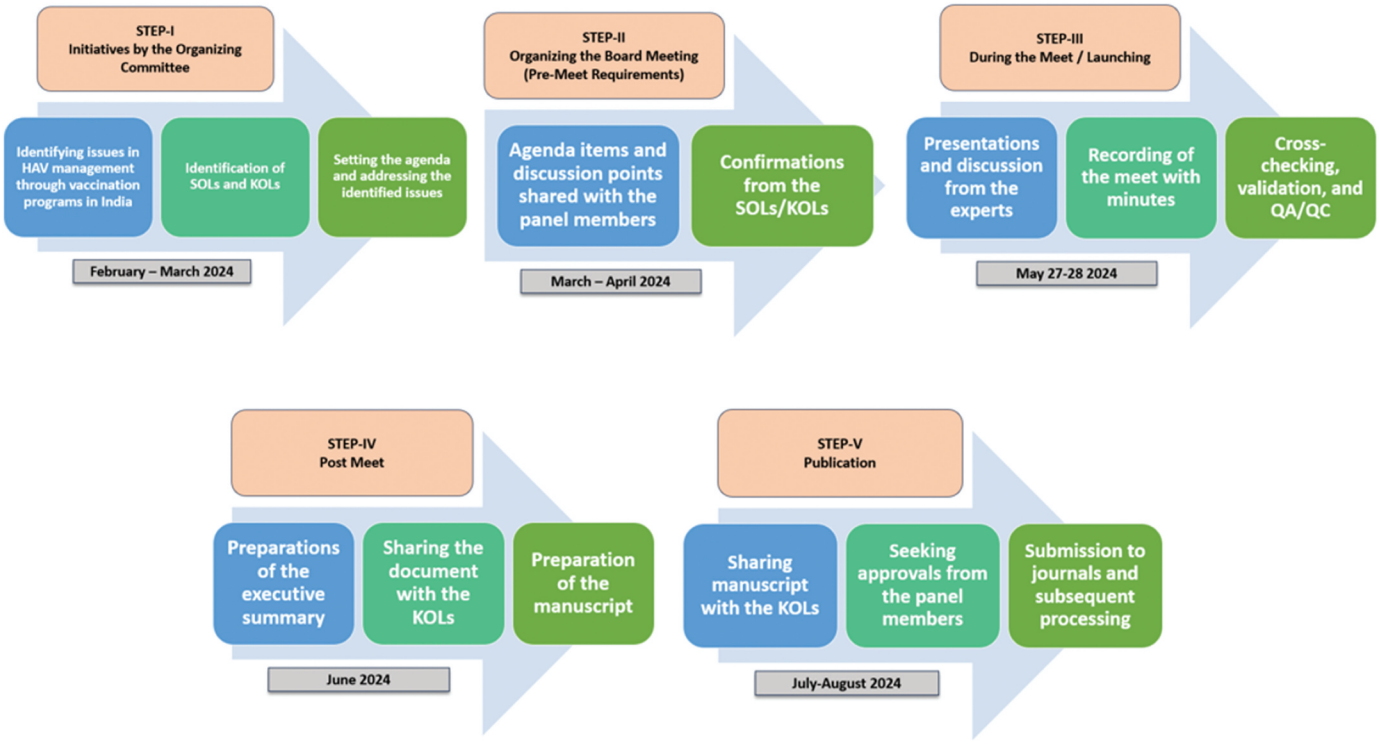

Figure 1. Proceedings of hepatitis A expert opinion board meet 2024: a stepwise approach. SOL, scientific opinion leaders; KOL, key opinion leaders.

presented pan-India HAV prevalence by comparing the studies on community-, hospital settings-, single centre/city-based, multicentric, and high-risk categories (Table S1 in Supplementary data).

Changing epidemiology among children/infants

Collecting data from single time point, longitudinal, age-stratified, or restricted ages, it has been observed that a few decades ago, hepatitis A was hyperendemic in developing countries due to the lack of sub-clinical exposure infection in young children and inadequate vaccination coverage.[12–28] India has been experiencing significant socio-economic growth over the last few decades, and reports are indicating a decline in HAV seroprevalence in India based on the ICMR-NIV data reported in 1982, 1992, 1998, 2002–05, and 2009.[29–34] When overall HAV seroprevalence in the '6–10' and '15–25' y age groups of nonexposed unvaccinated adults were compared from 1978 to 2022 by taking previously reported values from NIV, a marked decline was observed over the last two decades, while no decline was seen over two decades before 1998. However, when compared with 2009 seroprevalence, the decline in 2020 and 2022 was seen to be rapid during the last decade (from ~74% to ~44% to ~31%).[11,24,29] Echoing this trend, a longitudinal serosurvey conducted in Pune (Western India) in 2020 showed a significant decline in HAV seroprevalence in '15–25' y age group in urban (from 85.9% to 73.9%) and rural (from 98.6% to 91.4%) populations, suggesting that the trend probably started more than a decade ago.[29] Seroprevalence of HAV among urban lower socio-economic stratum '6–10' y children and nonexposed unvaccinated adults was found to be significantly higher (~70%) than that among the rural (44%) and urban children (40%). This population seems to have moved rapidly from 'high child immunity rates' (>90%) to 'low-medium immunity rates' (40%-59%) as per the WHO classification.[35–37]

Hepatitis A in adults

Though exact estimates are not available, according to accessed literature, the following picture emerged: (i) 'adult susceptibility rate' (proportion of nonimmune adults between 35 and 44 y) has remained very low (close to 0%) over the past two decades, and (iii) increased HAV seroprevalence in older age groups between 1992 and 2010 plausibly reflects historical exposure in early childhood prior to this period of economic development.[38–40]

Emergence of outbreaks of hepatitis A

The shift in HAV epidemiology was parallelly accompanied by outbreaks of hepatitis A in children, young adults, and adults. Among the 291 outbreaks reported in the last national Integrated Disease Surveillance Programme (IDSP) survey (2011–2013), at least one hepatitis outbreak was reported in 23 (66%) of 35 Indian states, 2/3rd of outbreaks was reported from rural areas, and about 163 (56%) outbreaks were with known etiology. Several hepatitis A outbreaks with high attack rates (particularly in adolescents and young adults) were noted in Kerala. The transformative epidemiological shift is evident in the rising burden of acute liver failure in children, previously an uncommon manifestation of HAV infection. HAV alone or in combination with other viruses constitutes over 50% of the fulminant hepatitis cases in children.[41–45]

Session 1: (b) Unusual manifestations and co-infections in acute hepatitis in children

Acute severe hepatitis with unknown etiology in children is a rising health concern, with 1121 cases and 27 deaths reported in 36 countries.[46] A study report from the experts of the KEM Hospital, Pune, showed unusual 23 pediatric (13 males, 10 females) cases of acute hepatitis, including ascites (9), edema (4), pleural effusion (3), hematuria (1), maculopapular rashes (2), and firm hepatomegaly (5) in different degrees and recovery was delayed (6 weeks to 6 months). A significant association between co-infections was also found as follows: HAV alone (8), HEV alone (2), HAV + hEV (8), HAV + hCV (2), HAV + hBV (1), HAV + *F. malaria* (1), and HAV + enteric fever (1), although a direct causal relationship has not been demonstrated.

Session 2: Long-term immunogenicity and immune persistence of live attenuated hepatitis A vaccine: Chinese and Indian studies

If the ambitious global targets of eliminating viral hepatitis, including hepatitis A, by 2030 are met and sustained, over 60 million deaths could be averted over the next century.[47] To reach these aspirational targets, the hepatitis A vaccination program needs to be scaled up, which might enhance existing efforts or address specific gaps. Two experts from the Institute of Child Health (Kolkata) and KEM Hospital Research Centre (Pune) identified the overarching contexts from the WHO 2022 position papers (with a particular emphasis on longer-term, *i.e.*, 3–7 y and >7 y follow-up studies, including data on efficacy and safety of single-dose regimens of live attenuated hepatitis A vaccines in children in India).

Live attenuated Hepatitis A vaccines derived from H2 strains through serial passaged propagation in Human Diploid Cell (KMB 17 cell line) were licensed for human use in 1992.[48,49] Since then, these vaccines have been used successfully in the Chinese population for the primary prevention of Hepatitis A infections as well as in the control of epidemics.

Data from China

Clinical trials in the 1990s conducted in China demonstrated that live attenuated hepatitis A vaccines had high efficacy, good safety, and persistent long-term immunity.[50] This was further demonstrated in a 4-y vaccine efficacy study of the H2-based vaccine conducted by Mao et al.[51] in children 1–15 y of age at 11 primary schools in Shaoxing County, China, in which no hepatitis A cases were reported during 18,102 cumulative person-years in the vaccination group, while in the control group, 495 cases occurred during 242,168 cumulative person-years (vaccine efficacy 100%). In a large-scale vaccination of children aged 1–15 y in Jiaojiang City, China, the presence of anti-HAV IgG antibodies was documented after 15 y in 72%-88% of the vaccinees[51] and was associated with a 32-fold

reduction in reported HAV incidence, implying that in most cases, long-term protection against hepatitis A is achieved following single dose of this vaccine.

A systematic review by Irving et al.[52] included five trials assessing the live attenuated vaccine ($n = 690690$). Sub-group analyses confirmed the clinical effectiveness of live attenuated hepatitis A vaccines (effectiveness: 93%; 95% CI: 83–97) to prevent clinically apparent HAV infection.

Several large population studies in China have demonstrated the impact of mass vaccination strategies using live attenuated vaccines, showing a 50% to 84% reduction in HAV incidence across all age groups before and after implementing a universal single-dose live attenuated vaccination schedule.[53–55]

A national-level analysis of provinces using a single dose live attenuated HAV vaccine at 18 months (115 million doses administered) showed an increase in coverage from 82.4% to 98.4%, while annual reported HAV cases dropped from 7489 (2007) to 4576 (2008) to 237 (2018), marking an overall 96.8% decline.[56] In Henan province, expanded HAV immunization in 2008 resulted in a 94.8% decrease in incidence by 2018, with a 98.2% decline among adolescents. The proportion of hepatitis A cases in patients under 10 y decreased from 41.6% in 2012 to 3.8% in 2018, while cases in those over 40 y rose to 69.2%.[57]

In a 17-y follow-up of 47 children administered the hepatitis A vaccine, Chen et al.[58] demonstrated seroprotection of 62% (antibody titers ≥ 20 mIU/ml); all participants had detectable titers. GMCs of anti-HAV IgG, i.e., 64.8 mIU/ml exponentially rose to 1832.1 mIU/ml. This proves the anamnestic response of the live attenuated HAV even in the individuals whose antibodies were below the minimum protective titer. However, persistent memory T cells (amnestic response) were demonstrated in 94% of the 31 individuals receiving a booster at 17 y post-primary vaccination, including 13 cases who were seronegative at this time point.

Data from India

The first study of this vaccine outside China was conducted in Pune, India, in 2004, and showed an immunogenicity of 95.8% by the end of 2 months after a single dose of the vaccine.[59] The original Pune cohort has been under regular follow-up since vaccination for anti-HAV antibodies 30 months post-vaccination (2007) in 131 of the original 143 children. Seroprotective antibody levels ≥20 mIU/mL were demonstrated in 87.8% of subjects with an overall GMT of 92.02 mIU/mL, with no hepatitis-like illness since vaccination. There were no adverse events in any except mild fever in one child.[60] A 10-y follow-up of the same cohort of children demonstrated a seroprotection rate of 98.1% (anti-HAV GMT of 100.46 mIU/mL) in those who showed adequate seroprotection in earlier studies. The seroprotection rate declined to 87.6%, on the exclusion of 13 participants who had to be given additional hepatitis A doses. Since the vaccine was not yet licensed, the ethics committee requested to give additional doses. This same cohort was assessed clinically every year for anti-HAV antibodies in 2004, 2007, 2010, and 2014, and further follow-up showed robust immunogenicity with a seroprotection level of 86.2% at 15 y after vaccination.[61]

The high immunogenicity of the single dose schedule in Indian children was corroborated in 2008 by a larger multicentre study spanning across four geographic zones (Kolkata, Delhi, Mumbai, and Chennai) in India, showing seroconversion of 95.1% and 97.9% at 6 weeks and 6 months, respectively.[62] A phase IV, 5-y follow-up with the same cohort of 343 subjects achieved a seroconversion rate and the GMC of 97.3% and 127.1 mIU/mL at 60 months, respectively.[63] Subjects with an antibody titer > 10,000 mIU/mL had no clinical history of hepatitis A, suggesting possible subclinical infections and supporting the anamnestic response. Of the 349 subjects, 23 had titers >5000 mIU/mL, and one had a titer >10,000 mIU/mL twice in consecutive years, yet none showed clinical signs of icterus. The sub-clinical infection (>10,000 mIU/mL) induced anamnestic response (>3000 mIU/mL) in the subjects was the reason for the long-term persistence of antibodies through natural boosting effect considering >20 mIU/mL as a positive response. Even for subjects who did not attain seroconversion (<20 ml/IU) post-vaccination, it was seen in subsequent follow visits they achieved very high titer values due to antibody boosting by the natural infection due to anamnestic responses. Hence, with the single dose, live attenuated vaccine even if the antibody titers appear to be below minimum protective titer at some time points post-primary vaccination, strong anamnestic response mediated exponential increase in antibodies on subsequent exposures confers long-term persistent immunogenicity.

The team concluded by briefly sharing a comparative account of the excellent immunogenicity of live attenuated HAV vaccines (Table 1). It was unanimously opined that HAV coverage should be addressed across the country and all children must be vaccinated with hepatitis A at 12 months and if missed catch-up vaccination should be encouraged. Based on the scientific and real-world evidence of more than three decades in China and two decades in India along-with a long history of research and development and promising clinical trials, single-dose live attenuated HAV has been proven to have good efficacy, safety, and long-term immunogenicity. The long-term prospective real-world follow-up studies (without any statistical modeling) illustrated the long-term immunogenicity mediated by a strong anamnestic response on subsequent exposures.[79,80] WHO position paper (2022) also mentioned single-dose live attenuated vaccine has good safety, efficacy, and immunogenicity. The Advisory Committee on Immunization Practices (ACIP) of Indian Academy of Pediatrics (IAP) too recommends single-dose administration of live attenuated H2 strain vaccine for all children at the age of 12–23 months and if missed catch-up vaccination is suggested; catch-up vaccination for children >2 y requires a single dose of the live HAV vaccine. However, pre-vaccination screening for hepatitis A antibodies is recommended for children >10 y.[81] In addition, this vaccine is endorsed for individuals with a high risk of HAV such as food handlers, travelers, and for any person wishing to obtain immunity.

Table 1. Description of seroprotection rate reported in long-term studies with live attenuated hepatitis a vaccine.

Study type	Author	Duration	Region/Source	Subjects (No. of participants)	Age group (years)	Seroconversion at end of study (%)
Randomized Controlled Trials						
Global scenario	Zhang et al.[64]	3.5 y	Zhengding County and the Jiaoqu District of Shijiazhuang city, China	37,000	1–8	94.4
	Xu et al.[65]	3 y	Guanxi, Hebei and Shanghai, China	457,251	3–13	75–80
	Wang et al.[50]	8 y	Zhengding, Hebei province, China	3515	1–12	72
	Zhuang et al.[66]	15 y	Shengsi county and Jiaojiang city in Zhejiang province, China	220	1–13	81.3
	Liu et al.[67]	1 y	Zhengding, China	924	1.5–6	91
	Liu et al.[68]	3 y	Nanchang City, China	239	16–21	65
	Ma et al.[69]	1 y	Xiangshui County, Jiangsu Province, China	3000	1.5–16	98
	Luo et al.[70]	3 y	Jiangsu Province, China	3000	1.5–16	98.08
Indian scenario	Faridi et al.[62]	1 y	Delhi, Mumbai, Kolkata and Chennai (India)	505	1.5–5	97.9
	Mitra et al.[63]	5 y	Kolkata, Delhi, Mumbai and Chennai (India)	343	1.5–5	96
Cohort studies						
Global scenario	Wang et al.[71]	24 months	Fudan, China	42	1–15	100
	Liu et al.[72]	7 y	Jingyuan County, Gansu Province	211	3–13	100
	Zheng et al.[73]	1 y	Chinese mainland	211	3–13	100
	Mao et al.[51]	4 y	Shaoxing County, China	228	1–15	100
	Zhuang et al.[74]	10 y	Shengsi county and Jiaojiang city in Zhejiang province, China	161,618	1–15	80.2
	Zhuang et al.[75]	10 y	Shengsi county and Jiaojiang city, Zhejiang Province, eastern coast of China	220	1–3	80.2
	Wang et al.[76]	1 y	Chinese mainland	42	1–15	100
	Chen et al.[58]	17 y	24 villages in China	3515	1–12	62%
Indian scenario	Bhave et al.[59]	2 months	Pune, India	143	1–12	95.8
	Bhave et al.[60]	30 months	Pune, India	143	1–12	87.8
	Bhave et al.[77]	8 weeks	Pune, India	140	1–12	99
	Bhave et al.[61]	10 y	Pune, India	143	1–12	98.15
	Bhave et al.[78]	15 y	Pune, India	143	1–12	94 (96%)

Concluding remarks

Across the presentations made in the sessions, close-out discussion points brainstorming, and recommendations continuously emphasized on the strong need for vaccination against hepatitis A in all children and continuously highlighted the strong track-record of single live attenuated vaccine for its proven strong efficacy, safety, and long-term immunogenicity mediated through strong anamnestic response. The benefits of live vaccine have been well established both in China and in India through robust scientific data and real-world experience. Considering the epidemiological shift in India and fear of multiple outbreaks across the country with morbidity and mortality, a strategy should be designed to include the vaccine in the national immunization schedule.

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Notes on contributors

Dr. Nitin Shah is a distinguished consultant paediatrician and paediatric haematologist oncologist at P D Hinduja Hospital and Medical Research Centre. With an impressive 34 years of experience, Dr. Shah is a renowned paediatric haematologist in Mumbai, Maharashtra, known for his dedication to the care of children with blood disorders. Prior to PD Hinduja National Hospital, he was associated with BJ Wadia Hospital for Children, Mumbai as a professor in the department of Pediatric Hematology Oncology. Dr. Shah holds esteemed positions, including President of the Indian Academy of Pediatrics (IAP) and Member (India) of the Asian Strategic Alliance for Pneumococcal Disease Prevention (ASAP). Apart from his clinical practice, Dr. Shah has served as the Editor-in-chief of the IAP Specialty Series Books and has been an Editor for publications like Pediatric Today, Pediatric Clinics of India, and the IAP Specialty Series Book on Hematology, Infectious diseases, Pediatric HIV, Rational anti-microbial. He has authored numerous publications for national and international journals.

Dr M.M.A. Faridi has advanced training in Neonatology. He has been decorated with State Award by Government of NCT Delhi. Dr Faridi has worked as Director Professor and Head of the Department of Pediatrics, and I/C Division of Neonatology, University College of Medical Sciences Delhi and has more than 44 years of teaching/training and clinical experience in reputed medical institutions of India and Nepal. Prof Faridi has been a National Resource Person to Government of India, Ministry of Health and Family Welfare, Medical Council of India, Periodic Safety Update Record (PSUR) Committee, Food & Drug Administration and many international organizations such as WHO, UNICEF, IBFAN, USAID and Norway

India Partnership (NIPI) etc. He has been invited as Infant & Young Child Feeding Counselling (IYCF) Consultant/Course Director by the UNICEF and WHO to several Asian and Arab countries. Prof Faridi has published two textbooks and contributed 25 chapters in the books. He has been nominated as Convener by the Indian Academy of Pediatrics IYCF Chapter to write National Guidelines on Complementary Feeding in 2023. He has participated in many vaccines and drugs trials. Prof Faridi is a Visiting Professor to multiple international institutes. He has delivered several prestigious orations, received many awards, published >200 scientific research papers, guided >100 postgraduate students for theses research work and is a reviewer to 20 journals. He has 3984 citations and an h-index of 36 and i-10 index of 88 to his credit on date. His Research Interest Score is 1724. With membership of many Institution Ethics Committees, Dr Faridi is an Associate Editor of Human Vaccines & Immunotherapeutics. He is a Fellow of Indian Academy of Pediatrics (FIAP), National Neonatology Forum of India (FNNF) and Fellow of International College of Nutrition (FICN) and WHO Course Director of Infant & Young Child Feeding Counselling Course.

Dr. Sheila Bhave is a renowned name in paediatrics in India. She holds a vast 42 years of experience in paediatric consulting, new born care, vaccination, immunization and neonatal nursing and treatments. Dr. Bhave is currently associated with KEM Hospital, Pune as a consultant paediatrician. Before that, she held the Honorary Professor position at B J Medical College, Pune. She is also a member of Medical Council of India (MCI). Aside the clinical practice, Dr. Bhave is a pioneer in paediatric research. Her research works have been published across various peer-reviewed journals. She has participated in numerous clinical trials as principal investigator. Her expertise in vaccination/ immunization and new paediatric treatments and therapies has brought an innovative approach to treat different paediatric populations with comprised immunity.

Dr. Apurba Ghosh is the Executive Director and Professor at Institute of Child Health, a leading children hospital in eastern region of India. Since 1979, Dr. Ghosh has been a leading name in Indian paediatrics practice. With a special interest in dysmorphology and growth-related disorders in children, endocrinological disorders, genetic conditions and rare diseases, Dr. Ghosh has successfully treated numerous rare cases. He has been a fellow member of Royal College of Paediatrics and Child Health and Indian Academy of Paediatrics. He is also a member of Royal College of Physicians (Edinburgh). Beside his clinical practice, Dr. Ghosh has devoted a significant time in clinical research. He has participated in numerous global as well as Indian clinical trials of Phase II to IV as a principal investigator. His research works have been published in many renowned international, national and state medical journals such as The Journal of Paediatrics, Rheumatology International, Infectious Disease Journal and many more.

Dr. S. Balasubramanian is a Visiting Consultant in Pediatrics & Former Medical Director at the Kanchi Kamakoti CHILDS Trust Hospital, Chennai, and a Trustee of the CHILDS Trust Medical Research Foundation. He is a former Professor of Pediatrics – SRMC & RI, Chennai, and an Honorary Pediatrician, Southern Railway Headquarters Hospital, Chennai. He has also been the Chairperson of IAP Infectious Diseases Chapter 2022, the Convenor of IAP ACVIP 2018-19, and Advisor of IAP ACVIP 2020-21. He is a distinguished DNB Teacher Awardee – NBE 2014, and a Lifetime Achievement Awardee of Dr MGR Medical University, Tamil Nadu. He is also an FIAP & MNAMS Awardee. Dr. Balasubramanian has 150 indexed publications and has delivered 40 orations and over 500 sessions in IAP Forums & over 500 PG Sessions. He is the IAP IDC Fellowship Coordinator at KKCTH, Chennai. His areas of interest include pediatric infectious diseases, PG teaching, vaccine research, and COVID-19.

Dr. Vidya Arankalle is a Senior Scientist and Head of Translational Virology at IRSHA, an Ex-Agharkar Chair of the Agharkar Research Institute, Pune, an Ex-ICMR Consultant, and Ex-Director-Grade-Scientist and Group Leader of Hepatitis at the National Institute of Virology, Pune. She is a Fellow of the Indian National Science Academy, Indian Academy of Sciences, National Academy of Sciences of India. She is rated as one of the top 2% of global scientists by four consecutive surveys conducted by the Stanford University. She is an expert in the field of virology and vaccinology with over 200 publications to her credit.

Dr. Raju Shah is one of the most reputed pediatricians of Ahmedabad, India. He has over four decades of experience in neonatology and paediatrics and is an expert in treating infectious diseases, medical education, general paediatrics, vaccinations, and neonatology. He is the first to establish a private sector NICU and PICU with ventilators in North and central Gujarat. He is a pioneer in the field of Neonatology, Pediatric Intensive Care and Infectious diseases in Gujarat. He has an experience of more than 40 years in the field of Paediatrics and Neonatology. He is the Medical Director at Ankur Institute of Child Health. He was the Former Professor and Head of Department at GCS Medical College, Ahmedabad. He was the National president of IAP during 2005 and President of Pediatric Association of SAARC from 2005 to 2008.

Dr. Amar Jeet Chitkara is a Senior Director of Pediatrics with over 46 years of experience. He is the Chairperson of IAP, Infectious Diseases Chapter (2014). His interests include pediatric infectious diseases and vaccinology. He hold the following memberships: Asian Society for Pediatric Infectious Diseases (ASPID) (1999), Indian Academy of Pediatrics Committee on Immunization (IAPCOI) (2000 - 2002) (2010 - 2012), Founding Member- Influenza Foundation of India (IFI), and Editorial Board Member of Indian Pediatrics, Journal of Pediatrics Infectious Diseases (Turkey), and Pediatrics Today.

Dr. Arun Wadhwa is a Consultant Paediatrician, in practice for 32 years. He is a Visiting consultant at the Rainbow Children's Hospital. He is a National Trainer for IAP Vaccinology Course, Strides and fever module, a National trainer for CASPER Asthma training module, and a Chief Patron of NGO iCare. Dr. Wadhwa is the Clinical Director of Special Olympics Bharat. He was the President 2023 and Founder Secretary of IAP SDB Study Group and NZ EB of CMIC chapter 2021-22, Delhi IAP EB twice. He has authored numerous publications in National and international Journals and book chapters in IAP textbooks. He is also an Editor of several books.

Dr. Jaydeep Chaudhry is a Professor at the Department of Pediatrics, Institute of Child Health, Kolkata. He has also been the Vice President (EZ) Central IAP 2019, Chairperson of IAP Infectious Diseases Chapter 2020, and Convener of IAP ACVIP 2015-16. He is the editor and author of several textbooks.

Dr. Ramesh Srinivasan is a distinguished Paediatric Gastroenterology with 23 years of experience in the medical field. He is proficient in multiple languages, ensuring effective communication with a diverse range of patients. He is known for his patient-centric approach, emphasizing the importance of understanding each patient's unique needs and medical history. Dedicated to staying updated with advancements in his field, Dr Srinivasan actively collaborates with other healthcare professionals to provide comprehensive care. His commitment to improving health outcomes continues to leave a lasting impact on the lives of his patients. His special interests include diagnostic and interventional endoscopy, gastroenterology , inflammatory bowel disease, enteral feeding support and nutrition, food allergy, liver diseases including transplant Hepatology, and evidence based gastroenterology.

Dr. M. Surendranath is the HOD of Pediatrics at the Vijay Marie Hospital , Hyderabad,Vice President of CIAP 2019, FIAP 2022, and President PATS 202. He is EB member CIAP 2014,2016, a Life member of IAP since 1988, a Life member NNF and IMA, and a Life member of The Indian College of Allergy, Asthma and Applied Immunology. He has been the vice President of Twin Cities Branch IAP 2009, Secretary NNF AP & Telangana State chapter 2016- 2017, Joint Secretary &Treasurer Family Benefit Society IAP 2011-2017, Secretary FBS 2017-2020, Treasurer Pediatric Academy of Telangana, Trainer for NRP Advanced and Basic, Mini Respire , HOPE, RAP, ATM, COPP, EPID, All about the fever, Vaccinology for Practicing Pediatrician. Dr. Surendranath is the Coordinator for Rational Antibiotic Practice and Faculty for more than 100 NRP courses conducted in AP and Telangana in India. He has conducted many school heath camp as IAP member. He has acted as

the co-chairperson of scientific committee APCP Pedicon 2016. He has been a member of ACVIP IAP 2017, contributed many chapters in vaccinology books, acted as the Organizing secretary of NCPID 2019, and Organizing Secretary of Vaccicon 2016 & Vaccindicon 2021, and TCB PATSCON 2021.

Dr. Amita Sapru is a pediatrician and an ardent researcher. She has worked in the field of clinical research since past twenty years, being involved in the conduct of studies about safety and immunogenicity of many new vaccines. She is involved in the conduct of a study on the long term immunogenicity of a live attenuated hepatitis A vaccine.

Dr. Monjori Mitra is an academician, researcher, author, editor, and a coveted office-bearer of the Indian Academy of Paediatrics (IAP) since 10 y; she has functioned as a member in the Committee of Immunization and as the Vice Chairperson of National Infectious Disease Chapter. She is a Professor at the Institute of Child Health, a leading hospital in the east zone of India. She has participated as a principal investigator in numerous global and domestic clinical trials, including regulatory studies in India. She is a pioneer researcher in the field of vaccines and is a member of numerous national and international advisory boards and working group committees on immunization guidelines. She is also a member of the Asia Pacific Pediatric Association Technical Advisory Group for Immunization. Dr. Mitra has authored several publications in peer-reviewed journals and text books on pediatric indications.

ORCID

M.M.A. Faridi http://orcid.org/0000-0002-9109-8677

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Ethics statement

All experts who participated in the Hepatitis A expert opinion board meet 2024 were the investigators of clinical trials as well as authors of articles in peer-reviewed journals; these trials were all conducted after obtaining approval from ethics committees at individual institutes. This article contains discussion of those studies only; no unpublished data was discussed. This article does not report any study involving human participants or animals. Therefore, ethical approval was not required.

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