DEVELOPMENT AND VALIDATION OF A PEDIATRIC DENTAL SCREENING INSTRUMENT

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ABSTRACT

A study to develop and validate a parent-administered dental screening instrument for 15-48 month-old children was undertaken. This was intended to serve as an oral health companion to the Nipissing District Developmental Screens (NDDS) for the early identification of children at risk for or having dental caries (oral diseases and/or disorders).

Methods: Questions for the screening instrument were generated in two stages: 1) through a review of relevant clinical literature, and 2) by an expert panel. The instrument was pre-tested using a convenience sample of parents of 18-21 month-old children and validated using a convenience sample of 15 to 48 month-old children. All were recruited from Public Health Department settings. Clinical data was obtained from dental screening examinations. The sensitivity, specificity and discriminant validity of the instrument was tested by investigating the associations between parental responses to questions comprising the instrument and the "gold standard" represented by the results of clinical examinations of their children.

Results: Seven questions enquiring about feeding and oral hygiene practices along with anticipatory guidance for parents for these questions were developed and completed by 184 parents. Responses were scored as a simple 'Yes/No' checklist. Overall scores representing counts of the "No" responses to the seven questions on the screen were calculated for each parent. Dental caries was present in 28% of the children whose parents participated in the study. Sensitivity and specificity for 3 or more "No" responses were 0.47 and 0.78 respectively. Parents of children with dental caries gave a significantly greater number of 'No' responses to the questions on the screening instrument when compared to parents of children without dental caries (2.6 vs 1.8). The KR-20 coefficient for the oral hygiene and feeding practices components of the questionnaire was 0.5.

Conclusion: The dental screening instrument is a valid and reliable screening tool for the early identification of young children at risk for dental caries and referral for further assessment by a qualified health professional. Further testing is required regarding validity and reliability on more age-specific groups.

INTRODUCTION

This project was undertaken to develop and validate a parent-administered dental screening instrument for 15-48 month-old children. It represents an oral health supplement to the Nipissing District Developmental Screen.

BACKGROUND, PURPOSE, OBJECTIVES

The Nipissing District Developmental Screens (NDDS) (1) are based on research demonstrating that primary prevention and early intervention among preschool children can be achieved through the use of screening questionnaires completed by parents. The development of the screens was initiated in 1993 by the Nipissing District Infant Development Program Committee in response to a concern about the observed number of children experiencing developmental delays who were not being identified in the first six years of life. Since then they have been adopted as useful tools in a wide variety of settings such as physicians' offices, Early Years Centres and child care centres.

When the Office of Integrated Services for Children and the Healthy Babies/Healthy Children Program (HB/HC) for the province of Ontario were established, the Nipissing Screens were recommended and subsequently accepted as screening instruments of choice by the majority of Ontario Public Health Units for the task of the development of Early Identification Guidelines. Further development of the Nipissing Screens ensued and evaluation of validity and reliability was completed in 2002 with the assistance of the Office of Integrated Services for Children. However, the NDDS Committee has retained the copyright and reproduction rights. The Ministry of Health and Long Term Care now has the NDDS included as part of the Evaluation of the HB/HC Program.

The NDDS is a series of thirteen check-lists for the following children of the following ages: 1 and 2 months; 4 months; 6 months; 9 months; 12 months; 15 months; 18 months; 2 years; 30 months; and each year from 3 to 6 years of age. All are designed for use by parents or caregivers. They are intended to identify aspects of a child's development that may require early intervention. The areas of development covered by the NDDS include vision, hearing, speech, language, and gross motor, fine motor, cognitive, social and self-

help skills. Each screen consists of questions requiring a “Yes” or “No” response and suggested activities for age appropriate outcomes. The role of the latter is to give advice to parents about the skills and habits expected for children of their child’s age and how they can be enhanced. A “No” response to two or more questions represents a “red flag” for a child’s referral to a qualified professional, as this might indicate the presence of a developmental difficulty.

The NDDS does not assess the oral health of children. This has been recognized by the Ministry of Health and Long Term Care and the recommendation has been made to develop and validate a dental adjunct for the NDDS.

Consequently, this project was undertaken with the aim of constructing an oral health companion to the NDDS for the early identification of young children at risk for or having oral diseases and/or disorders, primarily dental caries.

The specific objectives are:

1) to develop a dental screening instrument for 15-48 month-old children that will be integrated in the NDDS ;
2) to develop anticipatory guidance for parents for the content areas covered by the screening instrument.
3) to pre-test the screening instrument;
4) to test the validity and reliability of the screening instrument;

RESEARCH METHODOLOGY

Instrument development

Questions for the screening instrument were generated in two stages. First, a preliminary pool of questions was created by a review of relevant clinical literature and scientific articles as well as existing screening instruments and preventive educational materials. The following content areas were included: risk factors for early childhood caries, feeding patterns, oral hygiene practices, oral habits, and tooth development and appearance. Second, questions for the screening instrument were selected from this pool by an expert panel composed of those who will be its future users. Each question was accompanied with available evidence-based information or advice to parents that would correspond to its content. The response format for each question was a "Yes" or "No".

The instrument was formatted to be consistent with the NDDS. It was written at a grade-five literacy level. Grammar and language difficulty was established using two readability statistics: the Flesch Reading Ease Score and the Flesch-Kincaid Grade Level Score.

Instrument validation

1. Instrument pre-testing

The instrument was pre-tested to assess readability, comprehension and ease of administration. Convenience samples of parents of children ages 15-21 months were drawn from a variety of settings, such as Early Identification Clinics (EIC) and groups of relatives and friends. Data was collected in two stages. In the first, parents were asked to complete the screening instrument. In the second, they were asked to respond to a questionnaire with regard to the layout of the insrtument, their understanding of the instructions and the wording of questions. An iterative approach was employed, meaning that the pre-testing procedure was repeated with additional parents until no further modifications were required (2,3).

2. Instrument validation

The final instrument included seven questions in the following content areas: tooth development and appearance, risk factors for early childhood caries – such as oral hygiene practices, feeding patterns and oral habits (Appendix A). These were accompanied by anticipatory guidance for parents for the respective content areas. Responses to the questions were scored as a simple 'Yes/No' format. Similar to the Nipissing screens, it was hypothesized that a "No" response to two or more questions would represent a "red flag" for a child's referral to a qualified professional.

In evaluating the validity of a screening instrument, its ability to identify those with a given clinical condition is assessed. Two measures of a screening instrument's validity are its sensitivity and specificity (4,5). The first is defined as the percentage of patients with a condition who are correctly identified by the instrument as having the condition; the second is defined as the percentage of patients without a condition who are correctly identified as not having the condition. Sensitivity and specificity of the screening instrument was tested by investigating the associations between parents' responses to questions that aim to identify the presence of oral conditions (e.g. caries) and the "gold standard" represented by the results of clinical examinations of their children.

Evidence of discriminant validity was also sought. This involved testing the hypothesis that the scores on the feeding patterns and oral hygiene practices components of the instrument (Questions 2, 5, 6 and 7) are higher for caries afflicted than caries free children. The scores were obtained by counts of the "No" responses.

The internal consistency reliability of the instrument was assessed using the KR-20 statistic. Assessment of test-retest reliability was not undertaken as changes in the entities measured were expected to occur between the administrations of the questionnaire in response to oral health advice given to parents at baseline.

Data Collection

Data required for calculating a sample size to test differences between either means or proportions were not available. Consequently, a convenience sampling approach was used to collect data from two clinical groups i.e. a caries free group and caries afflicted group of children. Data was collected by means of the screening instrument completed by the parents and clinical data obtained from children's dental screening examinations conducted by Public Health Department personnel as part of their regular activities.

Participants

A convenience sample of parents of 12 to 48 month-old children, who speak and read English and who agreed to participate in the study by signing a consent form were recruited from different Public Health Department settings such as Early Years Centers, Screening Clinics, Early Identification Clinics, Preventive Centers and health fairs. Potential participants were approached by a dental health unit staff member or dental hygienist. Parents who met the inclusion criteria were informed about the nature of the study and given details of the research procedures. Those who agreed to participate were provided with a Participant Information Sheet and consent form. If they agreed to participate after reading the information sheet, they were asked to sign a consent form. The parent was given the screening instrument and subsequently, their child was examined for dental caries by a dental hygienist. Clinical findings concerning the presence of caries were recorded on a clinical examination form (See Appendix A).

Data Analysis

Responses on the questionnaire were scored as 'Yes" or 'No'. The number of "No" responses to the questions on the screening instrument were calculated for each child. The NDDS recommends a 2 flag rule i.e. two or more "No" responses indicate the need for further assessment by a professional since the children concerned are likely to have or are at risk of dental disorders requiring disease prevention and/or early treatment interventions.

The sensitivity and specificity of the screening instrument was tested by investigating the associations between the number of "No" responses to questions and the "gold standard" represented by the results of the clinical examinations. Sensitivity and specificity was determined using conventional formulas for calculating these two statistics (6). The *T*-test for independent samples and/or the Chi-square test was used to compare the scores of children with and without dental decay. Given the dichotomous nature of the screening instrument data, internal consistency reliability was estimated by means of the Kuder-Richardson coefficient (7).

RESULTS

Fourteen parent-child pairs participated in pre-testing of the instrument and 184 parent-child pairs participated in the validation study. They were recruited from various public health unit settings. The demographics of the participants are described in Table 1. The vast majority of the children were between 15 and 24 months with the average age being 24 months (range 12-49 months).

The face and content validity of the screening instrument were established by expert review. The distribution of the "No" responses to the seven questions are presented in Table 2. Parents reported that more than two-thirds of the children had never seen a dentist or a dental hygienist prior to this visit; about one-quarter of children were sleeping with the bottle and were not drinking from a cup. Twenty percent of these children did not have their teeth cleaned daily by an adult.

Of the 184 children who participated in the study, dental examination data was available for 177 children. Dental caries was detected in 28% of the children. Of these, 67.3% of the children had 1 to 4 teeth that were affected with dental caries, with one third (32.7%) having 4 teeth affected.

Validity:

Predictive validity: Chi-square analysis was performed to determine if there was an association between the number of "No" responses to the questionnaire and the presence of dental caries in the child (Table 3). .

Having three or more 'No' responses on the questionnaire was significantly associated with an increased odds of having dental caries (OR=3.2). Similarly, a child whose parent gave four or more 'No' responses to the questionnaire was 9 times more likely to have dental caries. As shown in Table 3, as the number of 'No' scores on the questionnaire increased the odds/probability of the child having dental caries also increased in a dose-response relationship.

Criterion validity: The sensitivity and specificity of the screening instrument was tested by investigating the associations between the number of 'No' scores and the presence dental caries which represented the "gold standard" to judge the criterion validity of the instrument. Table 4 provides the sensitivity and specificity of the questionnaire using various cut-off points. The positive and negative predictive values (PPV, NPV) for the instrument for the various cut-off points were also determined and are presented in Table 4. Positive predictive value is defined as the probability of disease in a patient with a positive test. For example - in this study, the probability that a child who had a positive test result i.e. 1 or more 'No' responses to the questionnaire actually has the disease (i.e. dental caries) was 27%. As shown in table 4, the PPVs for the questionnaire increased as the cut-of points included more 'No' responses. The rates of over referral and under referral were also determined for the various cut-off points and are presented in table 5.

An ROC curve was plotted for the various cut-off points and the area under curve was determined (Fig 1). The area under the curve was 0.6 and statistically significant. The optimal cut-off score, defined as the point on the ROC curve which is farthest from the diagonal, for this instrument was at the 3 or more 'No' responses to the questionnaire.

Discriminant Validity: The mean number of 'No' responses to the questions on the screening instrument were significantly higher among the children who were afflicted with dental caries than caries-free. The scores were 2.6 and 1.8 respectively. When the scores on the feeding patterns and oral hygiene practices components of the instrument were compared, the mean number of 'No' responses continued to be significantly higher for caries afflicted than caries free children (1.5 vs 0.7).

Reliability

Internal consistency reliability was calculated using the KR-20 (Kuder-Richardson coefficient). The over all KR-20 coefficient for the questionnaire was 0.3. For items related to the oral hygiene and feeding practices components of the questionnaire the KR-20 coefficient was 0.5.

DISCUSSION

Dental caries and its sequeale are the commonest health problems facing children below the age of six years (8). Early childhood caries (ECC) is a particularly virulent form of dental caries that begins soon after the eruption of the primary dentition and progresses rapidly with detrimental effects on the teeth (8). The etiology of ECC is multifactorial and involves the inter-relationship between microbiological, dietary and socio-economic risk factors (9-11). Prevalence of ECC is as high as 14% among children born outside of Canada as compared with children born with-in Canada at 10% (12,13). Studies have reported that increasing numbers of children with ECC are being treated under general anaesthesia or sedation with increasing costs associated with it (14,15). ECC may be preventable if the early signs and its risk factors are identified at an early stage. The objective of an early risk assessment is to screen the child at risk and counsel the parent who could both benefit from early intervention thus preventing the need for later complicated and costly interventions. Thus with this purpose in mind this dental screening tool was developed.

The present study was undertaken to develop and validate a paediatric dental screening instrument that would help identify children at risk for dental caries. The results

demonstrate that the dental screening instrument is a valid and reliable tool that can be used for the identification and referral of children at risk for dental caries. The results also demonstrate that instrument is brief and easy to use, and that screening and counselling using this instrument could be carried out in a feasible and reasonable way.

Dental caries was found in 28% of the children in this study. Although this is higher than the prevalences reported (12, 13), it should be noted that the children included in this study was based on a convenience sample. Concurrently it should also be noted that the commonest teeth affected were the upper anteriors which is typical of ECC.

In order to validate the tool the sensitivity and specificity of the instrument was assessed using the counts of "No" responses to the questionnaire. We also assessed the association between the counts of no responses and presence of dental caries. Although a cut-off at two or more no responses to the questionnaire had a good sensitivity, the specificity was relatively low and was not significantly associated with presence of dental caries. The Nipissing developmental screens presently use a 2 or more "No" responses to any of the questions as a red flag for referral to a qualified health professional for further assessment (1). However, this was not very applicable to this particular instrument and a higher cut-off point of 3 or more "no" responses was considered as a better cut-off point for the following reasons. When 3 or more no responses to the questionnaire was used as cut-off, the sensitivity was lower when compared with the specificity, but the predictive values were higher. Three or more no responses was also significantly associated with the presence of dental caries (OR 3.2, 95% CI 1.6 – 6.4). Moreover when rates of over referral and under referral were calculated, it was found that the rates were around of 15% for the cut-off at 3 or more no responses which was a better trade-off when compared with the other cut-off points. ROC curve analysis further demonstrated that the 3 or more no-responses was the ideal/optimal cut–off point.

Although we recommend that a "3 or more no responses" to the questionnaire as a red flag for referral, it should be noted that there is always a trade-off between sensitivity and specificity, and false-positives and false negatives. The choice of the cut-off point is not a

statistical decision, but a clinical one. This depends on the type of disease, the prevalence of the disease and costs or impacts associated with failing to identify children with the problem and cost of assessment of children who do not require any intervention (16). When considering dental caries, the consequence of a false negative is very undesirable as compared to identifying a false positive. Thus for a screening tool (like the one in this study) it is important for it to have a high specificity and negative predictive value. This will potentially ensure that all those identified as at risk will be further assessed to confirm the findings, diagnosis will be made and appropriate intervention will be provided.

The results showed that the instrument had good discriminant validity. The reliability of the instrument was fair. As the internal consistency reliability of an instrument is directly related to the number of items on the questionnaire (7), the low reliability of this tool can be attributed to the presence of only seven items on the questionnaire. In the interest of keeping the tool short and easy to complete, this questionnaire was limited to the seven most important and known risk factors for dental caries, along with available evidence-based anticipatory guidance.

This screening tool is the first parent-completed dental screening instrument that has been developed to screen children at risk for dental caries. Although there are several guides, pamphlets and booklets available for parents regarding oral health for infants and toddlers (17-19), none have been designed for the purpose of screening for risk factors of dental caries. This instrument was developed to as an oral health companion to the Nipissing district developmental screens that can be easily administered to a parent by any health professional. Although a similar caries-risk assessment tool has been put forth by the American Academy of Paediatric Dentistry, it is only meant for use by dental health professionals to asses the risk factors of ECC (20). Thus the dental screening instrument developed in this study is the first parent-completed risk assessment tool that is valid, reliable and can be administered by any health professional.

This study had some limitations. Firstly, the sample size for the study was set arbitrarily as there were no data in the literature from similar studies. There were some difficulties in obtaining the set sample size. The age of the children included in the study could not be restricted to include only 18-month-old children as initially planned. The inclusion age was broadened to include children up to the age of 4 years to obtain sufficient numbers for the study. This had no impact on the type of questions included as the risk factors were the same for all age groups. Only the question on number of teeth present in the child's mouth had to be modified to account for the change in the inclusion criteria. Secondly, good predictive values are an indication of the clinical usefulness of a tool but it strongly depends on the prevalence. Thus the predictive values from this study may not be applicable universally. Therefore it is not always necessary to impose the same cut-off points and it can vary based on the prevalence and disease in question. Lastly, as the sample included in the study was a convenience sample, the generalizability of the tool needs to be further investigated in different populations and settings.

CONCLUSION

The results of the study confirm the validity and reliability of a brief, parent-completed dental screening instrument for the early identification of risk factors for dental caries in children, and referral for further assessment by a qualified health professional. These results also indicate the need for further validation of the tool in different populations and settings.

References

1. Nippising District Developmental Screens. Available at http://www.ndds.ca. Accessed October 31, 2003.

2. Esposito JL, Rothgeb JM. Evaluating survey data: Making the transition from pretesting to quality of assessment. In: Lyberg, Biemer, Collins, de Leeuw, Dippo, Schwartz, Trewin, editors. Survey measurement and process quality. New York: John W & Sons 1997.

3. Collins D. Pretesting survey instruments: An overview of cognitive methods. Qual Life Res 2003; 12: 229-38.

4. Aday LA. Designing and conducting health surveys: a comprehensive guide. San Francisco: Jossey-Bass Publishers 1996.

5. Streiner DL, Norman GR. Health measurement scales: A practical guide to their development and use. Oxford: Oxford Medical Publication 1996.

6. Hennekens CH, Mayrent SL. Epidemiology in medicine. Bosto/Toronto: Little, Brown and Company 1987.

7. Carmines EG, Zeller RA. Reliability and validity assessment. Beverly Hills: Sage Publications 1979.

8. Clinical guidelines on infant oral health care. Pediatr Dent 2004; 26: 67-70.

9. Brice DM, Blum JR, Steinberg BJ. The etiology, treatment and prevention of nursing caries. Compend Contin Educ Dent 1996; 17: 92-103.

10. Febras C, Echeverri EA, Keene HJ. Parental awareness, habits and social factors and their relationship to baby bottle tooth decay. Pediatr Dent 1997; 19: 22-7.

11. Li Y, Caufield PW. The fidelity of initial acquisition of *Mutans streptococci* by infants from their mothers. J Dent Res 1995; 74: 681-5.

12. Leake JL, Goettler F, Stahl-Quinlan, Stewart H. Report of the sample survey of the oral health of Toronto children aged 5, 7, and 13. Faculty of Dentistry and Toronto Public health. Unpublished Document. 2000.

13. Abbey P. A case-control study to determine the risk factors, markers and determinants for the development of nursing caries. MSc Thesis. University of Toronto, Faculty of Dentistry, 1998.

14. Griffin SO, Gooch BF, Sutherland JN, Barsley R. Dental services, costs, and factors associated with hospitalization for medicaid eligible children, Louisiana 1996-97. J Public Health Dent 2000; 60: 21-27.

15. Milnes AR, Rubin CW, Karpa M, Tate R. A retrospective analysis of the costs associated with the treatment of nursing caries in a remote Canadian aboriginal preschool population. Community Dent Oral Epidemiol 1993; 21: 253-260.

16. Dahinten SV, Ford L, Lapointe V. Consortium for health, intervention learning and development:Validation of the Nipissing district developmental screen for use with infants and toddlers. Available at http://www.ndds.ca. Accessed January 31, 2006.

17. Ohio Department of Health. Available at http://www.odh.ohio.gov/hmg/parents/nutrition/child/healthyteeth.aspx. Accessed January 31, 2006

18. Centres for Disease Control. Available at http://www.cdc.gov/OralHealth/pressreleases/brush-htm. Accessed January 31,2006

19. National Maternal and Child Oral Health Resource Centre. http://www.mchoralhealth.org/pediatricOH/index.htm. Accessed January 31, 2006.

20. American Association of Pediatric Dentistry. Oral health Policies and Guidelines. Available at http://www.aapd.org/media/Policies_Guidelines/P_CariesRiskAssess.pdf. Accessed January 31, 2006.

Table 1 –Demographics of the participants

	n (%)
# of Participants by Health Unit /Region (N = 184)	
• York Region	87 (47.3)
• WDG Well Dufferin Guelph	35 (19.0)
• Peel Region	13 (7.1)
• Halton	29 (15.8)
• Simcoe Muskoka Region	1 (0.5)
• Toronto Public Health	19 (10.3)
Gender (N=183)	
• Male	94 (51.4)
• Female	89 (48.6)
Age (N=184)	
• Mean (months)	24.2 (± 8)
• Range (months)	12 – 49
• <15 months	4 (2.2)
• 15-24 months	114 (62.0)
• 25-36 months	49 (26.6)
• >36 months	17 (9.2)

Table 2 - Distribution of "No" responses to the questionnaire

	No (N =184)
If your child is between 18 - 36 months, does he / she have at least 12-16 teeth?	23 (12.5)
Are your child's teeth cleaned daily by an adult?	37 (20.1)
Are your child's teeth white and shiny?	38 (20.7)
Prior to this visit, has your child been seen by a dentist or a dental hygienist?	135 (73.4)
Does your child drink mostly from a cup (excluding a sippy cup)?	53 (28.8)
Does your child sleep without a bottle?	41 (22.3)
Does your child have set times during the day for meals and snacks?	33 (17.9)

Table 3 - Association between number of "No" responses on the questionnaire and dental caries

	Dental caries Absent %	Dental caries present %	OR 95% CI
1 or more "no" responses *	72.2	27.8	1.1 (0.3 – 3.5)
2 or more "no" responses	68.9	31.1	1.6 (0.8 – 3.1)
3 or more "no" responses	54.9	45.1	3.2 (1.6 – 6.4)
4 or more "no" responses	28.6	71.4	9.0 (3.2 – 24.9)
5 or more "no" responses	12.5	87.5	21.2 (2.5 – 177.1)
6 or more "no" responses	0	100	-

**Total score was developed by summing the number of "no" responses for each patient. The scores were then categorized based on number of "no responses as shown in the table.*

Table 4 - Sensitivity and Specificity at different cut-offs based on the number of "no" responses

Number of "no" responses	Sensitivity	Specificity	1-Specificity	PPV	NPV
None vs 1 or more	0.92	0.09	0.91	27%	73%
None or1 vs 2 or more	0.67	0.43	0.57	31%	77%
None, 1, 2 vs 3 or more	*0.47*	*0.78*	*0.22*	*45%*	*79%*
None, 1, 2,3 vs 4 or more	0.31	0.95	0.05	71%	78%
None, 1, 2,3,4 vs 5 or more	0.14	0.99	0.01	87%	75%
None, 1, 2,3,4,5 vs 6 or more	0.04	1.00	0.0	100%	73%

PPV- positive predictive value; NPV – negative predictive value

Table 5 – Over- and under- referral rates to dental professionals based on various cut-off points to the screening questionnaire

Number of "no" responses	% Over referral	% Under referral
None vs 1 or more	66%	2.3%
None or1 vs 2 or more	41.2%	9.0%
None, 1, 2 vs 3 or more	15.8%	14.7%
None, 1, 2,3 vs 4 or more	3.4%	19.2%
None, 1, 2,3,4 vs 5 or more	0.6%	23.7%
None, 1, 2,3,4,5 vs 6 or more	0	