

Review Article

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Sustainable Clinical Management of Dental Caries: A Global Snapshot of Prevalence, Prognosis and Management

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Abstract

Dental caries is a prevalent global health issue, affecting approximately 2.5 billion individuals worldwide. It is the most common biofilm-dependent disease, with a significant increase in cases over the past decade. This review explores dental caries' aetiology, prevention, and management, focusing on both fluoride and non-fluoride preventive measures. Caries development involves a dynamic process of demineralization and remineralization, influenced by various factors including diet, oral hygiene, and socio-economic conditions. Early childhood caries, often resulting from improper feeding practices and high sugar intake, remains a major concern. This manuscript also examines advanced diagnostic methods and the role of artificial intelligence in detecting and managing caries. AIdriven tools show promise in improving accuracy and efficiency in caries detection and treatment planning. Non-fluoridated formulations such as nanohydroxyapatite and casein phosphopeptide-amorphous calcium phosphate are highlighted for their remineralization potential, providing alternatives to traditional fluoride-based treatments. Emphasizing the role of pediatricians in early intervention and education, this review underscores the importance of a collaborative approach in promoting oral health and preventing dental caries from early childhood through adulthood.

Keywords: Dental caries; Childhood; Adulthood; Clinical management; Global health issue; Human health; Society

Introduction

Dental caries pose significant challenges to both human health and society at large. As the most prevalent biofilm-dependent disease globally, its impact is profound. The development of dental caries stems from the cyclical processes of acid demineralization and remineralisation occurring at the interface between the biofilm and tooth surfaces [1]. According to the findings of the Global Burden of Disease Study, dental caries ranks among the most prevalent preventable non-communicable diseases worldwide. Shockingly, an estimated 2.5 billion individuals are affected, with a staggering 14.6% increase in cases over a decade [2]. Recent data from 2023 reveal a striking global prevalence of 46.2% in primary teeth and 53.8% in permanent teeth, with variances across regions, notably lower rates in Europe and higher rates in Africa [3]. In India, for instance, prevalence rates among 13 to 19-yearolds stand at 36.7%, while in countries like Saudi Arabia, rates soar to an alarming 83% among 6-8-year-olds.3 Of the dental caries within the Indian population (affecting about 65%), periodontal diseases occupies a primordial space (approximately 85%) and India is considered to be capital of the oral cancer according to the recent estimates of the Ministry of Health and family

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welfare. With a state-wise dentists population ratio ranging from 1:1000 to 1:20,000, just 10% of dentists serve the rural Indian people and hence a true pooled prevalence remains a far-fetched pressing concern.

While advancements in diagnostic methods, preventive measures, and caries treatment have contributed to a gradual decline in the prevalence of dental caries, the situation remains diverse and concerning, particularly in primary teeth. Children may experience dental caries as early as 6 months of age with eruption of their first teeth [4]. Primary dentition, constituting 30% of the total caries experience, remains vulnerable due to its structural characteristics. Although a first dental visit is advisable at 1 year of age, in actual it is executed at not before 3 years [4]. As a consequence, paediatrician play a vital role in preventive oral health care in early childhood as they are the first point of contact for new parents. Although the National Oral Health Survey of India recommends 'Age One' policy, effective and optimal realization of such programme through paediatric dentists assumes utmost importance. Therefore, a thorough understanding of the key drivers/determinants underpinning the inequalities is a strategic goal of the WHO.

The process of caries development is understood as a dynamic interplay that can be halted or even reversed by environmental preventive measures, oral hygiene practices, and the use of anti-caries chemical agents, especially in primary and mixed dentition. For decades, fluoride has been recognized for its cariostatic potential, delivered through various vehicles. Through this review we aim to delve into both fluoride and non-fluoride agents as preventive and anticaries measures to combat childhood caries, shedding light on their potential impact in primary and mixed dentition [5].

Aetiology of Cariology

The oral cavity presents a hospitable and nutrient- rich habitat for the oral microbiota and, at the same time, regulates the bacterial colonization to deter harmful invaders. Yet, in certain circumstances, the intrusion of microorganisms disrupts the delicate balance of the host's commensal microbial population, leading to dental conditions which have a multifaceted origin. Tooth demineralization is caused by acidogenic and aciduric bacteria as the intake of sucrose cause a rapid fall of pH in tooth adherent biofilms to 5.0 or below, leading to a so-called dysbiotic microbiome. Table 1 enlists the microorganism and their activities and role in cavitation. Cariogenic bacteria are transmitted to the child vertically and horizontally. The vertical transmission takes place through saliva from the mother to the child especially during the first 19-31 months (Window of infectivity). Horizontal transmission usually occurs between siblings and care givers [6]. These microorganisms constitute the biofilm that adheres to the tooth surface, metabolize sugars and starches to produce acids, which lowers the pH of the saliva and causes loss of minerals from the surface of the teeth. Neutral saliva redeposits the lost minerals, however a prolonged drop in the pH and frequent net loss of minerals lead to weakening and eventual cavitation of the tooth surface.

Table 1: Cariogenic microorganisms and their causal activities.

Microorganism	Activity
Streptococcus mutans	Initiation of dental caries
S. salivarius	Abundant in oral cavity
Lactobacilli fermentum	Progression of dental caries
Streptococcus sobrinus	Strongly associated with deep carious lesions
Streptococcus sanguinis	Causal agent for dentition connective tissue dysplasia
Actinomyces israelli	Most predominant species in plaque of ECC
Bifidobacterium spp.	Associated with deep carious lesions
Veilonella	Observed in lactate users; abundant in carious dentine
Enterococci	Found in oral cavity of medically and immunologically compromised patients
Candida albicans	Form a symbiosis with cariogenic bacteria and changes the sensitivity of teeth to caries formation

There are certain factors that influence the demineralization process namely; type of sugar, frequency of intake, size of the fermentable sugar particle, duration of retention of the sugar in the oral cavity, breast feeding habits, feeding patterns etc. Sucrose, fructose and glucose along with other fermentable carbohydrates play a role in the initiation and development of dental caries. They metabolize to produce dextrans which promote bacterial adhesion to tooth. A higher frequency of intake than the quantity alone and a prolonged period of retention (20-40 mins) in the oral cavity plays a vital role in the demineralization process. Also a smaller size of the fermentable sugar easily splits by the salivary amylase to a form that is easily metabolized by the plaque bacteria into acidic products resulting in demineralization.

Inappropriate frequency of use of the baby bottle plays a critical role in the incidence and severity of early childhood caries (ECC). The frequency and duration of contact of human milk with the enamel of teeth has been shown to result in acidogenic oral environment and shifting the demineralization-remineralization equilibrium towards demineralization especially after the age of 12 months. Prolonged night time use of baby bottle along with less saliva production at night results in higher levels of lactose in the resting saliva [7]. The potential inverse correlation between breast-feeding and ECC largely results in to the broader health benefits of breastfeeding, thereby encouraging increased



breastfeeding rates, particularly in low- to middle-income countries where rates are gradually declining. The increased age-dependent prevalence of ECC may be attributed to an increase in the number of teeth in the oral cavity and the progressive transition from an exclusive milk diet to a mixed diet with solid foods.

Children who live in impoverished state belonging to low ethnic or racial minorities, born to single mothers or parents with low educational level are more commonly found with higher incidence and prevalence of ECC. On mapping the current literature, it has become evident that preventing the development of dental and oral diseases in children is majorly contingent upon the following factors: family socioeconomic demography dynamics, development of dental fear and anxiety, knowledge and/or practices of oral health and hygiene, and timely utilization of dental facilities.

Categorization of Dental Caries

Carious lesion in the enamel: White spot lesions

White spot lesions, the earliest signs of demineralization in the enamel due to plaque accumulation have become more prevalent, ranging from 10% to 49% [8]. They appear as opaque white areas (optical phenomenon) due to high porosity in the subsurface caused by demineralization [9]. Although initially invisible, these lesions can be detected after the tooth surface dries. With prompt diagnosis, partial demineralization allows for potential remineralization, but inadequate oral hygiene and reduced saliva flow hinder this process, promoting caries development. Diagnostic methods include visual examination and emerging techniques like fluorescence and microcomputed tomography. Conservative treatments such as oral hygiene guidance, fluoride application, use of casein phosphopeptide-amorphous calcium phosphate (CPP ACP) and resin infiltration are effective management options available.

Carious lesion in the dentin

exhibit distinct Dentin and enamel structural characteristics: dentin possesses lower mineral content and contains microscopic tubules, facilitating bacterial ingress and mineral loss. Histologically, dentinal caries is classified into four zones: soft (infected), firm (affected dentin), dark, and transparent zones. The soft or infected dentin is the superficial, necrotic and irreparable form of dentin. Its minerals are dissolved by the acid and collagen matrix is denatured by proteolytic enzymes along with the dentinal tubules which are enlarged ad deformed and filled with bacteria not allowing it to be repaired. The affected dentin, a potentially remineralizable form, appears clinically pale brown and firm compared to infected dentin, owing to its higher mineral and collagen concentrations. Preservation of pulp and collagen cross-linking in affected dentin provides a scaffold for remineralization within the dentinal tubules.

Rampant caries

The most accepted definition of Rampant cariest was given by Massler (1945) as "a suddenly appearing, widespread, rapidly borrowing type of caries, resulting in early involvement of the pulp and affecting those teeth usually regarded as immune to ordinary decay [10]. There are 3 forms of Rampant caries:

- · Nursing bottle rampant caries
- Adolescent rampant caries
- · Xerostomia-induced rampant caries

Early childhood caries/ nursing bottle caries/ baby bottle caries:

It is a very common form of dental decay mostly occurring in children 6 years and younger. The enamel of deciduous teeth is built within a significantly shorter period (24 months) than the permanent teeth (up to 16 years); hence, it is thinner and has a less organized microstructure leading to faster demineralization. The sugary food consumption and improper feeding practices where the child sleeps with a bottle filled with sweetened milk are the causative factors. The lactic acid, low salivary stimulation and hence less cleansing action leads to an environment conducive to develop caries. Here, the upper incisors and molars are affected first, followed by lower molars and then finally lower incisors. To prevent this soft touches on the oral mucosa and gingiva during early infancy should be promoted to get the infant used to the brushing feel. For children brushing twice daily using a fluoridated tooth paste (500/1000 ppm fluoride) in the supervision of the caregiver is mandatory [11,12].

Adolescent rampant caries:

It commonly manifests during adolescence and childhood, particularly in individuals who habitually consume chocolates, toffees, and biscuits before sleeping, exacerbated by reduced salivary flow. Carious lesions typically emerge on the buccal and lingual surfaces of premolars and molars, as well as the proximal and labial surfaces of mandibular incisors. Multiple cervical carious lesions are common in rampant dental caries among adults, resembling nursing caries but involving the proximal surface of mandibular anterior teeth which is the distinguishing feature [13]. There's a high likelihood of permanent teeth being affected if rampant caries occurs in primary dentition, unless effective preventive measures are taken [14]. Premature tooth loss due to this condition can lead to decreased masticatory efficiency, loss of vertical dimension, and aesthetic-functional issues like malocclusion and space loss. The un-aesthetic appearance of teeth may also trigger psychological distress, potentially impacting the patient's personality and behavior [15].



Artificial Intelligence (AI)-Driven Detection and Classification of Dental Caries

With its capacity of comprehensive variety of machine learning algorithms and techniques, AI has substantially extended its application in dentistry for the assessment, localization, classification, diagnosis, and estimation of disease progression Most of the previous works regarding AI and the automated detection of dental caries were based off for presumptive qualitative identification of dental caries. Few studies also identified the extension of caries into enamel and dentin, DL-based dental caries detection or progression, deep convolutional neural network (CNN)-guided algorithms for the diagnosis of dental caries from periapical radiographs. AI-based visual inspections identify the degree of severity of caries in distinct ways. AI algorithms are trained on huge datasets and are capable of swiftly analysing vast amounts of data, which may allow them to detect caries with a high degree of accuracy. AI algorithms nevertheless rely on the integrity of the training data and the algorithms themselves. AI caries detection systems facilitate detecting dental caries at an earlier stage. Moreover, AI can quickly and objectively analyse images in difficult areas where the human observer may have difficulty detecting them. Visual examinations may accurately detect caries severity using visual inspection, an explorer, dental radiographs, patient history, and risk factors. However, visual examinations can be subjective and variable, as clinicians with varying levels of experience may interpret the presence and severity of dental caries differently. Overall, both AI caries detection and human visual examinations are suggested to be used in conjunction to improve the precision and efficacy of dental diagnosis and treatment planning.

Risk factor assessment and caries control by non-restorative approach:

The risk assessment methods commonly employed in medical practice typically possess the ability to precisely gauge an individual's susceptibility to disease and enable the implementation of preventive measures. It should be simple, practical, evidence based, inexpensive, and feasible to use on a child's first and follow up dental visit. There are questionnaire-based risk assessment tools (CRAFT Tool) in which parents are interviewed using a questionnaire which includes factors like diet, fluoride, decay and others. Based on the responses the child is categorized into very low/No risk, Low risk, Moderate risk and High risk. CRAFT also includes a comprehensive recommendations for the dentists helping them device a minimally invasive, restorative and surgical plan [16].

Also are available tools which can be used by practitioners that address social/medical/behavioural, clinical, protective and disease indicative parameters that enable them to assess the child's risk of developing caries and also plan the

management according to the level of risk. Table 2 (a) and (b) details the age-wise risk assessment of dental caries for practitioners [17-19].

Advantages of early detection of carious lesions:

- Enhanced opportunity for remineralisation of demineralized, non cavitated tooth surfaces
- Diminished risk of disease progression to the cavitated stage
- Retention of natural occlusion
- Maintenance of the natural aesthetic appearance of tooth enamel
- Decreased treatment expenses linked to false negative diagnoses

Management

Dental caries, a widespread infectious and multifactorial ailment, is usually prevented by the application of pit and fissure sealants, coupled with diligent oral hygiene and suitable dietary habits, although additionally, fluoride usage diminishes the occurrence of dental caries and can impede the advancement of existing lesions. Dietary fluoride is swiftly absorbed in the stomach and small intestine of which approx. one-quarter to one-third is incorporated into calcified tissues, while the remainder is excreted in urine. The recommended fluoride intake stands at 0.7 mg daily for toddlers, escalating to 3 mg daily for adult women and 4 mg daily for adult men [20].

With the pivotal moment of inception of 'artificial' water fluoridation for caries control in 1945 and 1946 in the United States (US) and Canada, respectively, the efficacy of water fluoridation in preventing and managing dental caries spurred the development of various fluoride-containing products, encompassing toothpaste, mouth rinse, dietary supplements, and professionally applied or prescribed gel, foam, or varnish [21]. Fluoride products aid in the incorporation of calcium and phosphate ions into crystalline structures, promoting the creation of fluoroapatite and enhancing tooth resilience against acidic attacks. Among fluoride compounds, sodium fluoride (NaF) is the most prevalent, closely followed by sodium monofluorophosphate (Na2PO3F). Nevertheless, stannous fluoride (SnF2) exhibits superior anti-biofilm characteristics in comparison to NaF. Additionally, Amine fluoride (AmF) has been shown to elevate enamel microhardness post-demineralization, outperforming NaF in this aspect [22].

Paediatric toothpastes often feature appealing flavours like strawberry or mint, potentially enhancing the swallowing tendency in toddlers and children. However, the inclusion of fluoride in these toothpastes raises safety concerns for children under 6, as it can lead to dental fluorosis. Recommendations



Table 2: Age-wise caries-risk assessment according to the current state-of-the-art.

(a) Caries-risk Assessment for 0-5 Years Old Factors			
Risk factors, social/beha	vioural/modical		
Nisk lactors, socialisent	HIGH RISK	MEDIUM RISK	LOW
Mother/primary caregiver has active dental caries	yes	WEDIOW RIOR	LOW
Parent/caregiver has life-time of poverty, low health literacy			
Child has frequent exposure (>3 times/day) between-meal sugar-containing	yes		
snacks or beverages per day	yes		
Child uses bottle or non-spill cup containing natural or added sugar frequently, between meals and/or at bedtime	yes		
Child is a recent immigrant		yes	
Child has special health care needs ^a		yes	
Risk factors, clinical			
Child has visible plaque on teeth	yes		
Child presents with dental enamel defects	yes		
Disease indicators ⁶			
Child has noncavitated (incipient/white spot) caries lesions	yes		
Child has visible caries lesions	yes		
Child has recent restorations or missing teeth due to caries	yes		
Protective factors			
Child receives optimally-fluoridated drinking water or fluoride supplements			yes
Child has teeth brushed daily with fluoridated toothpaste			yes
Child receives topical fluoride from health professional			yes
Child has dental home/regular dental care			yes
Management			
Fluoridated water and supplements	Drink optimally-fluoridated water (alternatively, take fluoride supplements with fluoride-deficient water supplies)		Drink optimally- fluoridated water.
Brushing habits with fluoridated tooth pastes	Twice daily brushing with fluoridated toothpaste		Twice daily brushing with fluoridated toothpaste
Recalls	Professional topical treatment every 6 months		Recall every 6 to 12 months
Diet	Dietary counselling and sealant application		
Other procedures required	Silver diamine fluoride on cavitated lesions		
(b) Caries-risk Assessment for ≥6 Years Old			
Risk factors, social/beha	vioural/medical		
	HIGH RISK	MEDIUM RISK	LOW
Patient has life-time of poverty, low health literacy	yes		
Patient has frequent exposure (>3 times/day) between-meal sugar- containing snacks or beverages per day	yes		
Child is a recent immigrant	yes		
Patient uses hyposalivatory medication(s)		yes	
Patient has special health care needs ^a		yes	
Risk factors, clinical			
Patient has low salivary flow	yes		



Patient has visible plaque on teeth	yes		
Patient presents with dental enamel defects	yes		
Patient wears an intraoral appliance		yes	
Patient has defective restorations		yes	
Disease indicators ⁸			
Patient has interproximal caries lesion(s)	yes		
Patient has new noncavitated (white spot) caries lesions	yes		
Patient has new cavitated caries lesions or lesions into dentin radiographically	yes		
Patient has restorations that were placed in the last 3 years (new patient) or in the last 12 months (patient of record)	yes		
Protective factors			
Child receives optimally-fluoridated drinking water or fluoride supplements			yes
Child has teeth brushed daily with fluoridated toothpaste			yes
Child receives topical fluoride from health professional			yes
Child has dental home/regular dental care			Yes
Management			
Fluoridated water and supplements	Drink optimally-fluoridated water (alternatively, take fluoride supplements with fluoride-deficient water supplies)		Drink optimally- fluoridated water
Brushing habits with fluoridated tooth pastes	Brushing with 0.5% fluoride gel/paste	Twice daily brushing with fluoridated toothpaste	
Recalls	Every 3 months	Every 6 months	Every 6 to 12 months
Diet	Dietary counselling and sealant application		
Other procedures required	Professional topical treatment every three months silver diamine fluoride on cavitated lesions	Professional topical treatment every six months	

^aPractitioners may choose a different risk level based on specific medical diagnosis and unique circumstances, especially conditions that affect motor coordination or cooperation. ^b While these do not cause caries directly or indirectly, they indicate presence of factors that do. Some of the risk factors and recommendations listed are specific to a North American/Western context. In countries like India, other relevant risk factors and recommendations, such as those highlighted in the CRAFT approach, should be considered [16-18].

vary between regions, with dentists advising a pea-sized amount for children under 3 in the US and Canada, while in Europe, a rice-sized smear is suggested for those under 2, and a pea-sized amount for ages 2 to 6 [23]. Despite efforts to limit ingestion by recommending small amounts for younger children, studies suggest that even toddlers inadvertently consume significant quantities. That's where toddler toothpastes are beneficial where they are fluoride, flavour, colour and odour free having no restrictions on swallowing.

Concerns over fluorosis and potential neurotoxicity on developing brains have spurred research into alternative active ingredients for toothpaste formulations. A variety of compounds within this category have been extensively studied, including hydroxyapatite (HAP), amorphous calcium derivatives like casein phosphoprotein amorphous calcium phosphate (CPP-ACP), calcium sodium phosphosilicate

(CSPS or Novamin, Bioglass), and beta-tricalcium phosphate (-TCP). These ingredients release calcium and phosphate ions under low pH conditions, inhibiting demineralization and promoting remineralisation by precipitating the released ions [24]. Nanohydroxyapatite (NHA) has emerged as a promising agent due to its resemblance to human enamel apatite crystals, with nanoscale particles exhibiting enhanced efficacy compared to traditional hydroxyapatite.

Numerous studies have meticulously compared a myriad of non-fluoridated formulations across varying fluoride concentrations (some representative examples are mentioned in Table 3), consistently revealing their parallel efficacy in preventing caries development and progression. These investigations underscore the remarkable potential for remineralization, showcasing the formidable control these formulations exert over caries in both adolescents



and children, regardless of dentition stage, be it primary or permanent. The resounding consensus across these studies not only bolsters confidence in the effectiveness of nonfluoridated alternatives but also illuminates the profound impact they wield in oral health preservation across diverse demographics.

Table 3: Recent progress in non-fluoridated formulations: some representative examples.

Author	Comparator groups	Results		
Manchery N et al. [25]	Group A (nanohydroxyapatite), Group B (NovaMin), Group C (fluoride)	-All three dentrifice were effective in remineralizing artificial carious lesionsNano hydroxyapatite dentifrice produced significantly better results compared to fluoride- and Nova Mincontaining dentifrices		
Amaechi B et al. [26]	10% hydroxyapatite and 500 ppm fluoride	Significant remineralization and resuction in lesion depth was noted with both pastes		
Schlagenhauf U et al. [27]	Fluoride-free microcrystalline hydroxyapatite (HAP) dentifrice and a 1400 ppm fluoride in caries active orthodontic patients	The impact on caries active patients is not significantly different in both the groups.		
Amaechi B et al.[28]	Hydroxyapatite-based gel (15% HAP) and Fluoride-based gel,12,500 ppm F ⁻ and Artificial saliva (AS)	15% hydroxyapatite is as effective in remineralizing initial caries lesions as highly concentrated 12,500 ppm fluoride gel.		
Kasemkhun P and Rirattanapong P [29]	Group I deionized water (control); Group II 1000 ppm F Group III Calcium glycerophosphate and calcium lactate Group IV casein phosphopeptides-amorphous calcium phosphate (CPP-ACP) paste Group V nano hydroxyapatite (NHA)	Non-fluoridated toothpastes containing CPP-ACP or NHA for young children had efficacy in remineralizing effect on primary teeth comparable with 1000 ppm fluoridated toothpaste.		
Samaha A H et al. [30]	Group 1 received laboratory made Gum Arabic varnish Group 2 received casein phosphopeptide amorphous calcium phosphate fluoride (CPP-ACPF) varnish Group 3 received 5% sodium fluoride (NaF) varnish	CPP-ACPF showed similar remineralization potential as 5% sodium fluoride and were able to arrest all active carious lesions.		
Yarbrough et al. [31]; Yang et al. [32]	Eight-fold repeats of aspartate-serine-serine (8DSS)	Block the demineralization process and the dissolution of $\mathrm{Ca^{2^+}}$ and $\mathrm{PO_4^{3^-}}$ ions in the surrounding medium (due to their adsorption to enamel crystals) and promote the capture of these ions from saliva so as to initiate and drive the mineralization process.		
Ruan and Moradian- Oldak [33]	Amelogenin-based polypeptides and derivates	In solution, amelogenin promoted the oriented bundle formation of rod-like FA in a dose dependent manner; in agar gel the amelogenin-supported enamel mineralization increased the surface micro-hardness significantly.		
Xu et al. [34]	Poly (Amido Amine) dendrimers (PAMAM)	Acts as "artificial proteins" and able to mimic the formation and function of organic matrices in modulating the mineralization processes of enamel.		
Shah [35]	Statherin peptides and composites	Prevents the excess of CaP precipitation on surfaces (enamel and dentin) and in the salivary fluids by inhibiting CaP crystallization and capturing Ca and P ions.		



Conclusion

In conclusion, this review article serves as an essential resource to create awareness amongst practicing paediatricians, emphasizing the critical role they play as the initial point of contact for parents concerning their child's oral health. Currently, the non-fluoride enamel remineralization systems are still under promising development as the available clinical evidence are either absent or poor and welldesigned randomised clinical trials are in demand. By raising awareness of childhood caries and elucidating the spectrum of non-invasive preventive measures, including fluoride and non-fluoride over-the-counter formulations, paediatricians are empowered to guide parents towards advocating early dental visits followed by preventive interventions as a part of proactive dental care strategy. By leveraging their influence, paediatricians can educate new parents about the detrimental impact of dental caries on physical, mental, and social well-being, ultimately fostering a community of informed guardians dedicated to safeguarding their children's oral health from the outset. This collaborative effort between paediatricians, dental specialists and parents stands as a cornerstone in the pursuit of preventive dental care and the promotion of lifelong oral health.

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Conflicts of Interest

The authors declare no conflict of interest. The sponsors had no role in the design, execution, interpretation, or writing of the study.

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