

# Pilot validation of the new Canadian Caries Risk Assessment Tool for preschoolers

Robert J Schroth<sup>§</sup>, DMD, MSc, PhD; Adam Siray<sup>†</sup>, DDS, MDent; Victor HK Lee<sup>§</sup>, MSc; Olubukola O Olatosi<sup>§†</sup>, BDS, MPH, PhD; Betty-Anne Mittermuller<sup>§</sup>; Amanda Finch<sup>‡</sup>, BSc, BSc(Dent), DMD; Ralph Hu<sup>§</sup>, BSc; Lisette Dufour<sup>Δ</sup>, RDH; Mario Brondani<sup>¶</sup>, DDS, MSc, MPH, PhD; Mary Bertone<sup>Σ</sup>, BScDH, MPH; Hamideh Alai-Towfigh<sup>‡</sup>, BSc, DMD, MDent

## ABSTRACT

**Background:** Caries risk assessment (CRA) is an important step in preventive and therapeutic management of caries in children. This study assessed the sensitivity and specificity of a new Canadian Caries Risk Assessment Tool (<6 years) for preschoolers to predict caries development. **Methods:** In this prospective cohort study, CRA was performed at baseline and 12 months among 190 children aged <6 years from 3 clinics in Manitoba, Canada. CRA included information on child's fluoride exposure, teeth cleaning, diet, socio-economic status, and oral examinations. Sensitivity and specificity were calculated, and logistic regression for new caries at follow-up was performed. **Results:** The sensitivity and specificity for baseline CRA rating and development of new caries at follow-up were 87.2% and 42.7%, respectively. Presence of visible caries and/or past evidence of dental treatment for caries at baseline was the strongest independent indicator of new caries by follow-up (OR = 6.49; CI = 3.28, 12.85;  $p < 0.001$ ). Children with high caries risk (score  $\geq 3$ ) were more likely to develop new caries by follow-up (OR = 4.58; 95% CI = 2.07, 10.11). **Discussion:** The combined sensitivity and specificity score is comparable to findings from other studies examining CRA. Results support the increased weighting of the score for the presence of visible caries and/or evidence of dental treatment for caries at baseline. Results from this study provide evidence for the CRA tool's predictability. **Conclusion:** The Canadian Caries Risk Assessment Tool for preschoolers has high sensitivity to identify children with high caries risk, and modest specificity to identify children with low caries risk. However, future population-based studies with primary care providers are recommended.

## RÉSUMÉ

**Contexte :** L'évaluation du risque de carie (ERC) est une étape importante dans la prise en charge préventive et thérapeutique des caries chez les enfants. Cette étude a évalué la sensibilité et la spécificité d'un nouvel Outil canadien d'évaluation des risques de carie (<6 ans) pour les enfants d'âge préscolaire afin de prédire le développement de caries. **Méthodes :** Dans cette étude de cohorte prospective, l'ERC a été effectuée au départ et sur 12 mois auprès de 190 enfants de moins de 6 ans provenant de 3 cliniques au Manitoba, au Canada. L'ERC comprenait des renseignements sur l'exposition de l'enfant au fluorure, le nettoyage des dents, le régime alimentaire, le statut socioéconomique et les examens buccodentaires. La sensibilité et la spécificité ont été calculées, et une régression logistique prenant en compte les nouvelles caries au moment du suivi a été effectuée. **Résultats :** La sensibilité et la spécificité de la cote ERC de base et du développement de nouvelles caries au moment du suivi étaient respectivement de 87,2 % et de 42,7 %. La présence de caries visibles ou de preuves de traitement antérieur au départ (base référence) était l'indicateur indépendant le plus solide de nouvelles caries au moment du suivi (RC = 6,49; IC = 3,28, 12,85;  $p < 0,001$ ). Les enfants présentant un risque élevé de carie (score  $\geq 3$ ) étaient plus susceptibles de développer de nouvelles caries par suivi (RC = 4,58; IC à 95 % = 2,07, 10,11). **Discussion :** Le score combiné de sensibilité et de spécificité est comparable aux résultats d'autres études examinant l'ERC. Les résultats appuient la pondération accrue du score pour la présence de caries visibles ou la preuve d'un traitement antérieur au départ (base référence). Les résultats de cette étude fournissent des preuves de la prévisibilité de l'outil ERC. **Conclusion :** L'Outil canadien d'évaluation des risques de carie pour les enfants d'âge préscolaire présente une sensibilité élevée pour identifier les enfants présentant un risque élevé de carie et une spécificité modeste pour identifier les enfants présentant un faible risque de carie. Toutefois, il est recommandé d'effectuer de futures études axées sur la population auprès de fournisseurs de soins primaires.

**Keywords:** caries risk assessment; early childhood caries; primary care; prospective cohort; risk factors; sensitivity; specificity  
**CDHA Research Agenda category:** risk assessment and management

<sup>§</sup>Department of Preventive Dental Science, Dr. Gerald Niznick College of Dentistry, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, MB, Canada

<sup>§†</sup>Children's Hospital Research Institute of Manitoba, Winnipeg, MB, Canada

<sup>†</sup>Department of Oral Biology, Dr. Gerald Niznick College of Dentistry, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, MB, Canada

<sup>Δ</sup>Health Canada, Ottawa, ON, Canada

<sup>¶</sup>Department of Oral Health Science, Faculty of Dentistry, University of British Columbia, Vancouver, BC, Canada

<sup>Σ</sup>School of Dental Hygiene, Dr. Gerald Niznick College of Dentistry, University of Manitoba, Winnipeg, MB, Canada

Correspondence: Dr. Robert J Schroth; robert.schroth@umanitoba.ca

Manuscript submitted 10 September 2024; revised 5 February 2025; accepted 30 March 2025

## PRACTICAL IMPLICATIONS OF THIS RESEARCH

- The Canadian Caries Risk Assessment Tool can be used by oral health and non-oral health primary care providers to screen preschoolers, provide oral health education and preventive oral care, and aid referrals to establish dental homes.
- This study raises awareness among oral health professionals, non-oral health professionals, and policy makers of the need for a prevention program in populations with a high burden of caries and limited access to oral health care.

**INTRODUCTION**

Dental caries in children remains a significant public health issue despite population-based oral health preventive measures. Early childhood caries (ECC) is caries experience in the primary dentition of children <6 years of age.<sup>1</sup>

ECC is a multifactorial disease. Bacteria and sugars are known to play key roles in the etiology of dental caries, but other factors are involved.<sup>2,3</sup> They include limited access to care, poverty, little or no exposure to fluoridated water, cultural beliefs, and poor access to affordable, nutritious foods.<sup>4,5</sup> Poor access to early, preventive oral health care can contribute to poor oral health and the need for dental surgery to treat ECC.<sup>6,7</sup> Unfortunately, surgery alone fails to address underlying risk factors for ECC, highlighting the importance of implementing an effective prevention regimen and early risk identification.

The multifactorial risk factors approach to managing dental caries is more promising because the etiology of dental caries involves numerous causes. This approach includes caries risk assessment (CRA), which is part of a comprehensive treatment plan based on the age of the child (starting with the visit at 1 year of age).<sup>1</sup> The goal

of CRA is to provide patient-centred caries prevention and management strategies for the individual. What makes caries risk-based care unique over traditional surgical/restorative approaches to dealing with caries lesions is that there is emphasis on intervening before the irreversible damage to teeth occurs.<sup>8,9</sup> Several CRA tools have been developed to help guide practitioners in determining an individual's likelihood of developing caries. CRA tools can also be used by non-oral health care providers to screen children, determine caries risk, and provide preventive services, including fluoride varnish, oral hygiene instruction, and anticipatory guidance.<sup>9</sup> Recently, a novel Canadian CRA tool was developed at the request of the Public Health Agency of Canada and the Office of the Chief Dental Officer of Canada. The Canadian Caries Risk Assessment Tool (<6 years) is a screening tool designed primarily for non-oral health primary care providers to assess the risk of tooth decay in children under 6 years of age.<sup>9,10</sup> This tool was developed from evidence and a systematic review of the literature.<sup>9</sup> One of the limitations of CRA tools is that a majority have not been validated, especially across different population groups.

Figure 1\*. Canadian Caries Risk Assessment Tool

**Canadian Caries Risk Assessment Tool (< 6 years)**

Child's Name: \_\_\_\_\_  
 Child's Date of Birth: \_\_\_\_\_  
 Date of Assessment: \_\_\_\_\_

Factors	Yes	No
Teeth cleaned with brush (or cloth if infant) at least twice daily by parent or caregiver	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)
Daily exposure to fluoride (e.g. fluoridated toothpaste, fluoridated water)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)
Feeding practices (one or more – please check all that apply):		
<input type="checkbox"/> Bottle-feeding > 12 months of age;		
<input type="checkbox"/> use of bottle or sippy cup between meals with liquid other than water (e.g. pop, fruit juices, milk, chocolate milk)		
<input type="checkbox"/> Bedtime/naptime bottle or sippy cup use	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
<input type="checkbox"/> No oral hygiene routine established after solid foods have been introduced while still breastfeeding or bottle-feeding after 12 months		
<input type="checkbox"/> Sugary snacks and drinks between meals (e.g. cookies, candy, sugary cereal, chips, pop, fruit juices, chocolate milk)		
Family is low income (e.g. "has difficulty making ends meet at the end of the month")	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
Visible plaque and/or food debris on teeth	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
Visible caries (including white spot lesions) and/or past evidence of dental treatment for caries (e.g. fillings, stainless steel crowns, extracted teeth)	<input type="checkbox"/> (3)	<input type="checkbox"/> (0)
<b>Total Score</b> (please add up points from each row)		

**Overall caries risk status:**  **High Risk** (score ≥ 3)  **Low Risk** (score < 3)

**RECOMMENDATIONS** (Please check all that have been reviewed with parent/caregiver)

**HIGH RISK:**

- If overall caries risk status is high, recommend the following in addition to the below:
- Refer to dental office for treatment if there is caries present.
- Apply fluoride varnish today.

**FOR ALL CHILDREN:**

- Refer to dental office (if child has not yet been to a dental office in the last year).

Caregiver Information – Recommend:

- That adult brushes child's teeth (< 8 years old) at least twice daily for 2 minutes with:
  - Water or non-fluoridated toothpaste only for 0-3 years of age (if total score = 0)
  - Smear (grain of rice size) of fluoridated toothpaste for 0-3 years of age (if total score > 0)
  - Green pea size of fluoridated toothpaste for 3-6 years of age
- Lowering sugar consumption or limiting sugary drinks/snacks
- Avoiding overnight bottle and sippy cup use with liquids other than water
- Initiate weaning off bottle by 12 months of age
- Initiate switching to an open cup/tidless sippy cup by 12 months of age
- Other: \_\_\_\_\_

**ADDITIONAL COMMENTS:**

Dental referral made to: \_\_\_\_\_  Not required (child has already been to dental office)

Provider signature: \_\_\_\_\_

December 20, 2019

University of Manitoba | Canadian Pediatric Society | Canadian Dental Association | Public Health Agency of Canada / Agence de la santé publique du Canada

**Canadian Caries Risk Assessment Tool (< 6 years)**  
**Signs of Plaque and Caries Lesions**

- Visible Plaque and/or Food Debris** (Image showing yellowish-brown deposits on teeth)
- Early Caries (White Spot Lesions)** (Image showing white, chalky spots on the enamel)
- Advanced Caries** (Two images showing deep cavities and decayed teeth)

Images courtesy of Dr. Robert Schroth

December 20, 2019

University of Manitoba | Canadian Pediatric Society | Canadian Dental Association | Public Health Agency of Canada / Agence de la santé publique du Canada

\*Please visit [cjdh.ca](http://cjdh.ca) and select the February 2026 issue (vol 60, no 1) to view the assessment tool in full size.

This study aimed to validate the newly developed Canadian Caries Risk Assessment Tool (<6 years) and to determine the sensitivity and specificity of the tool to predict new caries development in a cohort of young children followed in community-based dental public health clinics. The research team hypothesized that high-risk children with CRA scores  $\geq 3$  would have a higher likelihood of developing caries over the period of observation than children with low-risk scores  $< 3$ .

## METHODS

This was a prospective observational cohort study carried out among preschool children to validate and determine the sensitivity and specificity of the newly developed Canadian Caries Risk Assessment Tool (<6 years) to predict future caries (Figure 1).<sup>9,10</sup> Participants were recruited from January 2019 to January 2022 and were followed for approximately 12 months starting from the day of their baseline CRA. The inclusion criteria were children <72 months of age at the time of the baseline CRA and children attending community-based dental clinics (Access Downtown, Mount Carmel Clinic, and the Children's Hospital Dental Clinic) in Winnipeg, Manitoba, Canada. Children not accompanied by their parent or primary caregiver were excluded from the study.

The University of Manitoba's Health Research Ethics Board approved the study (HS21963/H2018:271). Written informed consent was not required as CRA was adopted as a standard practice in these clinics. Children were followed as part of their regular, ongoing dental diagnostic, preventive, and treatment visits.

The Canadian Caries Risk Assessment Tool was developed following a systematic review of the literature, accompanying assessment of the level of evidence, a comprehensive review of existing CRA tools for children, and Canadian evidence of risk factors for ECC.<sup>9,10</sup> The tool consists of 6 items. Four questions posed to parents/caregivers identify the child's frequency of tooth cleaning, daily fluoride exposure, feeding practices associated with increased caries risk and snacking between meals, and whether parents/caregivers are facing financial challenges. The remaining 2 items (assessed by a trained dentist in this study) establish the presence of visible plaque and/or food debris on children's teeth, and visible caries (including white spot lesions) and/or past evidence of dental treatment for caries. Each CRA question is assigned a score, and at the end of the assessment, scores are summed. The minimum and maximum potential CRA scores are 0 and 8, respectively. Children with a CRA score  $\geq 3$  are classified as high risk for future caries and children  $< 3$  are classified as low risk. The tool also includes anticipatory guidance recommendations and preventive care information.

At baseline, the CRA tool was administered by one of the study team/clinical staff members who was trained to use the tool. A trained and experienced dentist carried out all examinations of children's teeth at the community

clinics under artificial light. Children sat in a dental chair or were examined knee-to-knee. The presence of any caries, along with the number of decayed, missing due to caries, and filled primary teeth (dmft) and tooth surface (dmfs) scores were determined and calculated from clinic examination records. ECC and S-ECC were defined according to established case definitions.<sup>11</sup> At 12 months, children returned for a follow-up CRA. The CRA tool was completed, and an oral examination was done by the same dentist under the same conditions to determine if there were changes in the child's oral health status, including new caries lesions. The examiner was not blinded from the CRA information gathered at baseline. A child was classified as having new caries experience by the time of follow-up if they had the presence of any new caries lesions, including incipient caries (i.e., white spot) lesions and recurrent/secondary caries, missing teeth extracted due to caries, and restorations because of caries for previously healthy teeth. Reviews of records and clinical notes of children who did not have a follow-up CRA form completed but still returned for ongoing care were done to determine whether they had developed new caries lesions. Follow-up dmft and dmfs scores were recorded. Radiographs were also used, if available, to determine if a child had caries at baseline and follow-up. The principal investigator reviewed all clinical patient records to determine if new caries had been documented during the observation period.

Data from the CRA tool and dental examination were entered into an Excel (Microsoft Office, Redmond, Washington) database and saved on a secure server at the Children's Hospital Research Institute of Manitoba. Number Cruncher Statistical System (NCSS) (Version 2021, Kaysville, Utah) was used for statistical analysis. Descriptive statistics were calculated for all variables using means, standard deviations (SDs), and frequencies, as appropriate. Pearson's Chi-squared test and McNemar's tests were also used. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated using MedCalc's diagnostic test evaluation calculator ([medcalc.org/calc/diagnostic\\_test.php](http://medcalc.org/calc/diagnostic_test.php)). Logistic regression was performed to assess whether CRA variables were associated with development of new caries by the time of follow-up evaluation. Model 1 included the 6 CRA tool items. Model 2 included variables in Model 1 plus the total CRA score. Model 3 excluded the presence of visible caries and/or past evidence of dental treatment for caries (CRA Question 6) but included the baseline total CRA score to account for the interaction between CRA Question 6 and the total CRA score. The goodness of fit for the models was assessed using adjusted  $R^2$ , area under curve, and accuracy. Odds ratios (ORs), 95% confidence intervals (CIs), and  $p$  values were reported for these tests.

## RESULTS

Overall, 274 participants had a baseline CRA completed, of which 190 (54.7% male and 45.3% female, mean age  $40.1 \pm 17.6$  months) completed a 12-month follow-up assessment period and were included in the analysis. Of these 190 participants, 181 had complete CRA data (i.e., both baseline and follow-up completed); 9 participants (4.7%) were lost to follow-up (i.e., did not complete a follow-up CRA). Patient characteristics and CRA tool responses (at baseline and follow-up) appear in Table 1. A majority of participants had ECC at baseline (63.7%). Furthermore, 56.3% had their teeth cleaned twice daily, 86.3% were exposed to daily fluoride, 64.2% had visible caries and/or past evidence of dental treatment for caries, and 55.8% had poor feeding/dietary practices.

At the follow-up CRA evaluation, there was an increase in the number of children who had their teeth cleaned twice daily (60.8%), had daily exposure to fluoride (95.6%), had visible caries and/or past evidence of dental treatment for caries (71.3%), and who had poor feeding practices (58.0%). A majority of participants were from families facing financial challenges. Most of the participants had high caries risk (score  $\geq 3$ ) at the time of the baseline CRA assessment (72.1%) and at the time of the follow-up CRA (79%). The mean CRA scores at baseline and follow-up were  $4.0 \pm 2.0$  and  $4.0 \pm 1.9$ , respectively. The mean dmft scores at baseline and follow-up were  $3.9 \pm 4.6$  and  $4.7 \pm 4.8$ , respectively. The average time between baseline and follow-up for the cohort was  $13.1 \pm 4.4$  months.

Table 2 compares participants' development of new caries by the follow-up visit with baseline responses and CRA ratings. Participants who had visible plaque on teeth were 2 times more likely to have developed new caries by

follow-up (unadjusted OR = 2.12; 95% CI = 1.12, 4.02;  $p = 0.02$ ). In addition, those who had visible caries and/or past evidence of dental treatment for caries at baseline were more than 6 times more likely to develop new caries by the follow-up visit than those who were caries-free at baseline (unadjusted OR = 6.49; 95% CI = 3.28, 12.85;  $p < 0.001$ ). Those who had high caries risk at baseline were 5 times more likely to develop new caries by the follow-up visit than those who were determined to be of low caries risk (unadjusted OR = 5.09; 95% CI = 2.46, 10.55;  $p < 0.001$ ). Although not significant, participants who did not have their teeth cleaned or brushed twice daily, those who had poorer feeding practices, and those from families facing financial challenges were more likely to develop new caries at follow-up evaluation. When looking at risk difference, the risk of developing new caries was increased by 37.2 percentage points in the high-risk group compared to the low-risk group.

Logistic regression analyses were performed to determine whether the baseline CRA tool responses and total scores were associated with new caries onset by the time of the follow-up assessment. The research team also looked at possible multicollinearity between baseline visible caries and/or past evidence of dental treatment for caries (Q6) and treatment with silver diamine fluoride (SDF). There were no significant findings. Model 3, which was chosen as the best fit after comparing the 3 models, revealed that those who were determined to be at high risk for caries (OR = 4.58; 95% CI = 2.07, 10.11), those who had visible plaque and/or food debris on teeth (OR = 1.56; 95% CI = 0.79, 3.10), and those from families facing financial challenges (OR = 1.31; 95% CI = 0.69, 2.48) at baseline were more likely to develop caries by the time of the follow-up assessment.

**Table 1.** Baseline and follow-up characteristics and CRA tool responses of participants

Variables	Results
Participants with complete (clinical) dental data	190
Participants with complete CRA form data (baseline and follow-up)	181
Sex:	
Male	104 (54.7%)
Female	86 (45.3%)
Mean age (months)	$40.1 \pm 17.6$
Clinic attended:	
Access Downtown	125 (65.8%)
Children's Dental Clinic	17 (9.0%)
Mount Carmel Clinic	48 (25.3%)
Early childhood caries:	
Yes	121 (63.7%)
No	69 (36.3%)
Severe early childhood caries:	
Yes	112 (59.0%)
No	78 (41.0%)
Average time between baseline and follow-up assessments (months)	$13.1 \pm 4.4$

*Continued...*

Table 1. Continued

Variables		Baseline results	Follow-up results
Q1. Teeth cleaned with brush (or cloth if infant) at least twice daily by parent or caregiver:	Yes	107 (56.3%)	110 (60.8%)
	No	83 (43.7%)	71 (39.2%)
<sup>a</sup> Q2. Daily exposure to fluoride:	Yes	164 (86.3%)	173 (95.6%)
	No	26 (13.7%)	8 (4.4%)
Q3. Feeding practices (i.e., bottle-feeding >12 months of age; use of bottle/sippy cup between meals with liquid other than water; bedtime/naptime bottle/sippy cup use; no oral hygiene routine established after solid foods have been introduced while still breastfeeding/bottle-feeding >12 months of age; sugary snacks and drinks between meals):	Yes	106 (55.8%)	105 (58.0%)
	No	84 (44.2%)	76 (42.0%)
Q4. Family is low-income:	Yes	118 (62.1%)	111 (61.3%)
	No	72 (37.9%)	70 (38.7%)
Q5. Visible plaque and/or food debris on teeth:	Yes	56 (29.5%)	46 (25.4%)
	No	134 (70.5%)	135 (74.6%)
<sup>a</sup> Q6. Visible caries (includes white spot lesions) and/or past evidence of treatment for caries (e.g., fillings, stainless steel crowns, extracted teeth):	Yes	122 (64.2%)	129 (71.3%)
	No	68 (35.8%)	52 (28.7%)
CRA score:	0	8 (4.2%)	9 (5.0%)
	1	15 (7.9%)	20 (11.1%)
	2	30 (15.8%)	9 (5.0%)
	3	19 (10.0%)	25 (13.8%)
	4	35 (18.4%)	39 (21.6%)
	5	38 (20.0%)	34 (18.8%)
	6	26 (13.7%)	29 (16.0%)
	7	15 (7.9%)	16 (8.8%)
	8	4 (2.1%)	0 (0.0%)
Mean total CRA score		4.0 ± 2.0	4.0 ± 1.9
Overall CRA rating:	High risk (≥3)	137 (72.1%)	143 (79.0%)
	Low risk (<3)	53 (27.9%)	38 (21.0%)
Mean dmft		3.9 ± 4.6	4.7 ± 4.8
Mean dmfs		8.0 ± 11.2	11.7 ± 15.9
Mean change in dmft from baseline			0.9 ± 1.8
Mean change in dmfs from baseline			3.8 ± 7.8

<sup>a</sup>McNemar's test: statistically significant change from baseline,  $p < 0.05$

Table 3 reports the comparison of baseline CRA risk ratings and increases in dmft and dmfs scores by follow-up. Sixty-eight (35.8%) and ninety-four (49.5%) children had increased dmft and dmfs scores, respectively. Of those with increased dmft and dmfs scores at follow-up, 85.3% and 89.4% had high caries risk according to the CRA tool. Participants who were classified as high risk at baseline had 3 times the odds of having increased dmft score by follow-up (OR = 3.16; 95% CI = 1.47, 6.80;  $p = 0.002$ ), while those who were classified as high risk at baseline

were 6 times more likely to have increased dmfs scores by follow-up (OR = 6.82; 95% CI = 3.16, 14.71;  $p < 0.001$ ).

The comparison of baseline CRA ratings and accuracy to predict the development of new caries and increases in dmft and dmfs scores is reported in Table 4. Eighty-two children who developed new caries at follow-up were also classified as at high caries risk at baseline (87.2%). Results showed that the CRA tool had high sensitivity to predict new caries at follow-up (87.2%), as well as increases in dmft (85.3%) and dmfs scores (89.4%). The CRA tool

**Table 2.** Comparison of new caries noted at follow-up with baseline responses and rating from the Canadian Caries Risk Assessment form

Baseline variable	New caries clinically noted at follow-up		p value <sup>a</sup>	Crude ORs (95% CI)	Adjusted ORs Model 1 (Q1–Q6)	Adjusted ORs Model 2 (Q1–Q6, baseline CRA ratings)	Adjusted ORs Model 3 (Q1–Q5, CRA ratings)
	Yes n (%)	No n (%)					
<b>Q1. Teeth cleaned with brush (or cloth if infant) at least twice daily by parent/caregiver:</b>							
No	45 (54.2)	38 (45.8)	0.25	1.40 (0.78, 2.49)	1.92 (0.97, 3.81)	2.00 (1.00, 3.99)	1.49 (0.78, 2.83)
Yes (reference)	49 (45.8)	58 (54.2)					
<b>Q2. Daily exposure to fluoride:</b>							
No	12 (46.2)	14 (53.8)	0.72	0.86 (0.37, 1.96)	0.81 (0.30, 2.18)	0.87 (0.31, 2.47)	0.59 (0.24, 1.49)
Yes (reference)	82 (50.0)	82 (50.0)					
<b>Q3. Feeding practices:</b>							
Yes	57 (53.8)	49 (46.2)	0.18	1.48 (0.83, 2.62)	1.01 (0.52, 1.94)	1.07 (0.55, 2.08)	0.98 (0.51, 1.87)
No (reference)	37 (44.0)	47 (56.0)					
<b>Q4. Family is low-income:</b>							
Yes	64 (54.2)	54 (45.8)	0.09	1.66 (0.92, 3.00)	1.43 (0.74, 2.75)	1.49 (0.77, 2.09)	1.31 (0.69, 2.48)
No (reference)	30 (41.7)	42 (58.3)					
<b>Q5. Visible plaque and/or food debris on teeth:</b>							
Yes	35 (62.5)	21 (37.5)	0.02	2.12 (1.12, 4.02)	1.34 (0.65, 2.74)	1.36 (0.66, 2.80)	1.56 (0.79, 3.10)
No (reference)	59 (44.0)	75 (56.0)					
<b>Q6. Visible caries and/or past evidence of dental treatment for caries:</b>							
Yes	79 (64.8)	43 (35.2)	<0.001	6.49 (3.28, 12.85)	6.62 (3.14, 13.96)	10.8 (2.59, 44.51)	—
No (reference)	15 (22.1)	53 (77.9)					
<b>Baseline CRA rating:</b>							
High risk	82 (59.9)	55 (40.1)	<0.001	5.09 (2.46, 10.55)	—	0.53 (0.11, 2.46)	4.58 (2.07, 10.11)
Low risk (reference)	12 (22.6)	41 (77.4)					

OR = odds ratio; CI = confidence interval

<sup>a</sup>Pearson's Chi-squared test

showed modest specificity to predict the absence of new caries (42.7%), as well as unchanging dmft (35.3%) and dmfs scores (44.8%). The PPV for the prediction of new caries and increases in dmft and dmfs scores were 59.9%, 42.3%, and 61.3%, respectively. The NPV for the prediction of new caries and increases in dmft and dmfs scores were 77.4%, 81.1%, and 81.1%, respectively.

Table 5 reports the individual variables in the CRA tool, the sensitivity, specificity, NPV, and PPV for developing new caries at follow-up. The presence of visible caries (including white spot lesions) and/or past evidence of dental treatment for caries (Q6) had the highest sensitivity (84%) for predicting the development of new caries by follow-up. In comparison, exposure to daily fluoride had the highest specificity for predicting absence of caries (85.4%). The combined specificity and sensitivity was the highest for visible caries and/or past evidence of dental treatment for caries (Q6).

## DISCUSSION

Findings from this prospective study revealed that the Canadian Caries Risk Assessment Tool has high sensitivity and modest specificity to identify young children at risk for developing caries. The results provide evidence of the tool's predictability. Participants were followed for approximately 12 months, which is a sufficient observation period for preschoolers with faster caries progression.<sup>12</sup>

Overall, for a CRA tool to be useful, it has been suggested that there be a combined sensitivity and specificity score of at least 160%, and that it should be relatively well balanced between the 2 measures.<sup>13</sup> The combined score of the present study was 129.9%, which is similar to the findings of 3 other studies reporting combined scores ranging from 127% to 143%.<sup>13–15</sup> Although the combined sensitivity and specificity of this new CRA tool is below the ideal of 160%, it demonstrates great potential for identifying children

Table 3. Comparison of baseline caries risk assessment ratings and increase of dmft/dmfs

Scores	Participants at follow-up n (%)	High risk baseline CRA rating n (%)	Low risk baseline CRA rating n (%)	Comparison of increase in scores with baseline high and low CRA ratings	
				p value <sup>a</sup>	OR (95% CI)
Increase in dmft score from baseline:					
Yes	68 (35.8)	58 (85.3)	10 (14.7)	0.002	3.16 (1.47, 6.80)
No	122 (64.2)	79 (64.8)	43 (35.2)		
Increase in dmfs score from baseline:					
Yes	94 (49.5)	84 (89.4)	10 (10.6)	<0.001	6.82 (3.16, 14.71)
No	96 (50.5)	53 (55.2)	43 (44.8)		

OR = odds ratio; CI = confidence interval

<sup>a</sup>Pearson's Chi-squared test

with true caries risk, and modest potential for identifying low-risk children who do not develop future caries. Similar findings of high sensitivity were noted with respect to risk rating and an increase in dmft and dmfs scores. This study is the first attempt to validate this tool. It can be further refined and improved, but in its current form, it is a fair predictor of high or low caries risk in preschool children.

Children were classified into 2 risk groups: high CRA score ( $\geq 3$ ) or low CRA score ( $< 3$ ) based upon responses to 6 questions. CRA questions were based upon evidence arising from a systematic review of the literature,<sup>9</sup> while the tool was formatted based upon feedback obtained during pilot testing.<sup>10</sup> Negative responses to the first 2 questions (twice daily brushing and daily fluoride exposure) were given scores of 1, while responses in the affirmative to questions 3 (feeding practices), 4 (family is low income), and 5 (visible plaque/debris) were scored as 1. However, the final question relating to the presence of visible caries and/or past evidence of dental treatment for caries was given a higher weighted score of 3 because of the overwhelming evidence from the systematic review that past caries experience is the greatest predictor of future caries risk in children.<sup>9</sup> The present study revealed that the presence of visible caries and/or past evidence of dental treatment for caries at baseline was the strongest independent indicator of new caries onset in children by follow-up. Children who had high caries risk (score  $\geq 3$ ) were 4 times more likely to develop new caries by follow-up after controlling for that CRA tool item. This finding confirms and justifies the increased weighting score for this final question in the Canadian Caries Risk Assessment Tool. In fact, this decision is consistent with other evaluations of different pediatric CRA systems where baseline disease status was the most reliable predictor of future caries incidence in preschool children.<sup>13,16-18</sup> This weighting does not imply that the other items in CRA tools are not fundamental

to contributing to the caries process; rather, evidence of existing decay or history of decay demonstrates that there was an imbalance of pathologic and protective factors, and without intervention, there would be further progression of the disease process.<sup>17,19</sup> The present study is consistent with past evidence that CRA prompts oral health care providers to consider multiple patient variables when assigning risk status, with the goal of identifying potentially modifiable factors in an individualized caries management strategy.<sup>20,21</sup>

By focusing on early identification of risk factors and behaviours that can promote caries, as well as recommending protective factors known to minimize the risk of onset, a practitioner can individually tailor clinical care decisions to the patient's needs, and ultimately reduce the risk of irreversible damage and need for traditional surgical/restorative techniques.<sup>22</sup> An ideal CRA tool should not only have good precision and accuracy, but it should also be easy to use in daily practice and utilize risk factors that can be scored in a reliable way. In addition, the process should be rapid and the outcome understandable, so it can be used as a didactic tool in patient motivation. This means that tools should be sensitive enough to identify as many as possible of those with a true caries risk, but also correctly identify those at low risk.<sup>23</sup> However, sufficiently validated multivariate screening tools to determine children at higher risk for dental caries are limited.

To date, some of the most notable and commonly recognized pediatric CRA tools include Caries Management by Risk Assessment (CAMBRA), the American Dental Association's (ADA) Caries risk form (ages 0-6), the American Academy of Pediatric Dentistry's (AAPD) tools, and the Cariogram. Unfortunately, while the literature on risk factors for ECC is vast, studies on the accuracy of CRA tools are limited. Thus, uncertainty remains regarding the validity of CRA tools in predicting dental caries.<sup>16,24,25</sup> The diverse reporting of the accuracy of different CRA tools makes it

**Table 4.** Comparison of baseline CRA ratings with sensitivity, specificity, PPV, and NPV for new caries and increases in dmft and dmfs

Variables		High risk baseline CRA rating n (%)	Low risk baseline CRA rating n (%)	Comparison with baseline high and low CRA ratings			
				Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
New caries noted at follow-up:	Yes	82 (87.2)	12 (12.8)	87.2	42.7	59.9	77.4
	No	55 (57.3)	41 (42.7)	(78.8, 93.2)	(32.7, 53.2)	(55.2, 64.3)	(65.7, 85.9)
Increase in dmft score from baseline:	Yes	58 (85.3)	10 (14.7)	85.3	35.3	42.3	81.1
	No	79 (64.8)	43 (35.2)	(74.6, 92.7)	(26.8, 44.4)	(38.4, 46.4)	(69.8, 88.9)
Increase in dmfs score from baseline:	Yes	84 (89.4)	10 (10.6)	89.4	44.8	61.3	81.1
	No	53 (55.2)	43 (44.8)	(81.3, 94.8)	(34.6, 55.3)	(56.6, 65.8)	(69.7, 89.0)

CI = confidence interval; PPV = positive predictive value; NPV = negative predictive value

**Table 5.** Analysis of Canadian Caries Risk Assessment form questions with regard to sensitivity, specificity, PPV, and NPV for new caries formation

Baseline variable		New caries clinically noted at follow-up		Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
		Yes n (%)	No n (%)				
Q1. Teeth cleaned with brush (or cloth if infant) at least twice daily by parent/caregiver:	No	45 (54.2)	38 (45.8)	47.9	60.4	54.2	54.2
	Yes	49 (45.8)	58 (54.2)	(37.5, 58.4)	(49.9, 70.3)	(46.1, 62.1)	(47.9, 60.4)
Q2. Daily exposure to fluoride:	No	12 (46.2)	14 (53.8)	12.8	85.4	46.2	50.0
	Yes	82 (50.0)	82 (50.0)	(6.8, 21.2)	(76.7, 91.8)	(29.5, 63.7)	(47.2, 52.8)
Q3. Feeding practices:	Yes	57 (53.8)	49 (46.2)	60.6	49.0	53.8	56.0
	No	37 (44.0)	47 (56.0)	(50.0, 70.6)	(38.6, 59.4)	(47.4, 60.0)	(47.9, 63.7)
Q4. Family is low-income:	Yes	64 (54.2)	54 (45.8)	68.1	43.8	54.2	58.3
	No	30 (41.7)	42 (58.3)	(57.7, 77.3)	(33.6, 54.3)	(48.6, 59.7)	(49.1, 67.0)
Q5. Visible plaque and/or food debris on teeth:	Yes	35 (62.5)	21 (37.5)	37.2	78.1	62.5	56.0
	No	59 (44.0)	75 (56.0)	(27.5, 47.8)	(68.5, 85.9)	(51.3, 72.5)	(52.3, 60.6)
Q6. Visible caries (includes white spot lesions) and/or past evidence of dental treatment for caries (e.g., fillings, stainless steel crowns, extracted teeth):	Yes	79 (64.8%)	43 (35.2%)	84.0	55.2	64.8	77.9
	No	15 (22.1%)	53 (77.9%)	(75.1, 90.8)	(44.7, 65.4)	(59.1, 70.0)	(68.2, 85.3)

CI = confidence interval; PPV = positive predictive value; NPV = negative predictive value

difficult to draw conclusions about their effectiveness, and they cannot yet be generalized to individual patients from different populations.<sup>26</sup> While limited in evidence to support the use of a specific type of CRA, these studies lend support to and justify the notion that a comprehensive CRA should be carried out at a child's first dental visit.<sup>27</sup>

There are several reports of the importance of CRA of preschool children,<sup>8,9,16,22</sup> but to date, there are no randomized control trials to determine the benefits or harms of a preschool-aged child being managed using a caries risk-based approach. One study demonstrated that preschool children identified as high risk for caries development had significantly more dental work done compared to those identified as low or moderate risk.<sup>17</sup> This finding illustrates an important limitation in the evaluation of CRA tools in that, when performed in a clinical setting, the estimated risk level would be managed by specific preventive and restorative actions. Therefore, as research continues in the field of CRA, there is a critical need for studies to address the benefits and harms associated with managing preschool children based on their classification of caries risk.

As there are no negative side effects of performing a CRA of preschool children, there is clearly potential for the procedure to promote the overall well-being and oral health of the child. As such, the use of CRA is still of vital importance in patient-centred caries prevention and management strategies, with the goal of reducing the need for extensive surgical intervention and overall improvement of oral-health related quality of life for the patient. Moreover, CRAs can serve as guides for public policy, allocation of resources in vulnerable segments of the population, design of dental public health programs, and the identification of common risk factors with other conditions.

As previously mentioned, this Canadian Caries Risk Assessment Tool was primarily developed for use by non-oral health primary care providers in non-dental clinic settings. The current study relied on a sample of children. A key follow-up to this study will be implementing the tool in different health care settings, with evaluation carried out by non-oral health professionals. Primary care providers often utilize structured checklists to aid in applying clinical practice guidelines.<sup>28</sup> The Canadian Caries Risk Assessment Tool would offer the necessary guidance for health care providers during their evaluation of caries risk in infants and young children and their subsequent referral. Such direction is important as evidence suggests that a physician's dental referral increases the likelihood that a child will see a dentist and the promptness for booking their first appointment.<sup>29</sup>

Despite its findings, this study is not without limitations. Participants were selected from community clinics in Winnipeg, which typically serve children from high-risk populations with lower socio-economic backgrounds. There may be issues with generalizability. In addition, behaviour, preventive practices, and presence of existing

caries may have been an indication for a general dentist to refer individuals for care at a pediatric-centred clinic. As such, there could be an unintended bias towards screening individuals who have a predisposition to the high-risk CRA category. Unfortunately, the research team did not have information on the preventive services children received. The possibility for recall bias exists, as some parents may not have been able to accurately answer some of questions related to feeding practices and oral hygiene habits.

Another important limitation in the evaluation of CRA tools is the fact that individuals with an estimated risk level would be managed by specific preventive and restorative actions. If these interventions are successful in preventing caries formation and progression, the accuracy of any CRA tool will be decreased.<sup>30</sup> Also, the outcome of CRA tools can differ between populations. Different populations have unique risk factors, and the CRA can be done with many types of groups. It is important to note that each child has their own unique set of circumstances, risk factors, and protective factors, as this is evident in the number of children who developed caries after 12 months. Nevertheless, the CRA tool can support health care providers in identifying children at risk for caries in their clinical practices or communities. An additional strength of our study is that, despite the COVID-19 pandemic, the team was able to perform clinical follow-up assessments for a significant portion of children.

## CONCLUSIONS

This study provides evidence on the validation of the new CRA tool for young children in Canada for use by non-oral health care providers and primary care professionals. The outcomes on the sensitivity and specificity of the CRA tool, along with the confirmation and validation of the existing questions in the tool, provide some support for the use of the tool. However, future population-based studies that compare the Canadian Caries Risk Assessment Tool with existing pediatric CRA tools are necessary to corroborate findings.

## ACKNOWLEDGEMENTS

Funding for this study was provided by the Network for Canadian Oral Health Research Seed Grant and unrestricted research funds from the University of Manitoba. At the time of this study, Dr. Robert J Schroth held a Canadian Institutes of Health Research (CIHR) Embedded Clinician Researcher salary award. He presently holds a CIHR Applied Public Health Chair in Oral Health – "Public Health Approaches to Improve Access to Oral Health Care and Oral Health Status for Young Children in Canada".

**CONFLICTS OF INTEREST**

The authors declare that there are no conflicts of interest.

**REFERENCES**

- American Academy of Pediatric Dentistry. Caries-risk assesment and management for infants, children, and adolescents. In: *The Reference Manual of Pediatric Dentistry*. Chicago (IL): AAPD; 2022. pp 266–72.
- Agnello M, Marques J, Cen L, Mittermuller B, Huang A, Chaichanasakul Tran N, et al. Microbiome associated with severe caries in Canadian First Nations children. *J Dent Res*. 2017;96(12):1378–1385.
- de Jesus VC, Shikder R, Oryniak D, Mann K, Alamri A, Mittermuller B, et al. Sex-based diverse plaque microbiota in children with severe caries. *J Dent Res*. 2020;99(6):703–712.
- Kirthiga M, Murugan M, Saikia A, Kirubakaran R. Risk factors for early childhood caries: a systematic review and meta-analysis of case control and cohort studies. *Pediatr Dent*. 2019;41(2):95–112.
- Harris R, Nicoll AD, Adair PM, Pine CM. Risk factors for dental caries in young children: a systematic review of the literature. *Community Dent Health*. 2004;21(1 Suppl):71–85.
- Schroth RJ, Halchuk S, Star L. Prevalence and risk factors of caregiver reported severe early childhood caries in Manitoba First Nations children: results from the RHS Phase 2 (2008–2010). *Int J Circumpolar Health*. 2013;72.
- Schroth RJ, Mittermuller BA, Au W, Hai-Santiago K, Martin H, Martens P, et al. Prenatal, maternal, and early childhood factors associated with dental general anesthesia to treat severe early childhood caries. *Pediatr Dent*. 2019;41(6):477–85.
- Fontana M, Young DA, Wolff MS. Evidence-based caries, risk assessment, and treatment. *Dent Clin North Am*. 2009;53(1):149–61, x.
- Schroth RJ, Rothney J, Sturym M, Dabiri D, Dabiri D, Dong CC, et al. A systematic review to inform the development of a Canadian caries risk assessment tool for use by primary healthcare providers. *Int J Paediatr Dent*. 2021;31(6):767–91.
- Schroth RJ, Kyoan-Achan G, Levesque J, Sturym M, DeMare D, Mittermuller BA, et al. A mixed methods approach to obtaining health care provider feedback for the development of a Canadian pediatric dental caries risk assessment tool for children <6 years. *Front Oral Health*. 2023;4:1074621.
- Pitts NB, Baez RJ, Diaz-Guillory C, Donly KJ, Alberto Feldens C, McGrath C, et al. Early childhood caries: IAPD Bangkok Declaration. *J Dent Child (Chic)*. 2019;86(2):72.
- Shwartz M, Grondahl HG, Pliskin JS, Boffa J. A longitudinal analysis from bite-wing radiographs of the rate of progression of approximal carious lesions through human dental enamel. *Arch Oral Biol*. 1984;29(7):529–36.
- Gao X, Di Wu I, Lo EC, Chu CH, Hsu CY, Wong MC. Validity of caries risk assessment programmes in preschool children. *J Dent*. 2013;41(9):787–95.
- Petersson GH, Isberg PE, Twetman S. Caries risk profiles in schoolchildren over 2 years assessed by Cariogram. *Int J Paediatr Dent*. 2010;20(5):341–46.
- Utreja D, Simratvir M, Kaur A, Kwatra KS, Singh P, Dua V. An evaluation of the Cariogram as a predictor model. *Int Dent J*. 2010;60(4):282–84.
- Tellez M, Gomez J, Pretty I, Ellwood R, Ismail AI. Evidence on existing caries risk assessment systems: are they predictive of future caries? *Community Dent Oral Epidemiol*. 2013;41(1):67–78.
- Chaffee BW, Featherstone JD, Gansky SA, Cheng J, Zhan L. Caries risk assessment item importance: Risk designation and caries status in children under age 6. *JDR Clin Trans Res*. 2016;1(2):131–42.
- Mejare I, Axelsson S, Dahlen G, Espelid I, Norlund A, Tranaeus S, et al. Caries risk assessment. A systematic review. *Acta Odontol Scand*. 2014;72(2):81–91.
- National Institutes of Health Consensus Development Panel. Diagnosis and management of dental caries throughout life. National Institutes of Health Consensus Development Conference statement, March 26–28, 2001. *J Dent Educ*. 2001;65(10):1162–1168.
- Fisher-Owens SA, Gansky SA, Platt LJ, Weintraub JA, Soobader MJ, Bramlett MD, et al. Influences on children's oral health: a conceptual model. *Pediatrics*. 2007;120(3):e510–e520.
- Twetman S, Fontana M. Patient caries risk assessment. *Monogr Oral Sci*. 2009;21:91–101.
- Fontana M, Gonzalez-Cabezas C. Evidence-based dentistry caries risk assessment and disease management. *Dent Clin North Am*. 2019;63(1):119–128.
- Petersson GH, Isberg PE, Twetman S. Caries risk assessment in school children using a reduced Cariogram model without saliva tests. *BMC Oral Health*. 2010;10:5.
- Christian B, Calache H, Adams G, Hall M, Dashper S, Gibbs L, et al. A methodological study to assess the measurement properties (reliability and validity) of a caries risk assessment tool for young children. *J Dent*. 2020;95:103324.
- Divaris K. Predicting dental caries outcomes in children: a "risky" concept. *J Dent Res*. 2016;95(3):248–54.
- Twetman S, Fontana M, Featherstone JD. Risk assessment—can we achieve consensus? *Community Dent Oral Epidemiol*. 2013;41(1):e64–e70.
- Tinanoff N, Baez RJ, Diaz Guillory C, Donly KJ, Feldens CA, McGrath C, et al. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: global perspective. *Int J Paediatr Dent*. 2019;29(3):238–48.
- Grimshaw JM, Winkens RA, Shirran L, Cunningham C, Mayhew A, Thomas R, et al. Interventions to improve outpatient referrals from primary care to secondary care. *Cochrane Database Syst Rev*. 2005(3):CD005471.
- Beil HA, Rozier RG. Primary health care providers' advice for a dental checkup and dental use in children. *Pediatrics*. 2010;126(2):e435–e441.
- Jorgensen MR, Twetman S. A systematic review of risk assessment tools for early childhood caries: is there evidence? *Eur Arch Paediatr Dent*. 2020;21(2):179–84.