



**University of Dundee**

## **Systematic Review of Clinical Practice Guidelines for Oral Health in Children With Cleft Lip and Palate**

Saikia, Ankita; Muthu, M. S.; Orenuga, Omolola O.; Mossey, Peter; Ousehal, Lahcen; Yan, Si

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# **Systematic Review of Clinical Practice Guidelines for Oral Health in Children with Cleft Lip and/or Palate**

## **Abstract**

*Objective:* Clinical practice guidelines (CPGs) exist to present recommendations and policies aimed at optimizing the oral health of children and adolescents born with cleft lip and/or palate (CLP). The aim of this review is to identify and assess the scope, quality, adequacy, and consistency of CPGs related to oral health in children and adolescents with clefts, along with reporting any differences and shortcomings.

*Methods:* A systematic review of the literature of CPGs following PRISMA (Preferred Reporting Items for Systematic Reviews) guidelines was conducted. Assessment of selected CPGs was performed using the AGREE II (Appraisal of Guidelines for Research & Evaluation) methodological quality instrument.

*Results:* Only 7 CPGs fulfilled the criteria. Of these, 4 were from the American Cleft Palate-Craniofacial Association (ACPA), and one each from the American Academy of Pediatrics (AAP), the Academy of Breastfeeding Medicine (ABM), and the American Academy of Pediatric Dentistry (AAPD). The lowest overall mean scores were in the domain 'Rigor of Development' (mean 29.58%, SD 17.11), revealing lower quality in methodology of the guideline. The domain 'Clarity of Presentation' (mean 73.80%, SD 7.87) revealed the best score.

*Conclusions:* Our review results reveal a lack of integrated high-quality CPGs that can be used as universal guidelines by health workers in a range of disciplines for improving oral health in children and adolescents with cleft problems.

## **Keywords**

cleft, children, guideline, oral health, systematic review,

## Introduction

Congenital anomalies, defined as abnormalities of structure, function, or metabolism that are present at birth, are a major public health concern due to their life-threatening nature or potential to result in disability or death. Worldwide, it is estimated that 303,000 newborn infants die within four weeks of birth every year due to congenital anomalies (World Health Organization, 2015). Clefting of the lip with or without palate is the most common congenital craniofacial anomaly, with the global prevalence estimated at 1 in 700 live births (World Health Organization, 2006), and it is estimated that a child with a cleft is born somewhere in the world approximately every two minutes (Mossey and Little, 2002). The prevalence of CLP differs according to gender, ethnicity, and socio-economic status (Messer et al., 2010). Boys are more affected with cleft lip and/or palate than are girls, with a reported ratio of 2:1, while females have a slightly greater risk for cleft palate only (Conway et al., 2015). Literature reports the presence of three different types of cleft based on their location: cleft palate (CP), cleft lip with cleft palate (CLP), and cleft lip (CL). A cleft of the lip and/or palate has serious consequences, affecting feeding, speech, and hearing. As well as appearance, it negatively affects an individual's self-esteem, social skills, behavior, and quality of life (QoL) (Turner et al., 1998; Hunt et al., 2005; Adeyemo et al., 2016). Studies have reported that children with CLP often display fear of toothbrushing due to limited access of cleft areas, making oral hygiene difficult. The scarring of tissue in the cleft region after surgical repair, crowded dentition, and reduced oral clearance by saliva and tongue accelerate the incidence of Early Childhood Caries (ECC) in children with CLP. A meta-analysis by Worth and colleagues, published in 2017, found a higher prevalence rate of dental caries in children with clefts when compared with non-cleft children in both the primary and permanent dentition.

Clinical practice guidelines (CPGs) are developed systematically to assist clinicians and patients to make the correct decisions on health care for each clinical circumstance (Dahllöf et al., 1989). While they are not a substitute for advice from physicians or other health care professionals or providers, they do identify and provide general recommendations. If issued by an organization such as the National Health Service (United Kingdom), American Academy of Pediatric Dentistry (AAPD) etc., these guidelines help to define the role of specific diagnostic and treatment approaches to the management of a disease or problem. Such guidelines provide evidence-based recommendations from robust systematic reviews and vigilant detailed analysis of the published medical literature. However, these guidelines are not protocols that must be followed but rather are intended to assist health care professionals and providers in treatment modalities (Hasslöf and Twetman, 2007). Many countries produce national guidelines, updated at various intervals, and often the content tends to differ with context (e.g., country and guideline developer/sponsor). The level of evidence underpinning recommendation statements and details of the recommendations also differs across guidelines and organizations (Clinical practice guidelines we can trust, 2011; Worth et al., 2017). Finally, despite the fact that the rehabilitative approach is often consistent clinically, the preventive approaches which are most significant in terms of oral health care are less apparent. The concrete evidence of ECC being a preventable disease is highly critical for children with clefts. However,

there is a consistent failure of the dental profession to implement this preventive agenda effectively.

From the clinician's perspective, having multiple guidelines that are inconsistent due to differences in assessments of evidence or scope may be confusing. The oral care for children with CLP is critical to reducing the caries burden in those who are already undergoing various treatments for the correction of an orofacial cleft. Therefore, this review is essential to provide clarity and overall consistency of the oral health promotion and treatment approach for patients with CLP. Hence, the primary objective of this review is to identify and systematically assess the methodological quality, scope, and consistency of the existing CPGs on oral health in children with CLP. Secondary objectives of this review are to appraise the available guidelines and organize them according to various groups [guidelines for oral health professionals (OHPs), non-oral healthcare professionals (NOHPs), and parents and caregivers], and to report any differences and shortcomings.

## **Methods**

The protocol for this systematic review was registered in PROSPERO in March 2020 (Acknowledgment Ref No.: 172258). This systematic review follows the PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses, guidelines ([https://www.nccih.nih.gov/health/providers/clinical practice](https://www.nccih.nih.gov/health/providers/clinical%20practice)). The checklist is given as supplementary material in Appendix 1.

## **Search Strategy**

The authors searched PubMed, EMBASE, CINAHL, the Cochrane Library, and ProQuest. Guideline-focused databases/repositories and other sources searched were Web of Science, National Guidelines Clearinghouse, BMJ Best Practice, Trip Database, National Institute for Health and Care Excellence, Scottish Intercollegiate Guidelines Network, and World Health Organization, FDI, Smile Train, American Cleft Palate-Craniofacial Association, and American Orthodontic Society. Hand searching was conducted across *The Cleft Palate-Craniofacial Journal*, *Plastic and Reconstructive Surgery*, *Journal of Orthodontics*, *Journal of Oral and Maxillofacial Surgery*, *Indian Journal of Plastic Surgery*, *Clinical Genetics* and *Journal of Cranio-Maxillofacial Surgery*. This search was limited to the last 20 years. For the identification of studies included or considered for this review, no restrictions were placed on the language of publication when the electronic databases were searched. Searches were carried out independently by both reviewers until 28th February 2020. Eligible guidelines on oral health care in children with CLP were shortlisted. The search strategy was designed based on MeSH (medical subject headings), terms (policy, guidelines, recommendations, oral health, cleft lip, cleft palate), and Boolean operators in the above-mentioned databases. Search strategies used in PubMed are detailed in Appendix 2.

## ***Selection Criteria***

### **Criteria for considering studies for this review**

Guidelines, Policy, or Clinical Practice Guidance documents with recommendations for oral healthcare in children with CLP that were produced in any language by national or international organizations or registered professional bodies catering to cleft care were included.

### **Types of participants**

Any guidelines or documents produced globally with recommendations for oral health in children with CLP and younger than 18 years of age were considered for inclusion.

### **Types of outcome measures**

The primary outcome assessed was evaluation of the available guidelines/policies or recommendations on the oral health of children with CLP and the identification of methodological quality, scope, consistency, and lacunae between and among existing guidelines. Efforts were made to assess the quality of the existing guidelines on oral health for children with CLP. Secondary outcomes were to identify the general recommendations about oral health and categorize them across groups of dentistry. The goal was to thus categorize the identified guidelines into three groups, namely, OHPs, NOHPs, and parents and caregivers.

## ***Data Collection and Analysis***

### **Selection of studies**

Two review authors, Ankita Saikia (AS) and Muthu Murugan (MS), independently scanned the title and abstract of every record retrieved. All documents that appeared to meet the selection criteria, as well as those that could not be adequately assessed from the information given, were retrieved and investigated as full text. Any disagreements in inclusion and exclusion were resolved by discussion between the reviewers, and if required, arbitration with other experienced review authors was sought. Those studies that did not meet the inclusion criteria were recorded in the 'excluded studies' section of the review, and the reasons for exclusion are summarized in the PRISMA flowchart (Fig. 1).

### **Appraisal, scoring and data analysis of guidelines**

To assess the quality and reporting of practice guidelines, the reviewers used the AGREE II (Appraisal of Guidelines, Research, and Evaluation) instrument (Hurdwar et al., 2007). This tool was exclusively designed to assess the quality and reporting of practice guidelines. The AGREE II tool has 23 items under 6 domains: 'Scope and Purpose (items 1-3)', 'Stakeholder Involvement (items 4-6)', 'Rigor of Development

(items 7-14)', 'Clarity of Presentation (15-17)', 'Applicability (items 18-21)' and 'Editorial Independence (item 22-23)'. Each of the 23-item is scored on a 7-point agreement scale from 1 (strongly disagree) to 7 (strongly agree).

The maximum possible score obtained by each domain is calculated by using the following formula:

Maximum possible score = 7 (strongly agree) x Y (items within domain) x 4 (appraisers)

For example, the maximum possible score for the 'Scope and Purpose' domain, is, calculated as below

$$7 \times 3 \times 4 = 84.$$

The minimum possible score for each domain is obtained by the following formula:

Minimum possible score = 1 (strongly disagree) x Y (items within domain) x 4 (appraisers)

For example, the minimum possible score for the 'Scope and Purpose' domain, is, calculated as below

$$1 \times 3 \times 4 = 12.$$

Using the above mentioned method, the scores for each of the six AGREE II domains were calculated independently for the four assessors.

To calculate the 'obtained score' for each domain, all the four assessors's scores were added for that particular domain. For example, the scores for domain 'Scope and Purpose' given by 4 assessors are 20,33,43,50 respectively. The overall obtained score for the Scope and Purpose domain is  $20+33+43+50 = 146$ .

We obtained the overall domain score by using the following formula

$$\frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100$$

Maximum possible score - Minimum possible score

Each guideline was independently rated by four assessors (AS, MS, LR, PM). All four assessors had independently performed the AGREE II assessment for the included guidelines using the AGREE assessment tool after completion of the AGREE II online tutorials ([www.agreetrust.org](http://www.agreetrust.org)) and user's manual training (Hurdowar et al., 2007). The scoring was given independently and anonymously by all authors.

For measurement of the reliability among assessors, an intraclass correlation coefficient (ICC) was calculated. Tabulation and analyses were performed with Microsoft Excel, version 15, and SPSS Statistics, version 21 (Hurdowar et al., 2007).

### **Interpreting domain scores**

Domain scores identified the strengths and limitations of the guidelines. The AGREE tool from the AGREE Trust was adopted to compare methodological quality between

and among guidelines. The evaluators determined the quality thresholds for each domain as >70% for high-quality guidelines, from 40% >70% as moderate, and less than 40% as poor-quality guidelines, as described in the AGREE II user's manual (Hurdowar et al., 2007).

## **Synthesis of guideline recommendations**

Each guideline was evaluated for its methodological quality, scope, and consistency, and a textual descriptive synthesis was used. The guidelines were categorized into three categories and discussed as guidelines for OHPs, NOHPs, and parents and caregivers.

## **Results**

### ***Selection of the Guidelines***

In total, 732 citations were screened, after which 28 articles were reviewed. Seven unique CPGs that were published by various national and international organizations were included (American Cleft Palate-Craniofacial Association, 1993; Moher et al., 2009; Brouwers et al., 2010; Rohde et al., 2013; Lewis et al., 2017; AAPD, 2019; American Cleft Palate-Craniofacial Association, 2019). Twenty-one review articles were excluded, since they were non-CPGs and lacked information on oral health within the guidelines (Lambadusuriya et al., 1988; Mendoza, 2009; Crawley et al., 2010; Reilly et al., 2013; Shkoukani et al., 2013; Kumar et al., 2014; Ness et al., 2015; Sell et al., 2015; American Cleft Palate-Craniofacial Association Commission on Approval of Teams, 2016; Crerand et al., 2017; Al-Namankany and Alhubaishi, 2018; Hlongwa and Rispel, 2018; Chung et al., 2019; ). The PRISMA flowchart is shown in Fig.1. The 7 CPGs included were scored based on the AGREE II instrument.

### ***Characteristics of the Included Guidelines***

The general characteristics of the included guidelines — such as title, year of publication, name of the publishing organization, target users, guideline reviewers, search strategy adopted, and level of evidence — are provided in Table1. Of the 7 guidelines, 4 were from the ACPA (American Cleft Palate-Craniofacial Association) on 'Parameters for evaluation and treatment of patients with cleft lip/palate or other craniofacial differences', 'Standards for approval of cleft-palate and craniofacial teams', 'Replacing a missing tooth', and 'Neonatal Cleft Lip and Palate: Instructions for newborn nurseries'. These guidelines are intended for all three categories of providers, OHPs, NOHPs, and parents and caregivers. One guideline was from the American Academy of Pediatrics (AAP) on 'The primary care pediatrician and care of children with cleft lip and/or cleft palate'. One guideline was from the Academy of Breastfeeding Medicine (ABM) on 'Clinical protocol - Guidelines for breastfeeding infants with cleft lip, cleft palate, or cleft lip and cleft palate'. These two guidelines were intended for pediatricians (NOHPs). The last guideline was from the American Academy of Pediatric Dentistry (AAPD) on 'Policy on management of patients with cleft lip/palate and other craniofacial anomalies'. This is intended for pediatric dentists and general dentists ( American Cleft Palate-Craniofacial Association, 1993; Moher et al., 2009;

Brouwers et al., 2010; Rohde et al., 2013; Lewis et al., 2017; AAPD, 2019; American Cleft Palate-Craniofacial Association, 2019).

### ***Methodological Quality***

The AGREE II domain scores for each guideline (n = 7) are shown in Table 2. The calculated mean score for the domain 'Scope and Purpose' was 69.63%. A mean score of 46.81% was calculated for 'Stakeholder Involvement', while 'Rigor of Development' accounted for nearly 29.58%. 'Clarity of Presentation', 'Applicability', and 'Editorial Independence' were reported as 73.80%, 35.17%, and 32.14%, respectively.

The intraclass correlation coefficient (ICC) was used to assess the agreement among the four assessors. The ICC values showed a fair agreement for the ACPA (Parameters), ABM (Breastfeeding), and ACPA (Neonatal), with ICC values ranging between 0.62 and 0.7. ICC values for the remaining four CPGs [AAPD, AAP, ACPA (Missing Tooth), and ACPA (Standards)] ranged from 0.75 to 0.82, indicating good agreement (see Table 3). All seven guidelines were assessed independently by four reviewers (AS, MS, OO, PM), and their recommendations regarding guideline use were graded as "yes", "yes with modifications", and "no". In evaluations regarding whether the guideline would be recommended by the reviewers, two of the guidelines (Replacing a missing tooth and Neonatal CL/P: Instructions for newborn nurseries) were assessed to be "Not recommended by two of the examiners". All remaining guidelines were scored either "Yes" (would be recommended as is) or "Recommended with modifications" by all four reviewers. The results of these assessments are given in Table 4.

### ***Guideline Quality Scores***

Overall, we found that the guideline with the highest AGREE II ratings of mean domain score percentage was the AAP guideline on 'The primary care pediatrician and care of children with cleft lip and/or cleft palate' and thus recommended by assessors with modifications. The mean scores for each of the domains are given in Table 2. The domain 'Rigor of Development' demonstrated the lowest overall score indicating a low quality in guideline methodology reporting. The domain that was most acceptable for distinctly highlighting the recommendations for treatment was 'Clarity of Presentation'. Based on the 70% quality threshold for each domain as per the AGREE II assessment manual, five guidelines had one or more domains with more than 70% scores. Two guidelines [AAPD, ACPA (neonatal)] did not score 70% in any of the six domains.

### ***Discussion***

CPGs have a potential role to play in the making of health policy (Crawley et al., 2010; ). The evolution of CPGs has been significant in addressing topics of healthcare (e.g., screening, diagnosis, and health promotion). It is crucial that methodologies and strategies used in the guideline development process be accurate and validated for successful implementation (Committee to Advise the Public Health Service on Clinical Practice Guidelines, 1990; Grol, 2001; Browman et al., 2003). Thus, the quality assessment of CPGs represents one of the most vital components of



healthcare quality improvement processes. It highlights the vital role of specific tools used to arrive at a meaningful appraisal and conclusion.

Children born with CLP or any other craniofacial anomalies may encounter numerous complex problems of feeding and nutrition. They are susceptible to middle ear infections, which may cause potential hearing deficiencies and difficulty in speaking. Other problems include dentofacial and orthodontic abnormalities and challenges in social adjustment. From birth to maturity, children with CLP undergo multidisciplinary surgical and non-surgical treatment, with considerable disruption to their lives, and often with adverse psychological consequences to themselves and their families (American Cleft Palate-Craniofacial Association, 1993). Therefore, evidence-based guidance is crucial for the accurate management of children and youth with CLP, reducing its long-term effects. The goal of this review was to examine the quality of existing guidelines on oral health concerning children and adolescents with CLP.

The authors used the AGREE II tool for assessment of all included guidelines. The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument (Hurdowar et al., 2007) was developed as a tool to assess the variability of guideline quality. This tool evaluates the rigor and transparency in the methods used for the development of guidelines and includes a framework to:

1. address guideline quality,
2. provide strategy for guideline development, and
3. assist in the assessment of information reported in guidelines.

The findings from this review indicate a moderate to low quality of the included CPGs on the oral health of children with clefts, since the overall mean scores were under 50% for five of the six domains when assessed with the AGREE II tool. Moreover, the scope and breadth of these guidelines varied greatly, which has implications for the clinical use of each CPG.

The majority of the guidelines were developed by organizations in two countries with potentially more resources and funding for research: the USA and Australia. Additionally, we could not identify any distinctive guidelines dealing with caries prevention in countries such as Japan, France, China, India, New Zealand, or Russia.

The AAPD's policy on the Management of Patients with CLP and other Craniofacial Anomalies endorses the statements of the American Cleft Palate-Craniofacial Association and enumerates a list of recommendations to be followed by all oral health specialists. This guideline scored the lowest in the 'Stakeholder Involvement' and 'Applicability' domains, and also lacked 'Rigor of Development' and 'Editorial Independence'.

The guideline by the AAP provides a brief background on children with CLP. The AAP also emphasizes multidisciplinary team care, the order of intervention for cleft care, recommendations for the cleft/craniofacial teams, and the importance of primary care by pediatricians. The scores for this CPG were less than optimum in three

categories, namely, 'Rigor of Development', 'Applicability', and 'Stakeholder Involvement'. It had the highest score among all the guidelines for 'Editorial Independence' and the second-highest score on 'Clarity of Presentation'.

The ACPA document on Parameters for Evaluation and Treatment of Patients with CL/P or Other Craniofacial Differences was developed through a project funded by The Maternal and Child Health Bureau. This document proposed specific recommendations in three major areas, namely, interdisciplinary teams, neonatal period and infancy, and longitudinal evaluation and treatment of individuals with CLP. This CPG scored the highest in the 'Stakeholder Involvement' domain among all the CPGs evaluated.

The ACPA's guideline on standards for approval of cleft palate and craniofacial teams emphasized the standards that identify essential characteristics of quality for team composition and functioning to facilitate the improvement of team care. It also emphasized the need to provide accurate information to patients and families/caregivers regarding services provided by those teams that meet specified standards. The recommendations also emphasized the following six components as essential to the quality of care provided by interdisciplinary teams, namely, team composition, team management and responsibilities, patient and family caregiver information, cultural competence, psychological and social services, and outcomes assessment. The domain scores of this guideline for 'Scope and Purpose' and 'Clarity of Presentation' were above 70%.

The ACPA's CPG on Replacing a Missing Tooth addressed the special planning needed to solve the functional and cosmetic problems related to the absence of a tooth in the cleft region. The domain on 'Clarity of Presentation' had the maximum score among the six domains within the guideline itself. 'Rigor of Development' and 'Editorial Independence' lacked significance.

The ACPA's guideline on Neonatal CLP - Instructions for Newborn Nurseries provides reassurance to parents that CLP is correctable and introduces the concept of a cleft palate craniofacial team. It also provides instructions for the successful feeding of CLP neonates and infants. It had the lowest AGREE II score on 'Rigor of Development' among the seven CPGs evaluated.

The ABM clinical protocol provides guidelines for Breastfeeding Infants with CLP. This guideline had the highest domain scores for 'Scope and Purpose' and 'Clarity of Presentation' among the seven guidelines evaluated.

Overall the guidelines on "ABM - Clinical Protocol #18 Guidelines for Breastfeeding infants with cleft lip, cleft palate or cleft lip and cleft palate" scored the highest in the following domains namely Scope and Purpose, Rigour of Development, Clarity of Presentation and Applicability. The objectives and scope were specifically described. This CPG declares that these recommendations were developed to guide breastfeeding mothers and infants. The quality of evidence used for each recommendation were based on the U.S. Preventive Services Task Force Ratings. The authors also recommended with an explicit link to quality evidence. The recommendations were specific, unambiguous and the key recommendations are easily identifiable. The guideline also provides advise and tools on how to instil the recommendations into

practice. In the editorial independence domain of the guideline by “AAP - The primary care paediatrician and care of children with cleft lip and/or cleft palate” had the best scores when compared to other guidelines. The authors of this CPG have indicated absence of external funding and no potential conflict of interest to disclose. “ACPA parameters for evaluation and treatment of patients with cleft lip/palate or other craniofacial anomalies” had the best scores on Stakeholder Involvement as the authors have described the target users of the guideline clearly, the view and preferences were sought from 71 experienced professionals in a consensus conference where attendees voted by ballot on resolution distilled by the grant committee from the written records of proceedings. The CPG was also subjected extensively to both wide-spread and selected peer review followed by subsequent revisions made by the committee in response to reviewer’s comments.

However, the AGREE II score alone should not determine the overall quality of the guideline. It is evident that future guidelines must be written/developed systematically, with considerable weight given to the AGREE II items or domains. It is therefore important for professional associations to adopt systematic procedures for guideline development according to known evidence and with the participation of a broad range of stakeholders. As an outcome of this review, we suggest the following guideline specific shortcomings and future recommendations as described in Table 5.

### ***Strengths and Limitations***

This review illustrates several strengths. A comprehensive search of CLP organizations and other globally recognized associations was conducted by reviewers to identify CPGs eligible for this review. For increasing the reliability of the appraisals, four trained assessors from different countries participated to evaluate the quality of included guidelines. We did not limit the search to only the English language, even though we did not find any CPGs for oral health of individuals with CLP in any other language. Additionally, the AGREE II tool was used for quality assessment, thus establishing the validity and reliability of the guideline (Davis and Taylor-Vaisey, 1997; Hurdowar et al., 2007). The limitation was the overall ICC agreement, which was in the range of good to fair among the four assessors, which is statistically acceptable.

### ***Clinical and Research Implications and the Future***

The conducting of a systematic review of practice guidelines is an extensive process that aims to create guidelines and recommendations in the form of syncretic postulates based on the best and most current evidence-based clinical outcomes to establish universal recommendations/protocols. This review has direct implications for the delivery of oral health care to individuals with CLP. The burdens of living with CLP and its comorbidities must be dealt with by these children and their families. Rigorous methods must be used to develop CPGs that are clear, consistent, and reported with transparency for the end-users. It is essential that the multidisciplinary team delivering care for these individuals have adequate guidance for managing patients with CLP. New practice guidelines must focus on the issues of dental caries in children with CLP. It is vital that guidelines recommend early interventions and prevention strategies.

Generally, guidelines are provided for a particular group of people, such as pediatricians, dentists, gynecologists, etc. However, in the case of CLP guidelines, a wider

team of specialty health care providers must be addressed. This is unique in terms of multidisciplinary care and needs to be considered in the development of guidelines for OHPs, NOHPs, and parents and caregivers. With the involvement of relevant stakeholders and facilitators discussing limitations for the successful implementation of guideline recommendations — including parent representatives, experts, social workers, etc., during guideline development and reporting (such as the search strategy used, systematic reviews consulted, etc.) — significant improvements can be made to the quality of CPGs.

There is a need for further improvement of core components such as ‘Scope and Purpose’, ‘Stakeholder Involvement’, and ‘Rigor of Development’ for each selected guideline. Dimensions such as ‘Editorial Independence’ also need to be fully described in future guidelines. Practical guidelines aim to provide a valuable aid for those making complex clinical decisions and, when rigorously developed, have the potential to enhance those decisions as well as healthcare quality. Almost all appraisers recommended five guidelines with/without modifications that can improve the guideline quality and methodology, thus making more impactful contributions to the oral healthcare of children and adolescents with clefts. These recommendations focus on integrating interventions such as the timing of cleft surgeries, orthodontic procedures, breastfeeding protocols, prenatal and postnatal recommendations, reconstructive surgeries, replacement of missing teeth, and management of neonatal teeth. However, there is little information on oral health with regard to the management of and preventive strategies for dental caries in children and adolescents with clefts. We further recommend the development of a new integrated guideline involving all key stakeholders and the use of quality validated appraisal tools. Future guidelines must frame recommendations for all three categories — OHPs, NOHPs, and parents/caregivers — to provide the best and most comprehensive management for children and adolescents with clefts.

The application of the RIGHT (Reporting Items for practice Guidelines in HealThcare) statement in the CPG development process — which is endorsed by the EQUATOR, or Enhancing the QUALity and Transparency Of health Research, Network for enhancing the quality of reporting published research and improvements in reporting — can lead to a higher quality of oral health guidelines for CLP individuals, primarily in areas like ‘Rigor of Development’ and ‘Editorial Independence’. Countries with limited resources for guideline development can utilize the ADAPTE (Adaptation of Clinical Practice Guidelines) approach, which involves updating and adapting existing high-quality guidelines to local settings. It is important that countries and institutions not use a *de novo* approach for the development of CPGs (Grimshaw and Russell, 1993).

## **Conclusions**

Overall, the seven included CPGs on aspects related to oral health were rated as being of moderate to low quality. Areas requiring significant improvements are ‘Rigor of Development’, ‘Editorial Independence’, and ‘Applicability’. It may be useful for stakeholders and interested organizations to work collaboratively with representatives of different specialties delivering care to individuals with CLP in developing and agreeing to these guidelines. The limited scope of the existing guidelines, with minimal or no recommendations with regard to dental caries prevention in children with

CLP, indicates the need for new guidelines. An additional benefit of our recommendation for guidelines is that they could be applied to all vulnerable populations with greater susceptibility to caries, such as those in areas of deprivation or low socioeconomic status. The unique situation of guidelines on oral health for individuals with CLP involves multiple stakeholders, OHPs, NOHPs, parents and caregivers.

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## Appendix 1. PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Yes
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Yes



<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Yes
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Yes
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Yes
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Yes
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Yes
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Yes
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Yes
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Yes
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Yes
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Yes
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.	NA

## **Appendix 2. Search strategy**

((((((("guideline"[Publication Type] OR "guidelines as topic"[MeSH Terms] OR "guidelines"[All Fields]) OR ("policy"[MeSH Terms] OR "policy"[All Fields])) OR recommendations[All Fields]) AND ("oral health"[MeSH Terms] OR ("oral"[All Fields] AND "health"[All Fields]) OR "oral health"[All Fields])) AND ("cleft lip"[MeSH Terms] OR ("cleft"[All Fields] AND "lip"[All Fields]) OR "cleft lip"[All Fields])) AND ("cleft palate"[MeSH Terms] OR ("cleft"[All Fields] AND "palate"[All Fields]) OR "cleft palate"[All Fields])) AND ("child"[MeSH Terms] OR "child"[All Fields] OR "children"[All Fields])) AND ("adolescent"[MeSH Terms] OR "adolescent"[All Fields] OR "adolescents"[All Fields]))

**Table 1.** Characteristics of the Included Guidelines.

Guideline Organization/Society/	Guideline Name	Year of Publication	Target Users	Guideline Writers	Guideline Review Process	Search Strategy for Evidence	Level of Evidence Included
AAPD	Policy on management of patients with cleft lip/palate and other craniofacial anomalies	2019	Pediatric dentists and General dentists	Not specified	Guideline development group	Not mentioned	Not specified
AAP	The primary care pediatrician and care of children with cleft lip and/or cleft palate	2017	Clinicians rendering pediatric care	Not specified	Reviewed by AAP Board	Not mentioned	Not specified
ACPA	Parameters for evaluation and treatment of patients with cleft lip/palate or other craniofacial anomalies	2018	NDHCP, Dentists, and Parents and Caretakers	ACPA committee	Peer review/ACPA committee	Not mentioned	Not specified
ACPA	Standards for approval of cleft-palate and craniofacial teams	2019	NDHCP, Dentists, and Parents and Caretakers	ACPA committee	Not specified	Not mentioned	Not specified
ACPA	Replacing of missing tooth	N/A	NDHCP, Dentists, and Parents and Caretakers	ACPA committee	Not specified	Not mentioned	Not specified
ACPA	Neonatal cleft lip and palate: Instructions for newborn nurseries	N/A	NDHCP, Dentists, and Parents and Caretakers	ACPA committee	Not specified	Not mentioned	Not specified
ABM	ABM clinical protocol # 18: Guidelines for breastfeeding infants with cleft lip, cleft palate, or cleft lip and cleft palate - Revised 2013	2013	NDHCP, Parents and Caretakers	Multidisciplinary	Not specified	Not mentioned	Not specified

**Table 2.** Domain Scores (%) for the 7 Guidelines According to the AGREE II Instrument.

Do- main	Des- crip- tion	Guidelines							Mean	SD
		AAP D Guid eline	AAP	ACPA Param eters	ACPA Stand ards	ACPA Re- plac- ing	ACPA Neon atal	ABM		
I	Scope and Pur- pose	61.1 %	79.16 %	77.77 %	73.61 %	54.16 %	58.33 %	83.33 %	69.63 %	11.55
II	Stake- holder In- volve- ment	30.5 %	62.5%	73.61 %	48.61 %	23.61 %	33.33 %	55.55 %	46.81 %	18.39
III	Rigor of De- velop- ment	18.2 2%	39.97 %	48.43 %	19.79 %	16.66 %	10.93 %	53.12 %	29.58 %	17.11
IV	Clarity of Pre- sen- tation	68.0 5%	80.55 %	79.16 %	70.83 %	70.83 %	62.5%	84.72 %	73.80 %	7.87
V	Applica- bility	11.9 %	46.87 %	40.62 %	37.5%	30.20 %	31.25 %	47.91 %	35.17 %	12.35
VI	Editorial In- de- pend- ence	16.7 %	81.25 %	41.66 %	20.83 %	12.5%	14.58 %	37.5%	32.14 %	24.47
	<b>Mean</b>	<b>34.4 1%</b>	<b>65.05 %</b>	<b>60.21 %</b>	<b>45.19 %</b>	<b>34.66 %</b>	<b>35.15 %</b>	<b>60.36 %</b>		

**Table 3.** Reliability Assessment - Intraclass Correlation Coefficient (ICC).

Guidelines	Cronbach alpha	Intraclass Correlation Coefficient*	Confidence Interval (95%)	P value
AAPD	0.84	0.82	0.66-0.91	0.001
AAP	0.832	0.751	0.48-0.88	0.001
ACPA parameters	0.706	0.622	0.3-0.82	0.001
ACPA standards	0.809	0.75	0.5-0.88	0.001
ACPA replacing	0.828	0.768	0.53-0.89	0.001
ACPA neonatal	0.748	0.68	0.4-0.8	0.001
ABM	0.763	0.70	0.42-0.85	0.001

\*The intraclass correlation coefficient (ICC) was used to assess the agreement among the 4 assessors. The ICC values show a fair agreement for ACPA (Parameters), ABM (Breastfeeding), and ACPA (Neonatal). The ICC values for AAPD, AAP, ACPA (Standards), and ACPA (Replacing a missing tooth) show good agreement. All agreements were statistically significant.

**Table 4.** Individual Reviewers' Scores for Recommendations of Guideline Use.

Would you recommend this guide for use? (3 = yes; 2 = yes with modification; 1 = no)							
Guidelines	AAPD guideline	AAP	Replacing missing teeth	Neonatal cleft lip	ABM	Standards	Parameters
Reviewer 1	2	3	2	2	3	2	3
Reviewer 2	2	3	2	3	3	3	2
Reviewer 3	2	2	1	1	2	2	2
Reviewer 4	2	2	1	1	2	2	2

**Table 5.** Shortcomings of each guideline and recommendations for future modifications

Guidelines	Outcome of the assessment	Reasons for judgements	Suggested strategies for future revision
1. AAPD	Yes with modifications	<p>This guideline has received overall low scores in Stakeholder Involvement, Rigour of Development and Editorial Independence. In the Scope and Development domain, specific description of the overall objectives of the guidelines received low scores. Under the applicability domain the following items received very low scores; availability of supporting tools for application of guidelines, discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations and presentation of key review criteria for monitoring and audit purposes.</p>	<p><b>Scope and Development</b></p> <ul style="list-style-type: none"> <li>• Specific description of the overall objectives of the guideline can be stated.</li> </ul> <p><b>Rigour of Development</b></p> <ul style="list-style-type: none"> <li>• Systematic methods must be used for searching evidence which is lacking in this CPG.</li> <li>• The criteria for selecting the evidence can be clearly described in this CPG.</li> <li>• The methods for formulating the recommendations can be clearly described. The CPG development team must provide an explicit link between the recommendations and the supporting evidences.</li> <li>• It is very important that the CPG is externally reviewed by experts prior to its publication.</li> <li>• The procedure for updating the guideline must be provided.</li> </ul> <p><b>Applicability</b></p> <ul style="list-style-type: none"> <li>• Any supporting tools for application of guidelines must be provided</li> <li>• Discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations can be mentioned</li> <li>• Presentation of key review criteria for monitoring and audit purposes can be reported.</li> </ul>



2. AAP	Yes with modifications	<p>This guideline received overall low scores in Rigour of Development domain and Applicability domain. Under the Stakeholder Involvement domain the item, whether or not the patients' views and preferences have been sought was also reasonably low.</p>	<p><b>Rigour of Development</b></p> <ul style="list-style-type: none"> <li>• Systematic methods must be used for searching evidence which is lacking in this CPG.</li> <li>• The criteria for selecting the evidence are not clearly described in this CPG.</li> <li>• The methods for formulating the recommendations are not clearly described.</li> </ul> <p><b>Stakeholder Involvement</b></p> <ul style="list-style-type: none"> <li>• Whether or not the patients' views and preferences have been sought can be reported.</li> </ul> <p><b>Applicability</b></p> <ul style="list-style-type: none"> <li>• Any supporting tools for application of guidelines must be provided</li> <li>• Discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations can be mentioned</li> <li>• Presentation of key review criteria for monitoring and audit purposes can be reported.</li> </ul>
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3. ABM	Yes with modifications	<p>This guideline received overall low scores for Rigour of Development domain, Applicability and Editorial Independence. Under the Stakeholder Involvement domain, item whether or not the patients' views and preferences have been sought was also scored low.</p>	<p><b>Stakeholder Involvement</b></p> <ul style="list-style-type: none"> <li>• The views and preferences of the target population (patients, public, etc.) must be sought.</li> </ul> <p><b>Rigour of Development</b></p> <ul style="list-style-type: none"> <li>• Systematic methods must be used for searching evidence which is lacking in this CPG.</li> <li>• The criteria for selecting the evidence can be clearly described in this CPG.</li> <li>• The methods for formulating the recommendations can be clearly described. The CPG development team must provide an explicit link between the recommendations and the supporting evidences.</li> <li>• It is very important that the CPG is externally reviewed by experts prior to its publication.</li> <li>• The procedure for updating the guideline must be provided.</li> </ul> <p><b>Applicability</b></p> <ul style="list-style-type: none"> <li>• Any supporting tools for application of guidelines must be provided</li> <li>• Discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations can be mentioned</li> <li>• Presentation of key review criteria for monitoring and audit purposes can be reported.</li> </ul> <p><b>Editorial Independence</b></p> <ul style="list-style-type: none"> <li>• The guideline is editorially independent from the funding body.</li> <li>• Conflicts of interest of guideline development members must be recorded.</li> </ul>
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4. Standards	Yes with modifications	This guideline was overall scored low in Rigour of development, Applicability and Editorial Independence domains. Under the Stakeholder Involvement domain item whether or not the patients' views and preferences have been sought was also low	<p><b>Stakeholder Involvement</b></p> <ul style="list-style-type: none"> <li>• Patients' views and preferences must be sought.</li> </ul> <p><b>Rigour of Development</b></p> <ul style="list-style-type: none"> <li>• Systematic methods must be used for searching evidence which is lacking in this CPG.</li> <li>• The criteria for selecting the evidence can be clearly described in this CPG.</li> <li>• The methods for formulating the recommendations can be clearly described. The CPG development team must provide an explicit link between the recommendations and the supporting evidences.</li> <li>• It is very important that the CPG is externally reviewed by experts prior to its publication.</li> <li>• The procedure for updating the guideline must be provided.</li> </ul> <p><b>Applicability</b></p> <ul style="list-style-type: none"> <li>• Any supporting tools for application of guidelines must be provided</li> <li>• Discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations can be mentioned</li> <li>• Presentation of key review criteria for monitoring and audit purposes can be reported.</li> </ul> <p><b>Editorial Independence</b></p> <ul style="list-style-type: none"> <li>• The guideline is editorially independent from the funding body.</li> <li>• Conflicts of interest of guideline development members must be recorded.</li> </ul>
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5. Parameters	Yes with modifications	<p>This guideline received overall low scores for both Applicability and Editorial Independence domains. Under the Rigour of Development domain the following items were scored low: Systematic methods were used to search for evidence, criteria for selecting the evidence are clearly described, methods for formulating the recommendations are clearly described, all health benefits, side effects, and risks have been considered in formulating the recommendations and whether the explicit link between the recommendations and the supporting evidence have been stated.</p>	<p><b>Rigour of Development</b></p> <ul style="list-style-type: none"> <li>• Systematic methods must be used for searching evidence which is lacking in this CPG.</li> <li>• The criteria for selecting the evidence can be clearly described in this CPG.</li> <li>• The methods for formulating the recommendations can be clearly described. The CPG development team must provide an explicit link between the recommendations and the supporting evidences.</li> <li>• It is very important that the CPG is externally reviewed by experts prior to its publication.</li> <li>• The procedure for updating the guideline must be provided.</li> </ul> <p><b>Applicability</b></p> <ul style="list-style-type: none"> <li>• Any supporting tools for application of guidelines must be provided</li> <li>• Discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations can be mentioned</li> <li>• Presentation of key review criteria for monitoring and audit purposes can be reported.</li> </ul> <p><b>Editorial Independence</b></p> <ul style="list-style-type: none"> <li>• The guideline is editorially independent from the funding body.</li> <li>• Conflicts of interest of guideline development members must be recorded.</li> </ul>
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6. Replacing missing teeth	No	<p>This guideline scored overall low scores in all items under the following domains : Scope and Development, Stakeholder Involvement, Rigour of Development, Applicability and Editorial Independence. Under Clarity of Presentation domain, for item that is key recommendations are easily identifiable was also scored low.</p>	<p><b>Scope and Development</b></p> <ul style="list-style-type: none"> <li>• Specific description of the overall objectives of the guideline can be stated.</li> </ul> <p><b>Stakeholder Involvement</b></p> <ul style="list-style-type: none"> <li>• Whether or not the patients’ views and preferences have been sought can be reported.</li> </ul> <p><b>Rigour of Development</b></p> <ul style="list-style-type: none"> <li>• Systematic methods must be used for searching evidence which is lacking in this CPG.</li> <li>• The criteria for selecting the evidence can be clearly described in this CPG.</li> <li>• The methods for formulating the recommendations can be clearly described. The CPG development team must provide an explicit link between the recommendations and the supporting evidences.</li> <li>• It is very important that the CPG is externally reviewed by experts prior to its publication.</li> <li>• The procedure for updating the guideline must be provided.</li> </ul> <p><b>Applicability</b></p> <ul style="list-style-type: none"> <li>• Any supporting tools for application of guidelines must be provided</li> <li>• Discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations can be mentioned</li> <li>• Presentation of key review criteria for monitoring and audit purposes can be reported.</li> </ul> <p><b>Clarity of Presentation</b></p> <ul style="list-style-type: none"> <li>• Key recommendations must be easily identifiable</li> </ul> <p><b>Editorial Independence</b></p> <ul style="list-style-type: none"> <li>• The guideline is editorially independent from the funding body.</li> <li>• Conflicts of interest of guideline development members must be recorded.</li> </ul>
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7. Neonatal cleft lip	No	<p>This guideline scored overall low scores in all items under the following domains : Rigour of Development, Clarity of presentation, Applicability and Editorial Independence. Under Stakeholder Involvement domain, the following items: the guideline development group includes individuals from all the relevant professional groups and is patients' views and preferences have been sought also received low scores.</p>	<p><b>Stakeholder Involvement</b></p> <ul style="list-style-type: none"> <li>• The guideline development group must include individuals from all the relevant professional groups</li> <li>• Patients' views and preferences must be sought.</li> </ul> <p><b>Rigour of Development</b></p> <ul style="list-style-type: none"> <li>• Systematic methods must be used for searching evidence which is lacking in this CPG.</li> <li>• The criteria for selecting the evidence can be clearly described in this CPG.</li> <li>• The methods for formulating the recommendations can be clearly described. The CPG development team must provide an explicit link between the recommendations and the supporting evidences.</li> <li>• It is very important that the CPG is externally reviewed by experts prior to its publication.</li> <li>• The procedure for updating the guideline must be provided.</li> </ul> <p><b>Applicability</b></p> <ul style="list-style-type: none"> <li>• Any supporting tools for application of guidelines must be provided</li> <li>• Discussion of organisational barriers in applying the recommendations, consideration of potential cost implications of applying the recommendations can be mentioned</li> <li>• Presentation of key review criteria for monitoring and audit purposes can be reported.</li> </ul> <p><b>Clarity of Presentation</b></p> <ul style="list-style-type: none"> <li>• Key recommendations must be easily identifiable</li> </ul> <p><b>Editorial Independence</b></p> <ul style="list-style-type: none"> <li>• The guideline is editorially independent from the funding body.</li> <li>• Conflicts of interest of guideline development members must be recorded.</li> </ul>
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