Maternal caries experience influences offspring's early childhood caries

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ORIGINAL ARTICLE







Maternal caries experience influences offspring's early childhood caries—a birth cohort study

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Abstract

Objective: To describe early childhood caries (ECC) patterns and evaluate the associations with maternal caries experience and other factors.

Methods: A secondary analysis was undertaken using data from the Study of Mothers' and Infants' Life Events Affecting Oral Health (SMILE), a population-based birth cohort study. It used data from 1040 mother/child dyads. Standardized oral examinations of the mothers and the children were conducted when children were 2-3 years old to determine the prevalence of ECC (main outcome) and maternal caries experience (main exposure variable). Maternal sociodemographic characteristics, time-restricting conditions (relationship status, work status and number of children in the household) and dental health behaviours (brushing frequency and sugary beverage consumption) served as covariates. Data on child dental health behaviours were collected at two years of age. Multivariable models were generated for ECC to estimate prevalence ratios (PR) for the association between ECC and maternal caries experience, controlling for the covariates.

Results: The prevalence of ECC among 2- to 3-year-old children was 10.6% (95%CI: 8.7%-12.5%). It was higher in children whose mothers had greater caries experience. Children whose mothers had higher caries experience had 86% (PR = 1.86 [1.27-2.72]) greater risk of having ECC than those whose mothers had low caries experience. Children whose teeth had not been brushed the night before had a higher risk of ECC (PR = 1.4 [1.01-1.9]) than their counterparts. Women born in Australia, New Zealand or the UK had offspring with lower risk of ECC.

Conclusions: Maternal caries experience was an independent risk factor for offspring ECC. However, good oral health behaviours practised by mothers for their children may alleviate such risk. Mothers need to be supported to adopt good oral health behaviours and a healthy diet for their child.

KEYWORDS

behaviour, early childhood caries, maternal caries experience

1 | INTRODUCTION

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Early childhood caries (ECC) represents one of the most common chronic diseases in infants and toddlers.¹ ECC is defined as the presence of one or more noncavitated, decayed, missing or filled tooth surfaces due to caries in any primary tooth in a child less than 5 years.² It leads to pain, chewing difficulties, speech problems, general health disorders, psychological problems and poorer quality of life.¹

Previous research has shown that diseases including ECC are caused by interaction between upstream and downstream determinants.^{3,4} Upstream economic and social determinants influence downstream determinants of ECC. Conversely, downstream determinants of ECC, such as unhealthy behaviours, may interact with the context of their upstream influences; for example, unhealthy behaviours such as eating less fruit and vegetables might be subject to upstream influences such as the absence of policy regulating the high price of fruit and vegetables.⁵

Parental health status and practices are recognized as the primary influence on children's health experience. Previous research supports the relationship between mothers' caries status and that of their children, 6-8 but the evidence is limited and most studies were of cross-sectional design. There are several well-supported pathways through which maternal caries status and its determinants can directly influence the offspring's oral health. Maternal caries experience is a likely indicator of their health knowledge and attitudes which are associated with family dietary choices and the extent of preventive behaviours of their children.^{6,8} Maternal caries experience is a result of interaction between societal determinants and their own health behaviours. Such interactions would continue to affect oral health of their offspring. Other possible pathways explaining the relationship of mothers' caries and ECC include an inoculation of cariogenic bacteria in which a mother passes mutans streptococci to her child, or genetic factors inherited by the child from the mother. 9-11 Dyadic pair studies of mother and offspring can enhance understanding of the relationship in order to inform relevant policies and practice guidelines to tackle the problem.

While the practices of both parents can influence a child's behaviour, 12 the mother has more influence on the offspring's development, possibly due to more time dedicated to child rearing. 13,14 However, some time-restricting conditions—such as being a single mother, a full-time working mother or having other children-may limit time mothers spend with very young children. Working mothers reported that they spent too little time with their children and had less time to care for their child and had higher stress than mothers who did not work. 15 Similarly, findings from Japan's 2011 National Survey of Households with Children revealed that time spent with children and the frequency of shared dinners are lower for single mothers than for their married counterparts. 16 All of these studies show that maternal time-restricting conditions can impact dedicated attention to and caring for young children, leading to poorer child oral health. It is expected that those maternal time-restrictive conditions could be eased under favourable social conditions.

Oral health-affecting behaviours, such as brushing frequency and sugar-sweetened beverage (SSB) consumption, are strong predictors for dental caries. A population-based survey in South Australia found that 35% of Australians are moderate consumers of SSB, while 16% are frequent consumers. Of Australian children, 14% are considered as high SSB consumers, while 66% are low-moderate consumers. These estimates are alarming, given the evidence that higher consumption of sugar-sweetened beverages (SSBs) is associated with metabolic dysfunction and greater dental caries experience. Auternal oral health behaviours might also influence children's behaviours and act as risk indicators for ECC. Amoreover, toothbrushing among very young children is mostly dependent on their mothers/primary caregivers.

The literature has emphasized the needs for prospective studies starting from the earliest possible age to provide information on maternal factors that could be targeted in order to prevent ECC. ^{2,23,24} The Study of Mothers' and Infants' Life Events Affecting Oral Health (SMILE), ²⁵ a comprehensive longitudinal birth cohort study following socioeconomically diverse South Australian young children, provided an opportunity to investigate the association between ECC and maternal caries experience, maternal sociodemographic factors, maternal time-restricting conditions, children's and maternal behavioural factors. Thus, this prospective study aimed to examine maternal caries experience as an independent risk factor for the offspring's early childhood caries. The findings could assist in targeting maternal factors in order to prevent ECC.



2 | MATERIALS AND METHODS

2.1 | Study population

The target population for the SMILE study was children born in Adelaide during the period from mid-2013 to mid-2014. All new mothers giving birth in the three major maternity hospitals in Adelaide, and who were sufficiently competent in English to be able to understand the description and instructions of the study, were invited to participate. Study methods, including sampling, study size, recruitment and data collection, are described in detail elsewhere.²⁵

2.2 | Data collection

The baseline questionnaire data were collected through face-to-face interviews at the time of recruitment, soon after the case child's birth. Additional questionnaires were completed when the child was aged 3, 6 and 12 months. When the children had turned 24 months of age, mothers also completed an additional questionnaire, and both the children and their mothers were invited to an oral examination by four trained and calibrated examiners, including two authors (LGD and DHH). All examiners were trained and calibrated by LGD in a two-day training session. Because

of children's young age, re-examinations were not conducted. Instead, examiners worked together as examiner/recorder pairs during the first stage to develop consistency. The examiners took turn to examine and discussed procedures and observations. Oral health assessment for the two-year-old children was conducted in the 'knee-to-knee' position and all teeth present were recorded. The oral examination was conducted based on visual inspection. Compressed air and two sources of light were used to assess five surfaces per tooth. Cavitated carious lesions, missing teeth due to caries and filled tooth surfaces due to caries could all be recorded, along with noncavitated (white spot) carious lesions. Oral health assessment for the mothers was conducted under similar conditions. The diagnosis of caries was based entirely on visual criteria, aided by compressed air.

2.3 | Data management

The dependent variable for this study was the prevalence of ECC at the age of 2 years, defined as the percentage of children who had at least one decayed, missing, filled or noncavitated tooth surface.² The main exposure of interest was maternal caries experience, defined as the number of decayed, missing and filled tooth surfaces (DMFS); this was used to categorize mothers into three caries experience groups: Low (≤5 DMFS); Medium (6-15 DMFS); and High (16 + DMFS). Other factors that served as covariates were collected through self-reported questionnaires at different child ages. These factors include maternal sociodemographic characteristics (age, level of education, income and country of birth taken from the baseline questionnaire soon after the child's birth), the child's dental health behaviour (whether or not mother brushed their child's teeth the night before, taken from the 24-month questionnaire), maternal behavioural factors (brushing frequency from the baseline questionnaire and consumption of sugary beverages from the 12-month questionnaire) and maternal time-restricting conditions (relationship status, work status and number of children in the family, all taken from the baseline questionnaire).

Maternal age was used as a continuous variable. Maternal education attainment was dichotomised into high school or vocational only vs university degree or above. Income was divided into less than A\$ 80 000 and A\$ 80 000 or above. Maternal country of birth was dichotomised into Australia, New Zealand and the UK vs other countries. Children's dental health behaviour was divided into brushing vs not brushing teeth the night before. Maternal brushing frequency and consumption of sugary beverages were dichotomised into brushing ≤1 times/d vs brushing 2 + times/d and consumed sugary beverages vs never consumed a sugary beverage during the previous week, respectively. In terms of maternal time-restricting conditions, maternal relationship status, work status and number of children in the family were all dichotomised (single/no partner vs living with partner/spouse; full-time employed vs part-time, self-employed, unemployed, home duties or pensioner; two or more children vs one child).

2.4 | Statistical analysis

The statistical analysis was performed in SAS version 9.4. Characteristics of all study participants and the final data set containing orally examined participants were initially analysed. The bivariate analysis of ECC by key characteristics was conducted, using the Kruskal-Wallis one-way ANOVA for the risk factor with three categories (mother caries experience) and the Mann-Whitney U test for the covariates with two categories because all distributions were not normal.

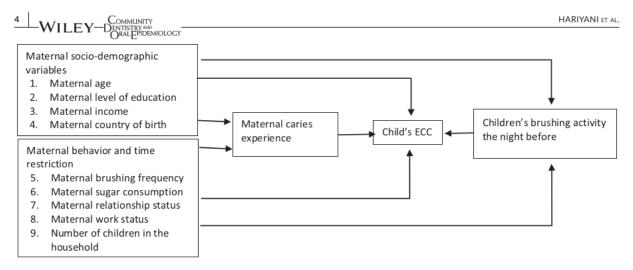
The multivariable analysis was conducted sequentially, following an underlying conceptual model presented in a directed acyclic graph (Figure 1). The first model included only the primary risk factor, mothers' caries experience, so that the unadjusted prevalence ratio (PR) could be obtained. Model 2 included maternal caries experience and maternal sociodemographic covariates. Model 3 did not include demographic covariates, but instead included child's brushing activity. Model 4 included maternal caries experience adjusted for mothers' behaviours and time-restricting conditions. Model 5 included maternal caries experience and all other covariates. Interaction between maternal brushing behaviour and child's brushing activity was also included. This interaction was tested because maternal brushing behaviour was found to be associated with the child's brushing activity. Based on Figure 1, it was conceptualized that maternal brushing behaviour led to the primary risk factor, mothers' caries experience, as well as child's brushing activity, and then subsequently to the primary outcome.

2.5 | Ethical review

Ethical approval was obtained from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC 50.13) and the Women and Children Health Network Human Research Ethics Committee (HREC/13/WCHN/69), Adelaide. Since this particular study was a secondary data analysis, new ethics clearance was not required.

3 | RESULTS

Some 2181 SMILE participants completed the baseline questionnaire, and 1040 mother-child dyads (47.7%) completed the oral examinations after the children had turned two years old. Table 1 shows the characteristics of study participants, comparing those who attended for an oral examination and those who did not. There was no difference between mothers who had the oral examination and those who did not in terms of maternal country of birth, timerestricting conditions and maternal or child behavioural factors. However, mothers who completed the oral examination were older (on average) and had a higher level of education and income than those who did not.



Models created include:

Model 1. Unadjusted model of Maternal caries and ECC

Model 2. Model of maternal caries and ECC adjusted with maternal socio-demographic variables

Model 3. Model of maternal caries and ECC adjusted with children brushing habit

Model 4. Model of maternal caries and ECC adjusted with maternal behavior and time restriction

Model 5. Model of maternal caries and ECC adjusted with all covariates

FIGURE 1 Directed acyclic graph of the analysis

Children's ages at the time of the oral examination ranged from 2 to 3 years of age (mean 2.5 years). The prevalence of early childhood caries among the children was 10.6% (95%CI: 8.7-12.5). Maternal caries experience ranged from 0 to 93 surfaces. The mean maternal DMFS score was 12.5 (95%CI: 11.7-13.3). Some 14.8% (95%CI: 12.6-17.0) of the mothers were caries-free, DMFS was zero.

The findings of the bivariate analysis are presented in Table 2. Higher maternal caries experience was associated with higher child ECC prevalence. Children of mothers born in Australia, New Zealand and the UK had lower ECC prevalence than those whose mother was born elsewhere.

The multivariable analysis of ECC prevalence is presented in Table 3. The unadjusted analysis showed that children of mothers with medium or high caries experience had higher prevalence of ECC than those with low caries experience. Children whose mothers had high caries experience had 2.27 times higher the risk of having ECC than those whose mothers had low caries experience. In all models, children of mothers with higher caries experience were more likely to have ECC. The adjusted prevalence ratios among children of mothers with high caries experience attenuated from the Model 1 to Model 5. However, the risk remained significant. Those children still had an 86% greater risk of having ECC than those whose mothers had low caries experience. Children whose teeth were not brushed the night before had a 46% greater risk of having ECC. Children of mothers born in Australia, New Zealand and the UK had lower risk of ECC than those whose mothers born elsewhere. None of the maternal time-restricting conditions included in the models were significantly associated with ECC experience. The interaction between maternal brushing behaviour and child brushing before bed was significant in the final model, and so it was retained.

4 | DISCUSSION

Our findings demonstrated a consistent association between maternal caries experience and the risk of offspring having ECC. Such an effect attenuated after controlling for maternal socioeconomic status and oral health behaviours. Child oral health behaviours were also risk factors for ECC. As the children were young, those behaviours were practised by people caring for the children, in this case their mothers. This fact further emphasizes the relationship between maternal behaviours and child oral health.

The finding that maternal caries experience was associated with their child's caries experience has been reported in previous studies. 6-8 Young children of mothers who have caries would be more likely to develop ECC due to multiple reasons, ranging from shared upstream socioenvironmental conditions to downstream factors such as transmission of *Streptococcus mutans* from mothers to offspring 10 via means such as shared eating utensils, sharing of health behaviours among family members 12 and potentially other reasons that were not measured in this study such as genotype and tooth morphology. A genetic predisposition coupled with exposure to environmental risk factors forms the basis for gene-environment interplay—that is, the situation where both genetic and environmental factors interact to influence health in individuals and populations. 9

Very young children are dependent on their mothers for their day-to-day care. Accordingly, early favourable dental health behaviours carried out by their mothers in this critical stage are very important in establishing their dental health. Our findings showed that mothers or other primary caregivers could reduce their offspring's risk of having ECC by brushing the child's teeth before bed from an early age. This finding supports evidence from

	All Participants	Orally examined participants
Risk Indicators	% [95%CI]	% [95%CI]
N	2181	1040
Outcomes		
Severity of ECC (mean[CI])		0.2 [0.04-0.3]
Prevalence of ECC		10.6 [8.7-12.5]
Exposure		
Mothers' caries experience (mean DMFS [CI])		12.5 [11.7-13.3]
Prevalence of mothers' caries experience		85.2 [83.0-87.4]
Range of maternal caries experience		0-93
Sociodemographic covariates		
Mothers' age (mean[CI])*	29.8 [29.5-30.0]	30.5 [30.2-30.8]
Maternal level of education *		
No university education	54.0 [51.9-56.1]	44.4 [41.3-47.4]
University degree or higher	46.0 [43.9-48.1]	55.6 [52.6-58.7]
Income*		
<au\$80k< td=""><td>53.9 [51.7-56.0]</td><td>45.9 [42.9-49.0]</td></au\$80k<>	53.9 [51.7-56.0]	45.9 [42.9-49.0]
≥AU\$80K	46.1 [44.0-48.3]	54.1[51.0-57.1]
Maternal country of birth		
Australia, New Zealand and the UK	73.0 [71.1-74.9]	75.1 [72.4-77.7]
Other countries	27.0 [25.1-28.9]	24.9 [22.3-27.6]
Child's behavioural covariates		
Brushing before bed the night before		
Yes	74.4 [71.9-76.9]	74.3 [71.6-77.0]
No	25.6 [23.1-28.1]	25.7 [23.0-28.4]
Maternal behavioural covariates		
Brushing frequency		
Brush ≤ 1 time a day	24.5 [22.6-26.3]	22.4 [19.9-25.0]
Brush > 1 time a day	75.5 [73.7-77.4]	77.6 [75.1-80.1]
Sugary beverage consumption		
Consumed sugary beverages (soft drink)	54.6 [51.8-57.3]	51.9 [48.6-55.2]
Never consume sugary beverages (soft drink)	45.4 [42.7-48.2]	48.1 [44.9-51.4]
Maternal time-restricting conditions		
Maternal relationship status		
With partner	92.0 [90.9-93.2]	94.0 [92.5-95.4]
Single/no partner	8.0 [6.8-9.2]	6.0 [4.6-7.5]
Maternal work status		
Full-time employed	36.5 [34.4-38.6]	39.4 [36.4-42.4]
Part-time, self-employed, unemployed, home duties, pensioner	63.5 [61.4-65.6]	60.6 [57.6-63.6]
Number of children in the household		
Two or more children	54.8 [52.7-57.0]	52. 8 [49.7-55.9]
One child	45.2 [43.0-47.3]	47.2 [44.1-50.3]

 $Abbreviations: 95\% CI, 95\% Confidence \ Interval; DMFS,, decayed, missing \ or filled \ tooth \ surfaces; N, Sample \ size.$

^{*}Significant



TABLE 2 Bivariate analysis of early childhood caries (ECC) with the explanatory variables

	Prevalence of early childhood caries	
Risk Indicators	%	[95%CI]
Maternal caries experience		
Low	6.8	[4.2-9.3]
Medium	10.5	[7.2-13.9]
High	15.3	[11.2-19.4]
Sociodemographic covariates		
Mothers' age		
<25 y old	10.5	[4.5-16.4]
25-34 y old	10.4	[8.2-12.6]
≥35 y old	10.8	[6.6-15.0]
Maternal level of education	25.3	
No university education	9.6	[6.9-12.3]
University degree or higher	10.8	[8.3-13.4]
Income		
<au\$80k< td=""><td>11.4</td><td>[8.5-14.3]</td></au\$80k<>	11.4	[8.5-14.3]
≥AU\$80K	9.3	[6.9-11.8]
Maternal country of birth		
Australia, New Zealand and the UK	8.3	[6.4-10.3]
Other countries	16.4	[11.8-21.0]
Child's behavioural covariates		
Brushing before bed the night before		
Yes	9.7	[7.6-11.9]
No	12.6	[8.5-16.6]
Maternal behavioural covariates		
Brushing frequency		
Brush ≤ 1 time a day	8.2	[4.7-11.8]
Brush > 1 time a day	11.0	[8.8-13.2]
Sugary beverage consumption	11.0	[0.0 10.2]
Consumed sugary beverages (soft drink)	9.6	[6.9-12.3]
Never consumed sugary beverages (soft drink)	10.1	[7.3-13.0]
Maternal time-restricting conditions	10.1	[7.0 10.0]
Maternal relationship status		
With partner	10.4	[8.5-12.3]
Single/no partner	11.3	[3.2-19.4]
Maternal work status	11.0	[0.2 17.4]
Full-time employed	9.7	[6.8-12.6]
•	10.8	[8.3-13.2]
Part-time, self-employed, unemployed, home duties, pensioner Number of children in the household	10.0	[0.3-13.2]
Two or more children	10.7	[9.1-12.4]
One child	10.7 10.1	[8.1-13.4] [7.4-12.8]

 ${\it Note:} \ {\it Bold:} \ {\it significant;} \ 95\% CI, \ 95\% \ {\it Confidence Interval.}$

previous research.^{26,27} Thus, to be able to reduce children's risk of caries, mothers and other primary caregivers need to adopt healthy oral health behaviours and become a good role model for their children. However, it is also possible that mothers who could brush the child's teeth before bed from an early age came from

better-off families which typically have more power and opportunities to live a healthy life than families that are less privileged. Thus, efforts to increase the autonomy of (and opportunities for) less privileged families would have a positive effect of reducing children's risk of caries.

TABLE 3 Multivariable model for ECC prevalence

	Early Childhood Caries (F	Early Childhood Caries (Prevalence of early childhood caries (DMFS prevalence)	aries (DMFS prevalence)		
	Model 1, crude model (unadjusted)	Model 2, adjusted for sociodemographic factors	Model 3, adjusted for child behavioural factors	Model 4, adjusted for maternal behaviour and brushing activities	Model 5, full model *
Risk indicators	PR [95% CI]	PR [95% CI]	PR [95% CI]	PR [95% CI]	PR [95% CI]
Mother caries experience					
Medium vs Low	1.56 [1.10-2.21]	1.59 [1.10-2.30]	1.53 [1.08-2.16]	1.45[1.00-2.11]	1.56 [1.06-2.29]
High vs Low	2.27 [1.63-3.15]	2.26 [1.59-3.22]	2.17 [1.56-3.02]	1.98 [1.38-2.84]	1.86 [1.27-2.72]
Sociodemographic					
Mothers' age		0.98 [0.96-1.01]			1.01 [0.97-1.04]
Maternal level of education (No university vs ref. University degree or higher)		1.06 [0.78-1.43]			1.15 [0.81-1.63]
Income (<au\$80k ref.="" td="" vs="" ≥au\$80k)<=""><td></td><td>0.93 [0.71-1.23]</td><td></td><td></td><td>1.10 [0.79-1.55]</td></au\$80k>		0.93 [0.71-1.23]			1.10 [0.79-1.55]
Maternal country of birth (Australia, New Zealand and the UK vs Other countries)		0.48 [0.36-0.65]			0.54 [0.38-0.77]
Child behavioural factor					
Brushing before bed the night before (No vs Yes)			1.32 [1.01-1.75]		1.46 [1.03-2.07]
Maternal behavioural factors					
Brushing frequency (brush ≤ 1 time a day vs Brush > 1 time a day)				0.42 [0.27-0.67]	0.63 [0.37-1.06]
Sugary beverage consumption (consumed SSB vs never consumed SSB)				1.04 [0.78-1.38]	1.00 [0.74-1.34]
Maternal time-restricting conditions					
Maternal relationship status (single/no partner vs with partner)				1.27 [0.70-2.31]	1.41 [0.76-2.59]
Maternal work status (full time vs part time, self-employed, unemployed, home duties)				1.00 [0.72-1.37]	1.03 [0.74-1.44]
Number of children in the household (two or more children vs One child)				1.18 [0.86-1.61]	1.03 [0.75-1.42]

Note: Bold: significant; Log Poison Regression model; PR: Prevalence Ratio; CI: 95% Confidence Interval. *: Mothers' age is continuous; Model adjusted for interaction between maternal brushing before bed was statistically significant.

Maternal country of birth plays an important role in the risk of ECC as our findings showed that children of mothers born in Australia, New Zealand and the United Kingdom have a lower risk of ECC. Women born in Australia, New Zealand or the UK might have experienced better socioeconomic conditions during their lives than women born elsewhere. Socioeconomic inequalities faced by immigrants can impact their general and oral health. 28,29 Immigration is a matter of serious concern in the pursuit of health and social justice. This could be related to type of foods or cooking methods preferred in each home country, which might contain hidden sugar. Our previous analysis of this same birth cohort reported substantial variation in the early introduction of foods and drinks high in free sugars,³⁰ with women who were born in other countries (particularly India) much more likely to do so than those born in Australia. Conditions which might restrict maternal time for caregiving (such as being a single and/or working mother or having more than one child) were not found in this study to be associated with ECC risk.

The strength of this study lies in its prospective study design and population-based study sample. Even though the dental examinations of mothers and children were effectively concurrent, the mothers' caries experience had accumulated over time; thus, their caries experience recorded at the examination was an effective proxy for their previous caries incidence. Further, most of the covariates were collected at the time of the child's birth, further ensuring the prospective nature of the design and analysis. Self-reporting of behaviour by the mothers could be subject to social desirability bias, which is another possible limitation, since respondents could have reported behaviours considered socially desirable or under-reported undesirable ones.31 Attrition is inherent in longitudinal research. The relatively lower retention rate among the low SES groups than the high SES groups was expected. More participants from the low SES groups have been enrolled in order to maintain adequate numbers of participants in the low SES groups in follow-up analysis. 25 While the younger and lower income mothers $\,$ failed to follow-up at a greater rate, the numbers in the followed-up sample were still adequate for the analysis.

Considering all of the findings, future policies or interventions should aim to reduce social inequality in order to reduce the burden of both maternal and child caries. If mothers and other primary caregivers of very young children are provided with opportunities and conditions to modify their oral health behaviours to favour protecting their offspring's oral health, the risk of ECC could be decreased. In order to achieve this, appropriate support should be provided to enable mothers of young children to enhance their awareness of healthy behaviours and practices, and to adopt healthy oral health behaviours and healthy diets for their children. The feasibility and effect of such interventions warrant future investigation.

5 | CONCLUSIONS

Maternal caries experience was associated with higher prevalence of ECC, after controlling for covariates. Modification of unfavourable maternal oral health behaviours towards healthy behaviours for their child may also reduce the risk of ECC. Mothers and other primary caregivers who care for young children require oral health information and support to consistently maintain good oral health behaviours and practise for themselves and their offspring.

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AUTHOR CONTRIBUTIONS

Ninuk Hariyani contributed to the conception of the article, data request, data cleaning, data analysis and interpretation, result interpretation and drafted the manuscript. Loc Giang Do, A John Spencer, W Murray Thomson and Jane A Scott contributed to the study design of SMILE, data acquisition, results interpretation and critically revised the manuscript. Diep H Ha contributed to the study design of SMILE, data acquisition, conception of the article, data analysis and interpretation, result interpretation and critically revised the manuscript. All authors gave final approval and agreed to be accountable for all aspects of the work.

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