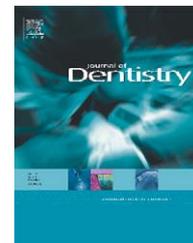


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Review

Why guidelines for early childhood caries prevention could be ineffective amongst children at high risk

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ARTICLE INFO

Article history:

Received 8 January 2010

Received in revised form

6 September 2010

Accepted 7 September 2010

Keywords:

Early childhood caries

Guidelines

Scientific evidence

Consensus

Inequity

Health literacy

Co-morbidity

Fatalism

ABSTRACT

Objective: This paper sought to investigate whether early childhood caries (ECC) prevention guidelines were able to produce a significant, long-term, homogeneous decrease in ECC prevalence/incidence within all socio-economic strata of the population and whether their development followed methodologies specifically designed for ECC prevention guidelines.

Methods: ECC prevention guidelines and specific methodologies published in English since 1995 were searched through MEDLINE, PUBMED and GOOGLE. Data regarding long-term and stratified effect of guidelines and specific methodologies were not found. The only review of methodology for guideline development which was found (produced by the Guideline Development Group of the WHO) was used and adjusted to draft a specific ECC-centred methodology.

Results: This procedure resulted in nineteen key methodological components for the optimal ECC prevention guideline development. In order to emphasize such necessity of specific methodologies, three of these components (assessment of the strength of scientific evidence, development of consensus amongst Dental Health Care Providers, identification of appropriate outcomes) were described in detail. These examples showed the shortfalls of ECC prevention guidelines developed using methodologies explicitly designed for the development of clinical practice (e.g., therapy, diagnosis, screening) guidelines.

Conclusions: Guidelines for ECC prevention could help control such disease and improve quality of life of children at high ECC risk. However, the lack of specific methodologies for their development led to the consequence that, despite the fact that many ECC prevention guidelines exist, their effectiveness in the final goal of obtaining a significant, long-term and homogeneous reduction of ECC incidence, is not proved.

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1. Introduction

Early childhood caries (ECC) is characterised by the presence of one or more decayed, missing or filled dental surfaces in any primary tooth affecting children up to five years of age.¹ Risk factors for ECC can be broadly split into factors associated with

the development of the lesions (biological risk factors) and the socio-economic, cultural, ethnic background which promotes the establishment of biological risk factors (social risk factors). The biological risk factors include nutritional variables, such as malnutrition, early start and frequent intake of foods containing rapidly fermentable carbohydrates, such as

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doi:10.1016/j.jdent.2010.09.002

Table 1 – Examples of ECC prevalence in low-to-medium income countries and in low-income communities from high-income countries.

Country or community	Year of the survey	Age group	ECC prevalence
Taiwan ¹⁴	1997	6 years	53%
Thailand ¹⁵	2001	1.5 years	68%
Iran ¹⁶	2005	1–3 years	26%
South Africa ¹⁷	2002	3–6 years	32%
Mexico ¹⁸	2007	3–5 years	35%
China (suburban area) ¹⁹	2000	2–4 years	12%
US (rural community) ⁶	2005	2–3.5 years	20%
Canada (aborigines) ²⁰	2002	1–2 years	30%
Israel (nomads) ²¹	2006	1–3 years	18%

sweets, snacks and soft drinks, inadequate intake of nutrients, low consumption of milk, dairy products, and, perhaps, complex carbohydrates^{2–4}; peculiar feeding habits, such as frequent and nocturnal use of baby bottle containing sweetened drinks and, possibly, prolonged breastfeeding^{2,5}; early colonization and high levels of cariogenic microorganisms^{2,5,6}; delayed start and poor toothbrushing and low fluoride exposure.⁷ The social risk factors include low parental education, low household income, immigrant status, fatalism and lack of awareness towards dental diseases and stress.^{8–10} The interaction between biological and social risk factors is so complex that the investigation of ECC determinants is difficult and systematic reviews may also disagree.^{5,11} ECC is particularly frequent amongst low-income communities and racial/ethnic minority groups, aborigines, immigrants and nomads.^{9,10,12} Such high ECC prevalence within deprived communities makes identification of high-risk groups more important, simple and cost-effective than identification of high-risk individuals.¹³ In fact, ECC is widespread in low-to-medium income countries, where prevalence values as high as 30–70% are reported,^{14–18} as well as in low socio-economic strata of high-income countries, where ECC may affect more than one-fourth of young children (Table 1).^{6,19–21}

ECC therapy is also remarkably costly, ranging between 300 and 800€ for children treated in the dental office and up to 7000€ for those requiring general anaesthesia.^{10,22,23} In addition, the dental pain caused by ECC may severely deteriorate the quality of life of children and their families, negatively affect children's behaviour and moods and waste parental time.²⁴ ECC is, therefore, a serious public health priority and requires effective control policies including also ECC prevention guidelines.

According to the US Institutes of Medicine, guidelines are systematically developed statements which assist the practitioner's decision about appropriate health care for specific clinical circumstances. Guidelines may refer to clinical practice, such as diagnosis, screening and therapy, but also to public health, health policy and disease prevention.²⁵ The systematic development of guidelines began in the 70s, when the US National Institutes of Health started to produce consensus statements. In the 90s, under the impetus of Evidence-Based Medicine, the methods changed and systematic literature review and explicit linkage of recommendations to supporting evidence became essential.²⁶ Nevertheless, despite the fact that the body of evidence available in databases was the same, recommendations on the same

topic could differ substantially (see, for example, Thomson et al.,²⁷ Eisinger et al.,²⁸ and Beck et al.²⁹). Disagreement between American guidelines, which strongly recommended breast self-examination for the early detection of breast cancer, and French guidelines, which did not recommend this procedure and warned that it could be detrimental because it could induce anxiety in women, is an explicable example.²⁸

This and other disagreements suggested that it was necessary to produce a methodology for the development of guidelines. Methodologies have been produced by many national and governmental agencies and medical specialty societies. However, these methodologies resulted variable and sometimes discrepant and suggested that it was necessary to develop an agreed methodology for the development of guidelines which was based on a systematic approach.²⁵

This paper focused on ECC prevention guidelines and, therefore, sought to investigate and compare the various methodologies for the development of ECC prevention guidelines and their long-term effectiveness.

2. Methods

The original idea of this review was to investigate: (i) whether ECC prevention guidelines were developed following methodologies specifically designed for ECC prevention and (ii) whether ECC prevention guidelines produced a significant and long-term decrease in ECC prevalence/incidence homogeneous within all the social strata of the population. Therefore, two literature searches were made to identify: (i) guidelines for prevention of ECC; (ii) reviews, expert opinions and consensus statements regarding the methodology for the development of ECC prevention guidelines.

In order to identify the guidelines, terms, such as “guideline”, “recommendation”, “consensus”, “public health” were matched with terms, such as “early childhood caries”, “baby bottle tooth decay”, “nursing caries”, “rampant caries”, and “baby bottle caries”. The long-term (at least two years after guideline release) and stratified (for socio-economic level) effect of the guidelines, identified through the literature search, were investigated searching articles that cited the guidelines and articles which investigated ECC prevalence/incidence, in the area where guidelines have been disseminated, before and after their release. The methodologies used for guideline development were individuated by searching the articles that were

cited by the guidelines and using the names of the authors. In addition, the websites of the scientific societies which developed guidelines were also searched. The databases used were MEDLINE, PUBMED, GOOGLE SCHOLAR, whilst GOOGLE was used for the search of websites. Papers published since 1995 and written in English were considered.

Data regarding the long-term effect of ECC prevention guidelines stratified for socio-economic status were not found. Methodologies specifically designed for the development of ECC prevention guidelines were not found either. Such lack of data changed the aim of this paper. More specifically, to draft a methodology for the development of ECC prevention guidelines using a systematic approach.

The only one systematic review of the methodology for the development of guidelines which was found, was used to draft the methodology for the development of ECC prevention guidelines. The key methodological components reported by this review were assumed to be the key components of the methodology for the development of optimal ECC prevention guidelines. Within these general components, some aspects which required a specific adaptation for ECC were highlighted and a series of methodological principles was formulated. Results were partly based on available evidence and partly on logical arguments. It is important to underline that, due to the aforementioned lack of available scientific information, the present paper did not seek to propose a definitive model of

methodology for the development of ECC prevention guidelines, but was aimed at proposing a basis for further discussions amongst experts. In addition, several examples were reported which demonstrated that if ECC prevention guidelines are developed using non-specific and non-systematically developed methodologies, they are likely to be ineffective amongst children at high ECC risk.

3. Results

The lack of ECC prevention-centred methodologies and of data on long-term effectiveness of guidelines was in open contrast with the number of guidelines found for caries prevention in childhood/teenage years.³⁰⁻⁴⁰ Most of these guidelines were based on methodologies designed for the development of clinical practice guidelines (see, for example, Refs. 40-43).

It was anticipated in Section 2 that only one systematic review of the methodology for the development of guidelines, produced by the Guideline Development Group of the World Health Organization, was found.⁴⁴ Such review identified nineteen key methodological components for an ideal guideline development. These components could not be adopted for the development of guidelines for ECC prevention as such, and required adjustments due to the peculiar characteristics of ECC. The original key components along

Table 2 – Key methodological components for the development of ECC prevention guidelines.

Key component	Number	Description
Choice of topic	1	The choice to develop ECC prevention guidelines must be justified by a high burden of disease
Expert panel composition	2	Scientific experts, DHCPs and tutors must be enrolled
Conflict of interest	3	Avoidance must be declared by the expert panel
Processes	4	Processes necessary for the production of guidelines must be pre-established
Identification of outcomes	5	Outcomes must account for the final goal of ECC prevention guidelines and periodically monitored
Definition of the question	6	The primary question is whether recommendations could be effective to prevent ECC amongst children at high risk
Type of study designs for different questions	7	There are different types of studies specific for the investigation of each primary and secondary question
Identification of scientific evidence	8	Criteria to assess the level of scientific evidence vary according to the different questions
Synthesizing the evidence	9	Scientific evidence must be summarised briefly and clearly at the same time
Specification of values	10	Guidelines must be ethical, practical and specific
Making recommendations	11	Recommendations must be agreeable to DHCPs
Taking account of equity	12	Guidelines must seek to restore equity
Grading evidence and recommendations	13	Grading methods used for clinical practice guidelines cannot be used for ECC prevention guidelines
Taking account of costs	14	The costs for ECC therapy are high and supportive of the development of prevention guidelines
Applicability transferability and adaptation of guidelines	15	Guidelines must be adapted to different contexts in order to ensure their transferability
Structure of report	16	Clear, logical and understandable by DHCPs
Methods of peer review	17	Scientific experts must consider that the levels of consensus amongst DHCPs and of compliance amongst tutors is to be high
Dissemination and implementation	18	Professional associations of DHCPs must be involved in these processes
Evaluation of the impact of guidelines	19	Long-term decline of ECC frequency, particularly amongst individuals and communities at risk

Adapted from Ref. 25.

with their adaptations for ECC prevention guidelines are listed below and in Table 2.

- (1) Choice of the topic of guidelines. In order to decide whether to develop ECC prevention guidelines, it is necessary that the burden of the disease (that is, ECC prevalence and distribution, the consequences of ECC on general health of affected children, costs for ECC therapy, etc.) is high enough and that feasible recommendations can be developed.⁴⁵
- (2) Expert panel composition. It must be accurate and include scientific experts in methodology, guideline implementation and in ECC prevention, along with public Dental Health Care Providers (DHCPs), governmental institutions and tutors of children at ECC risk.⁴⁶
- (3) Conflict of interest. Avoidance of conflicts of interest must be declared by all the members of the Expert Panel.
- (4) Process. Processes necessary for the production of guidelines, such as development, dissemination, outcome evaluation, revision, etc. must be pre-established.
- (5) Identification of important outcomes. The final goal of ECC prevention guidelines is to obtain a significant and long-term decrease in ECC prevalence/incidence homogeneous within all the socio-economic strata. The choice of the outcomes must account for such goal. Outcomes must be ranked and periodically monitored.⁴⁷
- (6) Explicit definition of the question. ECC preventive measures could be biologically effective but socially unacceptable or unfeasible or vice versa. Therefore, the primary question is whether recommendations could be effective in preventing ECC amongst children at high risk for ECC. In order to satisfy the primary question, it is necessary to satisfy a series of secondary questions, such as, how biologically effective, how applicable to high-risk children and how cost-effective preventive measures are.
- (7) Identification of the type of study design for each type of question. There are different types of studies specific for the investigation of each question. For example, observational studies amongst low-income individuals for the investigation of feasibility, field trials for the study of biological effectiveness of community-based preventive measures, etc.
- (8) Identification of scientific evidence. Criteria to assess the level of scientific evidence vary according to the different questions.
- (9) Synthesizing the scientific evidence. Scientific evidence must be summarised briefly and clearly.
- (10) Specification and integration of values. Guidelines must be ethical, practical and specific. Therefore, scientific evidence is not the sole determinant of their content. Other issues also are important, such as ethical aspects, social value judgements, policy imperatives, equality and diversity of legislation.⁴⁸ Social values are as important as scientific evidence for the development of ECC prevention guidelines, given the particular nature of such condition.
- (11) Making recommendations. The list of recommendations is the section of guidelines which is likely to be the most frequently read by DHCPs. Therefore, the content of recommendations must be agreeable to DHCPs and recommendations must produce the desired effect.
- (12) Taking account of equity. Since ECC has an unequal distribution, guidelines must seek to restore equity.
- (13) Grading evidence and recommendations. Scientific evidence and recommendations are graded to simplify their understanding and to promote their use amongst DHCPs. Since ECC preventive measures are not investigable using the same types of studies used for disease therapy, diagnosis or screening, the methods used to grade evidence and recommendations for ECC prevention are necessarily different from the methods used for clinical practice.
- (14) Taking account of costs. ECC therapy is very costly. Guidelines could be cost-effective even if their impact on disease prevention is moderate.
- (15) Applicability, transferability and adaptation of guidelines.⁴⁹ Guidelines applicable in a given context could be unacceptable or inapplicable in different contexts, for example, amongst different ethnic communities. Therefore, in order to ensure their transferability from a context to another, eventual adaptations must be taken into consideration.
- (16) Structure of report. The structure of the report may determine the use of guidelines by DHCPs. The report must be clear, logical and understandable.
- (17) Methods of peer review. Peer review is made by scientific experts. However, the necessity to develop high consensus amongst DHCPs and high compliance amongst tutors of children at risk may justify the use of unconventional methods of peer review.
- (18) Dissemination and implementation. Professional associations of DHCPs involved in guideline development must be involved in the processes of dissemination and implementation. Once again, it is important for the expert panel to cooperate with DHCPs in order to ensure that guidelines are extensively used.⁵⁰
- (19) Evaluation of the impact of guidelines. ECC prevention guidelines are aimed at achieving a stable decrease in the burden of this disease, particularly amongst individuals and communities at risk. Therefore, outcomes, such as the level of consensus amongst DHCPs or the overall (i.e., not stratified for the various social strata) decline in ECC frequency, are not valid instruments to assess the impact of guidelines.

The present is a basis for the development of effective ECC prevention guidelines and is, therefore, susceptible to changes and improvements. Three key methodological components are now described in detail to explain how important the ECC prevention-centred methodology is for the success of guidelines in terms of impact on the burden of disease.

3.1. Assessment of the strength of scientific evidence

The strength of scientific evidence is generally evaluated on the basis of consistency and quality of scientific studies. In order to assess their quality, studies are classified according to a hierarchy based on the level of internal validity.^{42,43,51-53} However, if this method is valid for the development of clinical practice guidelines, its extension to ECC prevention guidelines is not free of limits. Indeed, study quality is based on both

internal validity and external validity. Internal validity ensures that the study has been carried out carefully and the outcomes are likely to be attributable to the factor under investigation, rather than another factor or bias. High internal validity is obtained by enrolling subjects who are generally healthier than the general population, or with similar levels of other caries-related variables, a limit known as distorted assembly.^{54,55} For example, in order to investigate whether fluoride gels have caries preventing activity, subjects enrolled in randomised controlled trials (RCTs), must have similar levels of exposure to caries-associated variables, such as toothbrushing, cariogenic diet, etc. These criteria may allow to minimise the confounding effect of these variables, and to isolate the effect of gels from the effect of confounders.⁵⁶ The criteria used to assess the level of internal validity are objective and easy to grade.^{54,55} External validity is the extent to which the findings of a study are generalizable beyond the confines of the study and can be extrapolated to other subjects. High external validity is generally achieved by selecting samples with similar characteristics as those of the general population, an aspect known as representativeness.⁵⁷ For example, in order to assess whether the effect of fissure sealants on caries development is generalizable, the study samples must be representative of the underlying study-populations, and include children with different levels of exposure to other caries risk factors, and similar age and gender distributions as the study-populations.⁵⁸ The criteria used to assess the level of external validity are subjective and difficult to standardize.^{54,55}

Ideal studies have high internal and external validities at the same time. However, the selection of distorted assemblies decreases the representativeness of the samples and vice versa.⁵⁶ However, the quality of scientific studies is generally based on the level of their internal validity, whilst the importance of external validity, is underestimated^{42,43,51-53} for two important reasons. Firstly, studies with low internal validity have little value because no causal relationship can be inferred, whilst studies with high internal validity always have some value, even if the external validity is low. Secondly, criteria to evaluate the internal validity are more simple and objective than criteria to evaluate the external validity.⁵⁷

The role of external validity in the development of ECC prevention guidelines is as essential as the role of internal validity. In fact, a given preventive measure must be biologically effective (and thus, scientific studies with high internal validity which corroborate the causal relationship are needed) and socially effective (and thus, studies with high external validity with findings that are generalizable to low-income individuals and communities at high ECC risk are needed). For example, there are many consistent and well-designed RCTs reporting the caries preventing effect of fluoride toothpastes amongst children. Therefore, internal validity is high, the causal relationship is definitive and biological effectiveness is high, too.⁵⁸ However, community trials aimed at assessing the caries preventing activity of fluoride toothpastes amongst deprived children, reported low participation rates (see, for example, Ref. 59). Therefore, external validity and social effectiveness are low. This example suggests that, although fluoride toothpastes help prevent caries, the strength of scientific evidence of effectiveness in the peculiar context of children at high ECC risk cannot

be high, unless successful methods to make this measure acceptable by such children are found.

Another important aspect related to the assessment of the strength of scientific evidence is that this is generally evaluated using a hierarchy based on the potential level of study bias, which puts RCTs at the top.⁴⁸ Such standard hierarchy cannot find practical application in the design of ECC prevention guidelines. In fact, ECC preventive measures can be classified into individual-based treatments, such as topical applications of fluorides, antimicrobials or sealants, community-based treatments, such as water or salt fluoridation, and control of risk factors, such as the discontinuation of frequent/nocturnal and prolonged exposure to rapidly fermentable carbohydrates. Individual-based treatments are evaluable using RCTs, and are therefore likely to achieve the highest level of internal validity. The evaluation of community-based treatments requires community trials, which yield some uncertainty due to the real number of individuals in the experimental community exposed to the treatment and, therefore, are not at the top of the standard hierarchy. The control of risk factors cannot be studied using experimental studies, because in a hypothetical trial the test subjects would be either artificially exposed to the risk factor under investigation, or the risk factor would be removed from the test subjects leaving the control subjects exposed. These studies are obviously unethical and, therefore, the effect of risk factor control is investigable only using observational studies, with lower internal validity than experimental studies.⁶⁰

In the field of ECC prevention, the use of the standard evidence hierarchy leads to emphasize the importance of individual-based treatments and to underestimate the effects of community-based treatments and of risk factor control (see, for example, a review of methods to prevent ECC⁶¹). In fact, individual-based preventive treatments are more strongly recommended than risk factor control by the SIGN and the Canadian Task Force on the Periodic Health Examination,^{30,36} whilst the Task Force on Community Preventive Services, the Centers for Disease Control and Prevention and the French National Authority for Health focus only on preventive treatments.^{32,34,40}

The standard evidence hierarchy of internal validity must be replaced by another method which accounts for the type of preventive measure under investigation. For each measure, the type of scientific study with the lowest level of bias must be identified. Such study must be placed at the top of the hierarchy specific for that type of measure. These studies are, RCTs for individual-based treatments, community trials for population-based treatments and observational studies for the control of risk factors. For instance, in the event that there are only observational studies in favour of a given preventive measure, one thing is if that measure is the control of a risk factor, another thing is if that measure is an individual-based treatment. In fact, the preventive measure could achieve the highest level of scientific evidence only in the first case.

3.2. Development of consensus amongst Dental Health Care Providers

Guidelines for ECC prevention have no sense if they are not used by DHCPs. Passive dissemination of guidelines without

pre-testing the level of agreement amongst DHCPs does not adequately ensure the appropriate uptake of recommendations in most circumstances. For example, in 1975 the Health Education Council of England developed the four scientific evidence-based key messages to promote good oral health (i.e., diet, toothbrushing, fluoridation and dental attendance). Thirty years after the dissemination of such messages, preventive advice regarding fluorides still was rather uncommon amongst DHCPs, suggesting that some of them either had reservations or were unclear about the appropriate use of fluorides.⁵² Another example shows that, although the ECC prevention guidelines developed by the American Academy on Pediatric Dentistry (AAPD) set the time of the first oral examination at the time of the eruption of the first tooth,³⁸ only one-fourth of the AAPD members examined infants within such age.⁶³ Thus, DHCPs' opinions regarding the appropriateness of recommendations and their agreement must be assessed before the release of the guidelines.²⁶ A simple method to evaluate the level of consensus is that a representative sample of DHCPs is selected and is asked to classify recommendations using a Likert scale, generally ranging between strong agreement (score 9) and strong disagreement (score 1). DHCPs' opinions regarding the appropriateness of recommendations is estimated using the median of the scores: medians between 6.5 and 9 suggest that the DHCPs consider the recommendation appropriate, between 4 and 6 equivocal, between 1 and 3.5 inappropriate. The extent of disagreement around each recommendation is estimated using the mean absolute deviation from the median (MADM), which is the mean of the distance between the median and the individual scores. MADM values higher than one suggest that there is an unacceptable level of disagreement and suggest that the recommendation must be revised by the expert panel.⁶⁴

Recommendations yielding low consensus must be revised before, regardless of the level of scientific evidence and according to DHCPs' experience, beliefs, and values.⁶⁵ Yet, most scientific organizations that produce clinical practice guidelines develop the consensus within the expert panel, without investigating the opinion of health care providers.⁶⁶ Such approach, known as informal consensus development, does not perform as well as the various formal consensus development methods based on the opinion of health care providers.⁶⁷ The most important of these methods are the Consensus Conference, the Nominal Group Technique, the Delphi method and the RAND version.^{68,69} According to the Consensus Conference and the Nominal Group Technique, a group of health care providers and the expert panel discuss the areas of disagreement, and change the recommendations with low consensus. The difference between these methods is in the selection of the health care providers, nominally invited with the Nominal Group Technique and voluntarily participating to the conference with the Consensus Conference. Proponents of these methods argue that the face-to-face meeting may allow an exchange of different views and leads to a more realistic picture of the true consensus.⁷⁰ According to the Delphi method, recommendations rated as inappropriate or with high extent of disagreement are revised by the expert panel. Revised recommendations are sent again to the health care providers for a second rating round. This process goes on

until a satisfying level of consensus is achieved. Proponents of the Delphi method argue that the use of the anonymous questionnaire is more accurate because those who disagree with recommendations are likely to conform to the dominant viewpoint when they are in the face-to-face meeting.⁷¹ The RAND method, currently the preferred approach, is a hybrid method. As in the Nominal Group Technique, it involves a sample of health care providers for the face-to-face meeting to revise recommendations. As in the Delphi method, revised recommendations are rated anonymously by means of the postal questionnaire.⁷²

All these methods help improve DHCPs' consensus with demonstrated positive consequences on the success of guidelines.^{65,73}

3.3. Identification of appropriate outcomes

Outcomes help to evaluate whether guidelines had a positive impact on ECC prevention. Thus, the success amongst DHCPs is not necessarily a primary outcome. For example, the American Heart Association developed the recommendations to prevent infective endocarditis in dental healthcare setting.⁷⁴ The dissemination of such guidelines largely exceeded the US frontiers.^{75–79} The effects of such guidelines were: a significant decrease in the frequency of dentists' involvements in malpractice litigations due to potential endocarditis causation by the dental staff; a significant increase in public expense due to the excessive prophylactic use of antibiotics; and no positive impact on endocarditis prevention.⁸⁰

Another outcome frequently used to evaluate the impact of guidelines is the overall decline of disease frequency. Such outcome also is not necessarily a primary outcome. For example, in order to control childhood obesity epidemics in US, guidelines have been developed seeking to control such condition, particularly amongst low-income families.^{81,82} Despite this prevention-focused action plan produced a significant average decline in childhood obesity prevalence between 2003 and 2008, such decline was not homogeneous within all the socio-economic strata, since no change was reported amongst low-income children, thus suggesting that guidelines produced an increase in inequalities.⁸³ Another example, in order to prevent the detrimental effects on children's health caused by exposure to parental tobacco smoke, the American Academy of Pediatrics developed the "Guidance on tobacco-related counselling".^{84,85} Once again, despite prevalence of children's exposure to environmental tobacco smoke significantly declined globally,⁸⁶ it remained unchanged amongst low-income families. Thus, an apparent success of guidelines actually resulted in a failure and produced an increase in inequalities.⁸⁷

These examples suggest that conventional outcomes, such as the level of guideline dissemination, or the overall decrease in disease frequency could not be useful for the assessment of the impact of ECC prevention guidelines. Indeed, it is essential that outcomes help assess whether guidelines produced a significant and long-term effect in terms of ECC prevention within communities at high risk. Although specific examples regarding ECC which corroborate such assumption are lacking, there are several other examples of public dental health care interventions specifically implemented to improve

the dental health status of underprivileged groups which produced an increase in inequalities.

In 1997 in UK, for example, children could have free dental treatment with a dentist from the National Health System on condition that they were registered by their tutors and attended at least once every fifteen months. Nevertheless, more than one half of parents from the most deprived areas did not benefit from free dental treatments and many of those who registered their children did not attend in due time and lost their right to have their children treated for free.⁸⁸ In 2001 in US, children from low-income families who were covered by public dental insurance, had the fewest overall frequency of dental checkups and the highest frequency of use of emergency dental services for pain relief.⁸⁹ In 2003 in Brazil, public water fluoridation was implemented more frequently in municipalities with the highest level of human development index than in deprived municipalities.⁹⁰ Such paradoxical effect of public dental health interventions, called Inverse Care Law, which states that individuals and groups who are in minor need of an intervention may benefit more from it than those who are in major need,⁹¹⁻⁹³ corroborates the fact that the most appropriate outcome for the evaluation of the impact of ECC prevention guidelines is the long-term change in ECC prevalence/incidence stratified for the various socio-economic levels of the population.

Factors associated with inequalities and with the causes of the Inverse Care Law, such as, low ECC-related health literacy, high prevalence of co-morbidities and of fatalism amongst low-income individuals and communities, could be used as secondary outcomes for the evaluation of the impact of ECC prevention guidelines. The increase in ECC-related health literacy is believed to increase awareness and, ultimately, the request for ECC prevention or treatment.^{59,94} However, health literacy alone is not enough.^{8,9,89,95,96} Co-morbidity is the concurrent presence of more than one condition, not necessarily diseases, at the same time. Typical co-morbidity of low-income individuals is the psychological distress,^{54,92} which also may interest children⁹⁷ and exert a negative effect on ECC.⁹⁸⁻¹⁰⁰ Indeed, individuals with co-morbidities frequently concentrate their attention on only one condition, not necessarily the most serious, and not necessarily ECC.^{54,92,101,102} Fatalism is the view that we are powerless to do anything other than what we actually do¹⁰³ and is widespread amongst low-income communities and groups.¹⁰⁴ Fatalism is dramatically associated with poor health outcomes,^{105,106} including oral health.¹⁰⁷⁻¹⁰⁹ Preventive interventions directed to fatalistic individuals or communities are likely to fail.¹¹⁰⁻¹¹² Paradoxically, several medical and dental students from certain ethnic groups are also fatalistic.¹¹³⁻¹¹⁵

4. Conclusions

Guidelines for ECC prevention could help control such disease and improve the quality of life of children at high ECC risk and their families. They have been generally developed following methodologies produced for the development of guidelines for clinical practice, probably because specific methodologies for their development do not exist. This important shortfall led to the frustrating consequence that despite the fact that many

ECC prevention guidelines have been released, their effectiveness in the final goal of obtaining a significant, long-term and homogeneous reduction of ECC incidence, is not proved.

The key components for the development of ECC prevention guidelines, described in the present study, are a basis for the development of a standard and efficient methodology. Indeed, given the peculiar characteristics of ECC, key components require to be adjusted and specifically modelled around ECC. The assessment of the strength of scientific evidence, the development of consensus amongst DHCPs and the identification of appropriate outcomes are only examples of how urgent the necessity of specific methodologies is and how important the process of rearranging the key components could be.

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