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**AVALIAÇÃO DA RESPONSABILIDADE DO EARLY CHILDHOOD ORAL  
HEALTH IMPACT SCALE (ECOHIS) RELACIONADA À INCIDÊNCIA  
DE CÁRIE EM PRÉ-ESCOLARES – ESTUDO DE COORTE.**

Santa Maria, RS

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Trabalho de Conclusão de Curso  
apresentado ao curso de Odontologia da  
Universidade Federal de Santa Maria  
(UFSM, RS), como requisito parcial para  
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Orientador: Professor Dr. Thiago Machado Ardenghi

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**Aprovado em 28 de junho de 2016:**

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Santa Maria,RS  
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## RESUMO

### **AVALIAÇÃO DA RESPONSABILIDADE DO EARLY CHILDHOOD ORAL HEALTH IMPACT SCALE (ECOHIS) RELACIONADA À INCIDÊNCIA DE CÁRIE EM PRÉ-ESCOLARES – ESTUDO DE COORTE.**

AUTOR: Débora Menezes Lara

ORIENTADOR: Prof. Dr. Thiago Machado Ardenghi

O conceito de qualidade de vida relacionada à saúde bucal tem sido considerado um constructo multidimensional e refere-se ao impacto gerado pelas condições de saúde bucal nas atividades diárias, qualidade de vida e bem-estar dos indivíduos. As informações referentes à qualidade de vida relacionada à saúde bucal são mensuradas através de questionários denominados indicadores sócio-dentais. Especificamente para pré-escolares, o indicador mais utilizado é a escala *Early Childhood Oral Health Impact Scale* (ECOHIS). A versão brasileira do ECOHIS já foi validada e mostrou confiabilidade. Além dessas características, outro aspecto importante de um questionário é a responsividade, ou seja, sua capacidade de detectar diferenças importantes. Nosso objetivo foi, então, verificar a responsividade do ECOHIS, na sua versão brasileira, à incidência de cárie em crianças. Crianças em idade pré-escolar e seus responsáveis participaram deste estudo longitudinal. As crianças foram avaliadas quanto à cárie através do *International Caries Detection Assessment System* (ICDAS) tanto no exame inicial quanto no acompanhamento (dois anos depois). Pais/responsáveis responderam aos ECOHIS, da mesma forma, nos dois momentos. Mudanças no escore total do ECOHIS foram calculadas e a responsividade foi avaliada observando esses scores e a incidência de lesões de cárie. Modelos Multiníveis de Regressão de Poisson foram usados para verificar a associação entre incidência de cárie e piora na qualidade de vida relacionada à saúde bucal. Nós também avaliamos o risco relativo para piora na qualidade de vida considerando os domínios do ECOHIS, baseado na diferença na incidência de cárie. Depois de dois anos de acompanhamento, 352 crianças e seus responsáveis foram encontrados e reexaminados (73,6% de taxa de resposta). A incidência de cárie de 1 a 4 superfícies foi de 26,7% enquanto que a incidência de lesões de cárie em mais de 4 superfícies foi de 14,2%. Um total de 124 crianças mostrou piora na sua qualidade de vida relacionada à saúde bucal considerando qualquer mudança no escore do ECOHIS. A média (DP) de piora nos escores do ECOHIS foi de 1,2 (6,1). A incidência de cárie levou a um maior risco para piora na qualidade de vida relacionada a saúde bucal ( $p < 0,001$ ). A responsividade do ECOHIS à incidência de lesões de cárie foi observada uma vez que os escores mudaram com o aumento do número de lesões.

Palavras-chave: Cárie, Crianças, ECOHIS, incidência, OHRQoL,

## ABSTRACT

### **RESPONSIVENESS ASSESSMENT OF EARLY CHILDHOOD ORAL HEALTH IMPACT SCALE (ECOHIS) TO CARIES INCIDENCE IN PRESCHOOL CHILDREN – A COHORT STUDY.**

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ADVISER: Prof. Dr. Thiago Machado Ardenghi

Oral health-related quality of life has been considered a multidimensional construct. It refers to the impact caused by oral health conditions in the individual daily activities, quality of life and well-being. Information about oral health related quality of life are measured through questionnaires called socio dental indicators. Specifically for preschool children, the most used questionnaire is the Early Childhood Oral Health Impact Scale (ECOHIS). The Brazilian version of ECOHIS has already been validated and showed reliability. Besides these characteristics another important aspect of a questionnaire is its responsiveness. It is related with its ability in detect important differences. The aim of this study was to assess the responsiveness of the Brazilian version of Early Childhood Oral Health Impact Scale (B-ECOHIS) to incidence of caries lesions in preschool children. Parent-child pairs participated of this longitudinal study. Children were examined for dental caries based on the International Caries Detection Assessment System (ICDAS) and their parents completed the B-ECOHIS at baseline and follow-up (two years later). Changes in the total ECOHIS scores were calculated and the responsiveness was assessed by examining these scores and the incidence of caries lesions. Unadjusted and adjusted Poisson Regression models were used to verify the association between caries incidence and worsening in children oral health related quality of life. We also assessed the relative risk to worsening quality of life considering ECOHIS domains, based on different caries incidences. After two years of follow-up, 352 parent-child pairs were found and re-examined (73.6 % response rate). Caries incidence from 1 to 4 surfaces was 26.7%, while the incidence of caries lesions for more than 4 surfaces was 14.2%. A total of 124 children have showed worsening in their oral health related quality of life taking into account any change in the ECOHIS values. The mean (SD) of worsening in the ECOHIS scores were 1.2 (1.6). Incidence of caries led to a greater risk to worsening child oral health related quality of life ( $p < 0.001$ ). The responsiveness of B-ECOHIS to the incidence of caries lesions was observed, since the questionnaire scores have changed with the increase of caries lesions.

Key-words: Caries, Children, ECOHIS, incidence, OHRQoL.

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## 1 INTRODUÇÃO

A qualidade de vida das crianças pode ser influenciada por doenças e condições bucais que produzem sintomas que podem causar efeitos físicos, sociais e psicológicos (MCGRATH; BRODER; WILSON-GENDERSON, 2004). O conceito de qualidade de vida relacionada à saúde bucal (do inglês, *Oral health-related quality of life* - OHRQoL) tem sido considerado um constructo multidimensional e esse conceito refere-se ao impacto gerado pelas condições de saúde bucal nas atividades diárias, qualidade de vida e bem-estar dos indivíduos (LOCKER, 1988).

Esse constructo, para crianças, representa seus sentimentos e preocupações sobre sua própria saúde bucal (WEINTRAUB, 1998). Através de instrumentos utilizados para avaliar a qualidade de vida relacionada à saúde bucal é possível avaliar, também, o impacto das condições bucais no dia-dia de crianças e suas famílias (PAHEL; ROZIER; SLADE, 2007).

A cárie dentária tem demonstrado uma forte associação com qualidade de vida relacionada à saúde bucal. Crianças que apresentam lesões de cárie têm, em geral, maior probabilidade de apresentarem dor dentária, assim como preocuparem-se mais com sua condição de saúde bucal (PIOVESAN et. al., 2010). Os efeitos negativos da doença cárie incluem: dificuldade de mastigação, diminuição do apetite, perda de peso, dificuldade para dormir, alteração no comportamento (irritabilidade e baixa autoestima) e até diminuição no rendimento escolar (TESCH; OLIVEIRA; LEÃO, 2008).

As informações referentes aos aspectos de qualidade de vida relacionada à saúde bucal frequentemente são mensuradas através de questionários autoaplicáveis denominados indicadores sóciodentais (SLADE, 1998). Especificamente para as crianças pré-escolares, o indicador mais utilizado é a escala *Early Childhood Oral Health impact Scale* (ECOHIS) (PAHEL; ROZIER; SLADE, 2007). Atualmente, sua versão brasileira provou ser válida e confiável para avaliar o impacto negativo das condições bucais na qualidade de vida relacionada à saúde bucal de crianças brasileiras (Martins-Júnior et. al., 2012; SCARPELLI et. al. 2011; TESCH; OLIVEIRA; LEÃO, 2008).

Além de confiabilidade e validade, outra importante propriedade de um questionário é a sua responsividade ou capacidade de resposta. A responsividade é uma propriedade fundamental na escolha de um questionário para mensurar qualidade de vida relacionada à saúde bucal. Essa característica se refere à capacidade de um instrumento detectar uma mudança importante ou uma diferença clinicamente



significante. A responsividade é considerada uma propriedade importante para um questionário, especialmente quando o objetivo é avaliar o efeito de alterações nas condições clínicas de um paciente relacionadas a desfechos como a qualidade de vida (HYLAND, 2003).

Tendo em vista que, ao nosso conhecimento, a maior parte dos estudos tem avaliado a responsividade do *Early Childhood Oral Health Impact Scale* (ECOHIS) frente a algum tipo de tratamento e, que nenhum estudo realizou uma avaliação longitudinal da responsividade frente ao aumento do número de lesões de cárie, justifica-se a realização deste trabalho.

Dessa maneira, nosso objetivo foi verificar a responsividade do *Early Childhood Oral Health Impact Scale* (ECOHIS), na sua versão brasileira, à incidência de cárie em crianças através de um estudo longitudinal.

Esse trabalho será apresentado na forma de artigo científico, o qual foi redigido sob as normas da revista *Community Dentistry and Oral Epidemiology*.

## 2 ARTIGO

### Title Page

RESPONSIVENESS OF EARLY CHILDHOOD ORAL HEALTH IMPACT SCALE (ECOHIS) TO CARIES INCIDENCE IN PRESCHOOL CHILDREN – A COHORT STUDY.

ECOHIS responsiveness to caries incidence

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### *Abstract*

*Objectives:* The aim of this study was to assess the responsiveness of the Brazilian version of Early Childhood Oral Health Impact Scale (B-ECOHIS) to incidence of caries lesions in preschool children. *Methods:* Parent-child pairs participated of this longitudinal study. Children were examined for dental caries based on the International Caries Detection Assessment System (ICDAS) and their parents completed the B-ECOHIS at baseline and follow-up (two years later). Changes in the total ECOHIS scores were calculated and the responsiveness was assessed by examining these scores and the incidence of caries lesions. Unadjusted and adjusted Poisson Regression models were used to verify the association between caries incidence and worsening in children oral health related quality of life. We also assessed the relative risk to worsening quality of life considering ECOHIS domains, based on different caries incidences. *Results:* After two years of follow-up, 352 parent-child pairs were found and re-examined (73.6 % response rate). Caries incidence from 1 to 4 surfaces was 26.7%, while the incidence of caries lesions for more than 4 surfaces was 14.2%. A total of 124 children have showed worsening in their oral health related quality of life taking into account any change in the ECOHIS values. The mean (SD) of worsening in the ECOHIS scores were 1.2 (6.1). Incidence of caries led to a greater risk to worsening child oral health related quality of life ( $p < 0.001$ ). *Conclusions:* The responsiveness of B-ECOHIS to the incidence of caries lesions was observed, since the questionnaire scores have changed with the increase of caries lesions.

Key-words: Caries, Child, ECOHIS, OHRQoL.

### *Introduction*

Oral health-related quality of life (OHRQoL) has been considered a construct with multiple dimensions. It is related to the extent in which oral disorders affect daily function of individuals (1). Such construct is also intrinsically linked to overall health and well-being comprising a range of subjective experiences and symptoms related to an individual's self-perception of health (2). For children this construct represents their feelings and concerns about their own oral health (3). Moreover, by measuring child oral health related quality of life (COHRQoL) it is possible to assess the impact of oral health in daily life of children and their family (4).

There are a range of instruments used with the aim of evaluating aspects related to oral health related quality of life (5). These instruments have been developed and tested in different sample sets (6). Even having the same conceptual basis (7), its psychometric properties can vary at different contexts (8). Specifically for preschool children, the most used instrument is the Early Childhood Oral Health Impact Scale (ECOHIS) (4). Currently, its Brazilian version has been shown to be valid and reliable to assess the negative impact of oral conditions on quality of life of Brazilian children (9-11).

In addition to reliability and validity, another important property of a questionnaire is its responsiveness. This characteristic refers to the ability in detecting some important change or a clinically relevant change of an outcome (12). In this sense, it is possible to assess the internal and external responsiveness of an instrument. The internal responsiveness can be assessed by testing mean differences between two evaluations or by means of effect size statistics (13). One can also assess the external responsiveness using multiple linear regressions (13). Li and colleagues, in 2008, have evaluated the responsiveness of ECOHIS to dental treatment among a sample of Canadian children. In this study authors have found a limited responsiveness of the instrument (14). In a randomized controlled trial, Arrow, 2016, demonstrated a modest responsiveness of ECOHIS in a sample of children from Australia attending to a primary care for early childhood caries (ECC) treatment (15). Generally, studies that have evaluated the responsiveness of ECOHIS to dental treatment under general anesthesia have found good results for this scale (16, 17).

Most of studies assessing ECOHIS responsiveness have been based on its ability to detect changes after some dental treatment (15, 16, 18). So, it can not be assumed that those measures will necessarily be suitable to be used in the evaluation of observational

longitudinal study outcomes. The responsiveness is considered a key property of a questionnaire, especially when the aim is to assess the effect of changes in clinical conditions on patient reported outcomes such as quality of life (19).

We did not find studies that have evaluated the B-ECOHIS responsiveness to changes in clinical status in a cohort design. Therefore, our study was carried out with the aim of assessing the responsiveness of the B-ECOHIS to changes as a result of caries incidence in preschool children. We hypothesize that the Brazilian version of ECOHIS would be able to detect changes in oral health related quality of life of children due to their increased caries experience.

### *Material and Methods*

This study has a longitudinal design of 2 years of follow-up. We evaluated preschool children from Santa Maria, RS, a southern city of Brazil. The whole city population comprised 263,403 inhabitants, with 27,520 children under 6 years old (20). The study was approved by the local Committee for Ethics in Research, and children's parents signed the informed consent form for both phases of the study.

The first step of our study was an epidemiological survey conducted in 2010 during the Nacional Children's Vaccination Day. At this data collect 478 children (1 to 5 years old) were examined by a team of fifteen trained and calibrated post-graduate examiners. Sample size calculation was based on the average of ECOHIS score of 2.1 (SD 3.8) for unexposed group (better OHRQoL), and 5.1 (SD 6.9) for exposed group (worse OHRQoL) (21). The ratio of exposed to non-exposed group was 1:1. We also adopted a standard error of 5% and a 95% confidence interval (CI). Once this survey was based on a two stage sampling, the design effect of 1.6 was considered. Furthermore, to prevent losses for non-response we added 20% to the final sample size. The necessary minimum sample size was 215 children. As this study, at that moment, was part of a survey with other outcomes the final sample recruited was greater than the minimum required.

The examinations were performed and the questionnaires were applied at 15 (of the 28 possible) health centers. The centers were randomly selected and distributed through the 5 administrative regions of the municipality. After examinations, all children with self-perceived or normative dental necessities were directed to receive treatment at the Pediatric Dentistry Clinic of Federal University of Santa Maria.

The second evaluation was carried out between May 2012 and February 2013, nearly two years later. All children surveyed in 2010 were considered eligible and were

sought. Our first strategy to find the children was making telephone calls, based on the numbers recorded in 2010. Then, we invite participants to attend the Pediatric Dentistry Clinic of University for re-examination. As this strategy has failed to find most of children, our second choice was search and assess children at their own home. Four examiners that participated of the 2010 survey were trained and calibrated again with the aim to re-examine the children (22).

Child Oral Health-Related Quality of Life was assessed by the Brazilian version of Early Childhood Oral Health Impact Scale (ECOHIS) (4, 9, 11), both in the first and the second evaluation. The questionnaire is divided in two main sections. The Child section is the first one and comprises 9 questions that measures child symptoms, child function, child psychology and child self-image (social interaction). The family impact is measured by 4 questions related to family distress and family function. Each of these 13 questions can be answered using a simple five-point Likert scale. The answers can vary from 0 = “never” to 4 = “very often”. At the end a total score is calculated as the sum of values obtained in each answer. For questionnaires with up 2 missing responses in the first (child) section and 1 in the second (family) section, we have imputed a score for missing items that represents an average of the remaining items for that section (4). The scores can vary from 0 to 52. As higher is the ECOHIS score, greater is the impact on COHRQoL.

In addition to the ECOHIS, children’s parents also answered another questionnaire related to demographic and socioeconomic characteristics. We have assessed individual features such as age (12-23 months, 24-35 months, 36-47months and 48-59 months) and sex (male or female). Questions related to parental education (>8 years, ≤8 years) and household income (less than 1 Brazilian Minimal Wage – BMW, 1.0-1.9 BMW, 2.0-2.9 BMW and 3.0 or more BMW) were also recorded.

Clinical examinations were performed at baseline and at the follow-up. The following conditions were assessed: dental plaque (presence or absence)(23), dental caries (based on International Caries Detection Assessment Sistem – ICDAS)(24), dental injuries (25) and dental malocclusion(26). All examiners for both, baseline and follow-up exams, were trained and calibrated according to each criteria.

Cohen’s Kappa coefficients were calculated previous to both phases of the study to measure inter and intra-examiner agreement. For dental caries examination at the baseline, the intra-examiner reproducibility varied from 0.77 to 0.94 and

interexaminer agreement from 0.86 – 0.92. At the follow-up this values ranged from 0.85 – 0.96 and 0.91 – 0.95, respectively.

Statistical analyses were performed using the Stata.12 software (Stata Corporation; College Station, TX, USA). Descriptive analyses were carried out to describe demographic and socioeconomic characteristics of the sample. Unadjusted and adjusted Multilevel Poisson Regression models were used to define associations between OHRQoL and predictor variables. The ECOHIS scores were used as a quantitative outcome (mean and standard deviation) variable and also as a qualitative one (worsening in quality of life: yes or no).

In the multilevel analysis the time of follow-up represented the first level and children were considered the second one. This analysis have been considered appropriated by consider the variance in each level. With this analytical approach, we estimate relative risk for worsening OHRQoL and the respective 95% confidence intervals (95% CI) were calculated. With the Poisson Regression Analysis we also estimate the Relative Risk of increasing ECOHIS scores depending on the caries incidence (1 to 4 new caries lesions or more than 4 new caries lesions). The Effect Size (ES) was also estimated through the rate of value obtained by subtracting follow-up and baseline ECOHIS means and standard deviation of mean ECOHIS score at baseline (27).

### *Results*

In our study a total of 352 parent-child pairs were found and re-examined (73,6 % response rate). The followed participants and those that were not found have comparable baseline characteristics. Losses were mainly due to our inability to find the children. From our current sample 52.3% were girls. The distribution of children related to their age was presented in table 1. Most of them had more than 36 months of age at the follow-up. Most of their parents/guardians had at least the formal instruction ( $\geq 8$  years); 63.5% of the subjects earned less than two Brazilian minimum wages, while 36.5% were in the richest level of income. Related to caries experience at the baseline, 32.3% of children did not have caries lesions. The prevalence of decayed surfaces with initial lesions was 34.1%, whereas the prevalence of at least one moderate and severe lesion was 8.5% and 25.3%, respectively. The incidence of 1 to 4 surfaces with caries lesions was 26.7%, while the incidence of caries lesions for more than 4 surfaces was 14.2%. All the descriptive results are shown in table 1.

From the total re-examined sample, 124 children showed worsening in their oral health-related quality of life taking into account any change in the ECOHIS values after two years. The mean (SD) of worsening in the ECOHIS scores obtained by subtracting values of the re-exam and baseline were 1.2 (6.1). Table 2 shows the distribution of children according to explanatory variables and the occurrence of worsening or not in the quality of life after two years follow-up. This table also shows the means of worsening in the ECOHIS scores for different categories of studied variables.

In the unadjusted analysis the total ECOHIS score at the baseline, the caries experience at the baseline and the incidence of caries lesions were associated to worsening in children's oral health-related quality of life (COHRQoL). Caries incidence showed an association when considered as a quantitative variable and also when considered a qualitative one. Other variables such as sex, age, household income and parental education did not show statistical significance in the unadjusted model (Table 3). In terms of magnitude of change, the effect size was 0.4 for the total ECOHIS score.

In the multiple model we used only the categorized variable of caries incidence. Thereby, children with higher ECOHIS scores at baseline showed a lower risk of worsening after two years. However, children that has 1 to 4 and those with more than 4 new caries lesions demonstrated a significant risk two and three times greater to worse their oral health related quality of life, respectively. Both comparisons were made with children who did not present incidence of caries lesions after two years. Children's experience of caries lost statistical significance in the multiple model and then was not retained (Table 3).

The outcome considered in the results shown in table 3 was the values obtained by subtraction between final and baseline scores of ECOHIS. These values were normalized to become greater than or equal to zero to perform the Poisson Regression analysis. It was observed a significant association in the unadjusted analysis with values of total ECOHIS at the final exam and caries incidence. These variables were also associated in the adjusted analysis. The lower the ECOHIS score, the greater the risk for worsening oral health related quality of life. The greater the number of new caries lesions, the greater the risk for worsening (Table 3).

We also performed analyses for different ECOHIS domains considering worsening or not in each one. It has been observed that children that had 1 to 4 surfaces with new caries lesions presented greater risk for worsening quality of life at all domains compared to children without new caries lesions after two years. This pattern



was not seen only for one domain: child self-image/ social interaction. Risk Relative values ranged from about two to three. However, for children that had developed more than 4 new caries lesions there were a significant worsening for all domains. The Relative Risk in those cases ranged from three to five times more when compared to risk for those children without new caries lesions (Table 4).

### *Discussion*

In our study we have evaluated the B-ECOHIS responsiveness to changes in clinical status such as incidence of caries lesions. The B-ECOHIS is a validated instrument used to assess oral health related quality of life of children between 0-5 years and their families (9, 10). Caries experience at baseline can be considered high (68%). This number was greater than those observed in national level studies (28). However, it could have occurred because we took into account initial caries lesions, instead of considering cavitated lesions only. The rate of caries incidence was 40.1% (Table 1). Our results showed that increasing incidence of caries lesions have led to a worsening ECOHIS scores in children after two years of follow-up. Those with greater number of new caries lesions have also a greater risk of worsening oral health related quality of life than children without new lesions.

A limitation in our study refers to our inability in follow all participants recruited at the baseline. The main reason for that was we could not find and then invite the children and their parents to be part of the study again (n=112). Other reasons were: refusal to participate (n=10), and improper filling of questionnaire (n=4). However, participants that were not reassessed were quite similar to those followed in terms of baseline characteristics.

In our analysis, we used dental caries variables (quantitative and qualitative) and its changes over time to evaluate the responsiveness of ECOHIS in detecting such changes. We chose to use caries measures based on the fact that this predictor have shown a strong association with oral health related quality of life measures (29-31). Piovesan and colleagues, 2011, in a cross-sectional study with Brazilian children-parent pairs showed that parents of children with caries experience have an increased prevalence ratio of relating poor perception of child's oral health (32). Moreover, Guedes et. al, 2016 showed that children with moderate and severe caries lesions have a greater impact on their oral health related quality of life than those with initial caries lesions only (31). Similarly, several studies with different samples and designs have already demonstrated the association of caries and OHRQoL(29, 33, 34).

Studies have already tested some ECOHIS properties such as validity and reliability (9-11). Related to its responsiveness, there are some controversial results. Abanto and colleagues, 2015, conducted an observational study to assess the ECOHIS responsiveness to a dental treatment on a sample of 3 to 5-year-old Brazilian children. In that study authors also considered participants with non-cavitated lesions. The responsiveness analysis showed that improvements in children oral health after treatment led to an increase in differences in total mean, and by domains scores of ECOHIS post and pre-treatment. The results demonstrated that the B-ECOHIS was responsive to the treatment (35). In contrast, our results demonstrated that the effect size (0.4) ranged from “low” to “moderate” for ECOHIS (36). Agreeing with us, Arrow, 2016, studying a sample of Australian children who sought for dental treatment of early childhood caries showed that the responsiveness of the ECOHIS to this type of treatment was modest (15).

In our Multilevel Poisson Regression analysis we demonstrated the external responsiveness of the ECOHIS. In the adjusted model, the incidence of caries lesions remained associated with worsening in oral health related quality of life, while other factors such as, sex, age, parental education and household income did not show statistical significance. When most of studies have analyzed the responsiveness to dental treatment (14-16), we demonstrated the ECOHIS responsiveness to an increase of caries lesions with a population sample of children.

The changes in both two sections of the scale (Child and Family sections) were statistically consistent, except for one domain. In the Child section, the self-image (social interaction) domain was not significant for children with 1 to 4 new caries lesions. On the other hand, Arrow, 2016, has found changes for both sections and all domains statistically significant after dental treatment (15). In contrast to these findings, Li and colleagues, 2008, did not find statistically significant differences between post and pre-treatment ECOHIS scores. In their study, the authors evaluated a convenient sample of children who sought for treatment (14). These differences between our study and other must be due to different designs, and goals. Our aim was not detect the ECOHIS responsiveness to a treatment, but to changes in clinical status (caries incidence).

To the best of our knowledge, most of studies assessing responsiveness of patient related outcomes, and especially for the ECOHIS questionnaire, have used convenient samples (15-17). Furthermore, these studies have evaluated responsiveness

of this instrument related to treatments. In our study we used a representative sample that allow us, with some caution, make inferences for the targeted population. Furthermore, although responsiveness of ECOHIS has already been assessed in preschool children, it has been argued that this property must be evaluated in different samples since it could vary in different populations and contextual features (37).

In conclusion, the Brazilian version of ECOHIS demonstrated to be responsive to caries incidence in a sample of children. Although we have found an effect size ranging from low to moderate, this magnitude must be considered. It is applied mainly due to the fact that we have assessing a subjective outcome such as COHRQoL. Our study brings important information to scientific community and also to the targeted population. As responsiveness can vary from different populations and contexts (37) we also suggest that further studies would be necessary considering other populations and changes in other oral health outcomes.

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**Table 1** – Demographic, social and clinical characteristics of the preschooler sample from Santa Maria, RS, Brazil.

Individual Variables	n/mean	%
<b>Sex</b>		
Boys	168	47.7
Girls	184	52.3
<b>Age</b>		
12 to 23 months	57	16.2
24 to 35 months	59	16.8
36 to 47 months	88	25
48 to 59 months	148	42
<b>Household Income</b>		
< 1 BMW*	70	20.8
1to 1,99 BMW	144	42.7
2to 2,99 BMW	57	16.9
≥ 3 BMW	66	19.6
<b>Mother's education</b>		
≥ 8years	182	53.2
< 8 years	160	46.8
<b>Father's education</b>		
≥ 8years	171	51.8
< 8 years	159	48.2
<b>Caries experience at baseline</b>		
Without lesions	113	32.1
Initial Lesion only	120	34.1
At least 1 moderate lesión	30	8.5
At least 1 severe lesión	89	25.3
<b>Caries Incidence (qualitative variable)</b>		
Without new caries lesions	208	59.1
1 to 4 surfaces with caries lesions	94	26.7
More than 4 surfaces with caries lesions	50	14.2

\*BMW: Brazilian Minimum Wage: nearly \$325.96.

**Table 2** – Distribution of children that presented worsening in oral health-related quality of life (OHRQoL) and differences between re-exam and baseline measures of values from Early Childhood Oral Health Impact Scale (ECOHIS) according to explanatory variables assessed. Santa Maria, RS, Brazil.

Explanatory variables	Worsening in OHRQoL		Differences in the ECOHIS values
	No	Yes	Mean (SD)
<b>Sex</b>			
Boys	105 (62.5)	63 (37.5)	1.14 (6.37)
Girls	123 (66.8)	61 (33.4)	1.20 (5.88)
<b>Age</b>			
12 to 23 months	41 (71.9)	16 (28.1)	0.70 (4.54)
24 to 35 months	37 (62.7)	22 (37.3)	1.36 (6.71)
36 to 47 months	60 (68.2)	28 (31.8)	1.43 (5.39)
48 to 59 months	90 (60.8)	58 (39.2)	1.12 (6.79)
<b>Household Income</b>			
Less than 1 BMW	47 (67.1)	23 (32.9)	1.41 (6.65)
From 1 to 1.99 BMW	97 (67.4)	47 (32.6)	0.91 (6.46)
From 2 to 2.99 BMW	33 (57.9)	24 (42.1)	0.88 (6.05)
3 or more BMW	41 (62.1)	25 (37.9)	1.97 (4.89)
<b>Mother's education</b>			
8 years or more	119 (63.6)	68 (36.4)	1.00 (4.52)
Less than 8 years	105 (65.6)	55 (34.4)	1.45 (7.60)
<b>Father's education</b>			
8 years or more	117 (68.4)	54 (31.6)	1.00 (4.52)
Less than 8 years	98 (61.6)	61 (38.4)	1.45 (7.60)
<b>Caries experience at baseline</b>			
without caries lesions	81 (71.7)	32 (28.3)	0.58 (3.73)
Initial lesions only	85 (70.8)	35 (29.2)	1.10 (5.01)
At least one moderate lesion	13 (43.3)	17 (56.7)	2.37 (8.27)
At least one severe lesion	49 (55.1)	40 (44.9)	1.61 (8.58)
<b>Total ECOHIS at baseline</b>			
Mean (SD)	2.6 (5.1)	1.2 (3.1)	-
<b>Time between baseline and follow-up (quantitative variable in days)</b>			
Mean (SD)	856.1 (97.9)	837.1 (89.7)	-
<b>Caries incidence (quantitative variable)</b>			
Mean (SD)	1.4 (3.3)	3.2 (4.4)	-
<b>Caries incidence (qualitative variable)</b>			
Without new caries lesions	158 (76.0)	50 (24.0)	0.28 (4.15)
1 to 4 surfaces with caries lesions	50 (53.2)	44 (46.8)	1.44 (6.38)
More than 4 surfaces with caries lesions	20 (40.0)	30 (60.0)	4.36 (10.17)

SD = standard deviation; BMW = Brazilian Minimum Wage



**Table 3** – Unadjusted and Adjusted Poisson Regression Analysis of association between explanatory variables and worsening in oral health-related quality of life (OHRQoL) (dichotomous variable) evaluated by the Early Childhood Oral Health Impact Scale (ECOHIS). Santa Maria, RS, Brazil.

Explanatory variables	Worsening in OHRQoL			
	RR unadjusted (95% CI)	P	RR adjusted (95% CI)	P
<b>Sex (ref.: boys)</b>		0.394		
Girls	0.88 (0.67 to 1.17)			
<b>Age (ref.: 12 to 23 months)</b>		0.437		
24 to 35 months	1.33 (0.78 to 2.26)			
36 to 47 months	1.13 (0.68 to 1.90)			
48 to 59 months	1.40 (0.88 to 2.22)			
<b>Household Income(ref.: Less than 1 BMW)</b>		0.560		
From 1 to 1.99 BMW	0.99 (0.66 to 1.50)			
From 2 a 2.99 BMW	1.28 (0.81 to 2.01)			
3.99 or more BMW	1.15 (0.73 to 1.82)			
<b>Mother's education (ref.: &gt; 8 years)</b>		0.700		
≤8 years	0.95 (0.71 to 1.26)			
<b>Father's education (ref.: &gt; 8 years)</b>		0.198		
≤8 years	1.21 (0.90 a 1.63)			
<b>Caries experience at baseline (ref.: children without caries lesions)</b>		0.001		
Initial caries lesions only	1.03 (0.69 to 1.54)			
At least one moderate caries lesion	2.00 (1.30 to 3.07)			
At least one severe caries lesion	1.59 (1.09 to 2.31)			
<b>Total ECOHIS at baseline (quantitative variable)</b>	0.92 (0.86 to 0.99)	0.021	0.90 (0.84 to 0.97)	0.004
<b>Time between baseline and follow-up (days) (quantitative variable)</b>	1.00 (0.99 to 1.00)	0.066	1.00 (1.00 to 1.00)	0.164
<b>Caries incidence (quantitative variable)</b>	1.06 (1.03 to 1.09)	<0.001		
<b>Caries incidence (qualitative variable) (ref.: without caries lesions)</b>		<0.001		
1 to 4 surfaces with caries lesion	1.95 (1.41 to 2.69)		2.08 (1.51 to 2.85)	<0.001
More than 4 surfaces with caries lesion	2.50 (1.79 to 3.48)		2.96 (2.16 to 4.06)	<0.001

RR = Relative Risk; 95% CI = Confidence Interval at 95%; BMW = Brazilian Minimum Wage

**Table 4** – Adjusted Poisson Regression Analysis of association between caries incidence and worsening oral health-related quality of life (OHRQoL) of each domain of Early Childhood Oral Health Impact Scale (ECOHIS). Santa Maria, RS, Brazil.

ECOHIS domains	Relative Risk *	
	(Confidence Interval at 95%)	
	1 to 4 surfaces with caries**	More than 4 surfaces with caries**
Children section		
Symptoms	2.44 (1.58 to 3.76)	4.27 (2.83 to 6.45)
Functional Limitation	1.94 (1.14 to 3.32)	2.99 (1.70 to 5.23)
Psychological Limitation	2.69 (1.45 to 5.01)	4.90 (2.66 to 9.02)
Self-image/Social interaction	1.52 (0.50 to 4.60)	4.48 (1.65 to 12.14)
Family Section		
Parental Stress	2.94 (1.56 to 5.54)	4.45 (2.30 to 8.61)
Familiar Function	2.26 (1.52 to 3.35)	3.39 (2.29 to 5.01)

\* values adjusted by time between examinations and total ECOHIS score at baseline.

\*\* Referential category: Children without new caries lesions.

## CONSIDERAÇÕES FINAIS

Este estudo avaliou a responsividade da versão brasileira do *Early Childhood Oral Health Impact Scale* (ECOHIS) relacionada à incidência de cárie em pré-escolares da cidade de Santa Maria, RS, Brasil. Através de nossas análises foi possível observar que, embora o tamanho do efeito detectado pelo ECOHIS para a piora na qualidade de vida relacionada à saúde bucal em função da incidência de cárie tenha variado de baixo para moderado, ainda assim o questionário foi responsivo frente à incidência de cárie. Houve um risco maior de piora na qualidade de vida relacionada à saúde bucal para crianças que tiveram maior número de novas lesões de cárie.

A maioria dos trabalhos que estudaram a responsividade do ECOHIS utilizaram amostras de conveniência e avaliaram esta característica frente a tratamentos odontológicos (ARROW, 2016; ALMAZ, et. al. 2014; MALDEN, et. al. 2008). Em nosso estudo avaliamos a responsividade à incidência de cárie, em um estudo longitudinal e em uma amostra representativa da população de crianças.

Em nossas análises estatísticas, a incidência de cárie manteve-se associada à piora na qualidade de vida relacionada à saúde bucal mesmo considerando fatores como sexo, idade, escolaridade dos pais e renda familiar. Foi possível observar, também, que todos os domínios do questionário, na sessão da criança e na sessão da família, demonstraram um maior risco para maiores escores em relação à incidência de cárie.

Uma limitação que pode ser apontada em nosso estudo é o fato de não termos conseguido acompanhar todas as crianças avaliadas no início do estudo. A principal razão para isso foi não termos encontrado esses participantes nos endereços registrados nas fichas da primeira avaliação. No entanto, nossas análises demonstraram que os participantes que não puderam ser reavaliados eram semelhantes aos que foram seguidos em relação às características iniciais. Dessa forma, podemos, com cautela, inferir nossos resultados para a referida população.

Dessa maneira, concluímos que a versão brasileira do ECOHIS foi responsiva à incidência de cárie em crianças. Embora o tamanho do efeito para detectar as diferenças tenha variado de baixo a moderado, essa magnitude deveria ser considerada, principalmente, por estarmos trabalhando com desfechos subjetivos de saúde como qualidade de vida. Nossos resultados trazem informações importantes tanto para a comunidade científica quanto para a população estudada. Uma vez que a responsividade pode variar de acordo com diferentes populações e contextos (REVICKI, et. al. 2006),

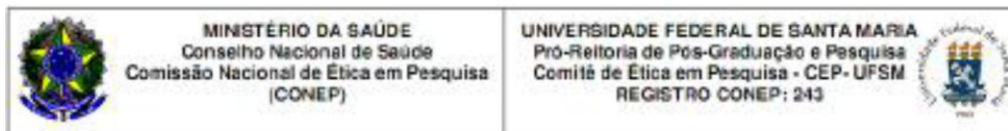
nós sugerimos que outros estudos, também, seriam necessários considerando outras populações e mudanças em outros aspectos clínicos além da incidência de cárie.

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## ANEXO

**Anexo A** – Carta de Aprovação do Comitê de Ética em Pesquisa da Universidade Federal de Santa Maria referente a primeira etapa da pesquisa.



## CARTA DE APROVAÇÃO

O Comitê de Ética em Pesquisa – UFSM, reconhecido pela Comissão Nacional de Ética em Pesquisa – (CONEP/MS) analisou o protocolo de pesquisa:

**Título:** Associação da presença e atividade de lesões de cárie em dentes deciduos com indicadores de risco biológicos e socioeconômicos

**Número do processo:** 23081.015059/2009-91

**CAAE (Certificado de Apresentação para Apreciação Ética):** 0270.0.243.000-09

**Pesquisador Responsável:** Thiago Machado Ardenghi

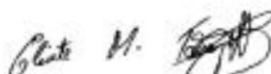
Este projeto foi APROVADO em seus aspectos éticos e metodológicos de acordo com as Diretrizes estabelecidas na Resolução 196/96 e complementares do Conselho Nacional de Saúde. Toda e qualquer alteração do Projeto, assim como os eventos adversos graves, deverão ser comunicados imediatamente a este Comitê. O pesquisador deve apresentar ao CEP:

Janeiro / 2011- **Relatório final**

Os membros do CEP-UFSM não participaram do processo de avaliação dos projetos onde constam como pesquisadores.



**DATA DA REUNIÃO DE APROVAÇÃO:** 15/12/2009

Santa Maria, 29 de Dezembro de 2009.



Elisete Medianeira Tomazetti  
Coordenadora do Comitê de Ética em Pesquisa-UFSM  
Registro CONEP N. 243.

**Anexo B** – Adendo do Comitê de Ética em Pesquisa da Universidade Federal de Santa Maria para a realização da segunda parte da pesquisa.

	<b>MINISTÉRIO DA SAÚDE</b> Conselho Nacional de Saúde Comissão Nacional de Ética em Pesquisa (CONEP)	<b>UNIVERSIDADE FEDERAL DE SANTA MARIA</b> Pró-Reitoria de Pós-Graduação e Pesquisa Comitê de Ética em Pesquisa - CEP - UFSM REGISTRO CONEP: 243	
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exames clínicos e entrevistas estruturadas com os responsáveis. Análise multinível será realizada para verificar a associação entre as variáveis preditoras com os diferentes desfechos.

**CONSIDERAÇÕES** (Comentários gerais sobre o projeto: coerência dos objetivos, experiência dos autores, fundamentação teórica, amostragem, sujeitos, métodos, riscos e benefícios, privacidade e confidencialidade dos dados, TCLE. Apresentar as ponderações e recomendações.)

O projeto apresenta revisão de literatura e justificativas satisfatórias para a sua realização. A metodologia descrita é similar a um projeto previamente aprovado pelo CEP-UFSM e conduzido pelo grupo de pesquisa estando bem descrita. A mesma inclui em detalhes as questões éticas relacionadas ao projeto uma vez que a amostra do estudo são crianças entre 3 a 5 anos de idade. O Termo de Consentimento Livre e Esclarecido está bem redigido e dentro das normativas da Resolução 196/1996. A documentação pertinente está completa

**ATENDIMENTO ÀS PENDÊNCIAS** (Em caso de protocolo Pendente, apontar a data do parecer e comentar o atendimento as questões recomendadas.)

Seu pedido de extensão de cronograma foi avaliado e obteve parecer favorável em 20/03/2012.

<b>PARECER</b>	
<b>SITUAÇÃO</b>	<b>Aprovado</b>

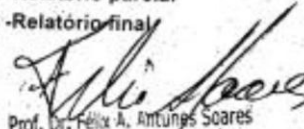
#### OBSERVAÇÕES FINAIS

1 - De acordo com a Resolução CNS 196/96, as pendências devem ser respondidas pelo pesquisador responsável no prazo máximo de 60 (sessenta) dias, a partir da data de envio do parecer pelo CEP. Após este prazo o protocolo será considerado retirado e havendo interesse deve-se reiniciar o processo de registro de um novo protocolo.

2 - O pesquisador deve apresentar ao CEP:

Janeiro/2013 -Relatório parcial

Janeiro/2014 -Relatório final

  
 Prof. Dr. Félix A. Antunes Soares  
 Coordenador do Comitê de Ética  
 em Pesquisa - UFSM

### Anexo C – Early Childhood Oral Health Impact Scale (ECOHIS)

“Problemas com dentes, boca ou maxilares (ossos da boca) e seus tratamentos podem afetar o bem-estar e a vida diária das crianças e suas famílias. Para cada uma das seguintes questões perguntadas pelo entrevistador, por favor, indique no quadro de opções de resposta a que melhor descreve as experiências da sua criança ou a sua própria. Considere toda a vida da sua criança, desde o nascimento até agora, quando responder cada pergunta”. Marque somente UMA OPÇÃO EM CADA PERGUNTA.

OPÇÕES DE RESPOSTA:					
0 = Nunca	1 = Quase Nunca	2 = As vezes (de vez em quando)	3 = Com frequência	4 = Com muita frequência	5 = Não sei
<b>PERGUNTAS</b>					
1. Sua criança já sentiu dores nos dentes, na boca, ou nos maxilares (ossos da boca)?					
2. Sua criança já teve dificuldade em beber bebidas quentes ou frias devido a problemas com os dentes ou tratamentos dentários?					
3. Sua criança já teve dificuldade para comer certos alimentos frios devido a problemas com os dentes ou tratamentos dentários?					
4. Sua criança já teve dificuldade de pronunciar qualquer palavra devido a problemas com os dentes ou tratamentos dentários?					
5. Sua criança já faltou a creche, jardim de infância ou a escola devido a problemas com os dentes ou tratamentos dentários?					
6. Sua criança já teve dificuldades de dormir devido a problemas com os dentes ou tratamentos dentários?					
7. Sua criança já ficou irritada devido a problemas com os dentes ou tratamentos dentários?					
8. Sua criança já evitou sorrir ou rir devido a problemas com os dentes ou tratamentos dentários?					
9. Sua criança já evitou falar devido a problemas com os dentes ou tratamentos dentários?					
10. Você ou outra pessoa da família já ficou aborrecida devido a problemas com os dentes ou tratamentos dentários de sua criança?					
11. Você ou outra pessoa da família já se sentiu culpada devido a problemas com os dentes ou tratamentos dentários de sua criança?					
12. Você ou outra pessoa da família já faltou ao trabalho devido a problemas com os dentes ou tratamentos dentários de sua criança?					
13. Sua criança já teve problemas com os dentes ou fez tratamentos dentários que causaram impacto financeiro na sua família?					



