Pilot Validation of a New Canadian Pediatric Caries Risk Assessment Tool for Preschool Children

By: Adam Siray

A Thesis submitted to the Faculty of Graduate Studies of the University of Manitoba

In partial fulfilment of the requirements of the degree of

MASTER OF DENTISTRY

Department of Preventive Dental Science

University of Manitoba

Abstract

Purpose: The purpose of this pilot study was to determine the sensitivity and specificity of a newly developed Canadian Caries Risk Assessment Tool for children < 6 years to predict caries development in a cohort of individuals followed in community-based dental clinics.

Methods: A prospective observational cohort study was conducted to test the Canadian Caries Risk Assessment Tool. Children were recruited over a 12-month period. The child's parent/caregiver completed a baseline CRA via interview, and dmft/dmfs were recorded. Participants returned for a follow-up examination at which time a second interview and changes in oral health, including new dental caries activity and dmft/dmfs were recorded. Data was analyzed using standard, bivariate statistics (chi square, t test, McNemar). Odds ratios (OR), sensitivity, specificity and positive/negative predictive values were calculated.

Data: Overall, 173 preschool children were initially enrolled. The average age was 39.9 ± 17 months. Baseline CRA enrollment and follow up occurred between January 2019 and October 2021 with an average time between assessments of 13 ± 4 months. 122 (70.5%) children were assigned a high CRA rating at their baseline appointment and 106 (61.3%) were found to have active caries or past evidence of dental treatment for caries. Baseline presence of visible caries and/or past evidence of dental treatment was found to be statistically significant ($p < 0.0001$) with new caries noted at their follow up assessment (OR=7.39). Individuals assigned to a high risk CRA rating were found to be significantly associated (p 0.0001) with formation of new caries noted at their follow up assessment (OR= 4.9). Sensitivity and specificity for baseline CRA rating (high and low risk) and new caries noted at clinical follow-up was determined to be 86.1% and 44.2% with a positive predictive value of 59.1% and a negative predictive value of 77.3%.

Conclusion: The current assessment of the Canadian Caries Risk Assessment Tool revealed a sensitivity of 86.1% and specificity of 44.2% when predicting new caries formation in preschool children, with a combined total of 130.3%, and a positive predictive value of 59.1% and negative predictive value of 77.3%. However, before it is to be utilized within different populations throughout Canada, further investigation is required into the development and refinement of the Canadian Caries Risk Assessment Tool.

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

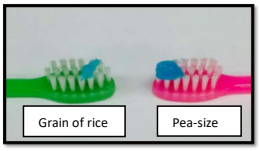
☐ Apply fluoride varnish *today*.

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/lidless 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: _____

University of Manitoba | Canadian Paediatric Society / Société canadienne de pédiatrie | CAPD ACDP | CAPHD ACSDP | Canadian Association of Public Health Dentistry / Association canadienne de la santé dentaire publique

December 20, 2019

Public Health Agency of Canada / Agence de la santé publique du Canada

Figure 2. Percentage of response to baseline/follow up Canadian Caries Risk Assessment form questions (McNemar's Test). * Statistically significant change from baseline.

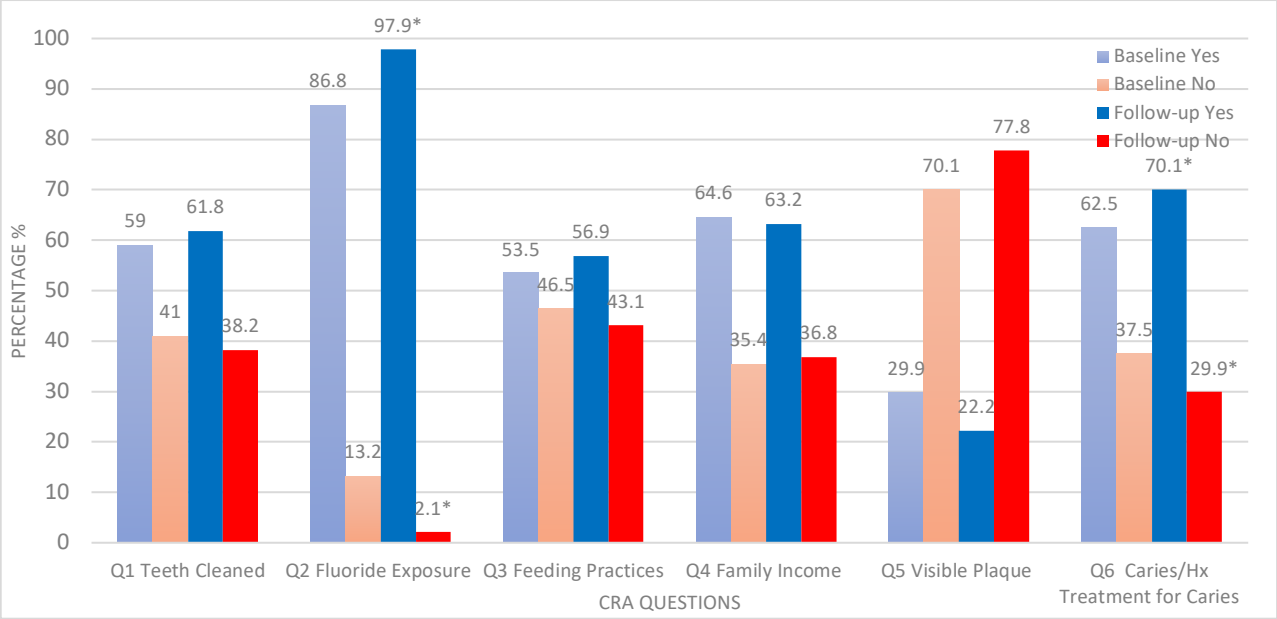


Figure 3. Percentage of individuals assigned to CRA risk rating at baseline and follow-up

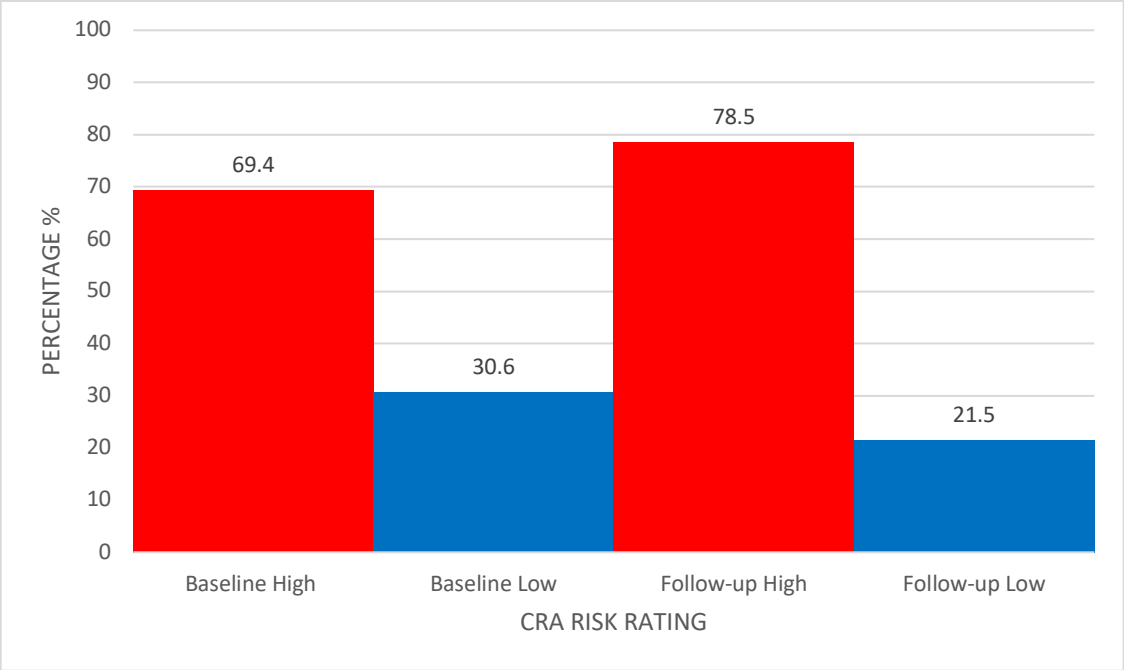


Table 1. Baseline characteristics of study sample

	n (%)
Sex	
Male	96 (55.5)
Female	77 (44.5)
Clinic Attended	
Access Downtown Clinic	108 (62.4)
Children's Dental Clinic	23 (13.3)
Mount Caramel Clinic	42 (24.3)
Mean age (months)	39.9 ± 17
Average time between baseline and follow-up assessment (months)	13 ± 4
Mean dmft	3.7 ± 4.7
Mean dmfs	7.8 ± 11.2
ECC	
Yes	105 (60.7)
No	68 (39.3)
S-ECC	
Yes	96 (55.5)
No	77 (44.5)

Table 2. Baseline frequency of responses and CRA score to baseline Canadian Caries Risk Assessment form

Baseline Variables	**Baseline Overall n (%)**
Q1. Teeth cleaned with brush (or cloth if infant) at least twice daily by parent or caregiver	
Yes	100 (57.8%)
No	73 (42.2%)
Q2. Daily exposure to fluoride?	
Yes	152 (87.9%)
No	21 (12.1%)
Q3. Feeding practices	
Yes	92 (53.2%)
No	81 (46.8%)
Q4. Family income is low	
Yes	111 (64.2%)
No	62 (35.5%)
Q5. Visible plaque and/or food debris on teeth	
Yes	54 (31.2%)
No	119 (68.8%)
Q6. Visible caries (incl. white spot lesions) and/or past evidence of dental treatment for caries (e.g., fillings, stainless steel crowns, extracted teeth)	
Yes	106 (61.3%)
No	67 (38.7%)
CRA Score	
0	9 (5.2%)
1	13 (7.5%)
2	29 (16.8%)
3	21 (12.1%)
4	28 (16.2%)
5	33 (19.1%)
6	24 (13.9%)
7	14 (8.1%)
8	2 (1.2%)
Mean total CRA score	3.9 ± 2.0
Overall CRA Rating	
High Risk	122 (70.5%)
Low Risk	51 (29.5%)

Table 3. Comparison of New caries noted at follow up and baseline response/rating on Canadian Cares Risk Assessment form

Variable Baseline	New caries clinically noted at follow-up		P Value	Odds Ratio
	Yes	No		
Sex				
Male	36 (45.0%)	44 (55.0%)	0.38	0.75
Female	36 (52.2%)	33 (47.8%)		
Q1. Teeth cleaned with brush (or cloth if infant) at least twice daily by parent or caregiver				
Yes	40 (45.5%)	48 (54.5%)	0.40	0.76
No	32 (52.5%)	29 (47.5%)		
Q2. Daily exposure to fluoride?				
	63 (48.5%)	67 (51.5%)	0.93	1.64
Yes	9 (47.4%)	10 (52.6%)		
No				
Q3. Feeding practices				
Yes	41 (51.9%)	38 (48.1%)	0.35	1.36
No	31 (44.3%)	39 (55.7%)		
Q4. Family income is low				
Yes	49 (51.6%)	46 (48.4%)	0.29	1.44
No	23 (42.6%)	31 (57.4%)		
Q5. Visible plaque and/or food debris on teeth				
Yes	27 (60.0%)	18 (40.0%)	0.06	1.97
No	45 (43.3%)	59 (56.7%)		
Q6. Visible caries (incl. white spot lesions) and/or past evidence of dental treatment for caries (e.g., fillings, stainless steel crowns, extracted teeth)				
Yes	61 (64.9%)	33 (35.1%)	< 0.0001	7.39
No	11 (20.0%)	44 (80.0%)		
Baseline CRA rating				
High risk	62 (59.0%)	43 (41.0%)	0.0001	4.90
Low risk	10 (22.7%)	34 (77.3%)		

Table 4. Follow-up Characteristics of Study Sample

	n
Participants	149
Mean CRA Score	3.9 ± 1.9
Mean dmft	4.7 ± 4.9
Mean dmfs	12.2 ± 16.5
Mean change in dmft from baseline	0.83 ± 1.9
Mean change in dmfs from baseline	4.2 ± 8.3

Table 5. Comparison of Baseline and Follow-up CRA rating and increase of dmft/dmfs

Variables	**Follow-up Overall (%)**	**Comparison of Baseline High & Low CRA Rating**			
		High Risk CRA rating	**Low Risk CRA rating**	**P-Value**	**Odds Ratio**
Increase in dmft score from baseline					
Yes	50 (33.6%)	42 (40.0%)	8 (18.2%)	0.01	3.0
No	99 (66.4%)	63 (60.0%)	36 (81.8%)		
Increase in dmfs score from baseline					
Yes	74 (49.7%)	66 (62.9%)	8 (18.2%)	<0.0001	7.6
No	75 (50.3%)	39 (37.1%)	36(81.8%)		

Table 6. Comparison of Baseline and Follow-up CRA rating with regards to sensitivity/specificity and positive predictive/negative predictive values for new caries and increase in dmft and dmfs

Variables	**Comparison of Baseline High & Low CRA Rating**					
	High Risk CRA Rating	**Low Risk CRA Rating**	**Sensitivity %**	**Specificity %**	**Positive predictive value %**	**Negative predictive value %**
New caries noted at follow-up						
Yes	62 (59.0%)	10 (22.7%)	86.1	44.2	59.1	77.3
No	43 (41.0%)	34 (77.3%)	(75.9-93.1)	(32.8-55.9)	(58.4-70.9)	(64.5-86.4)
Increase in dmft score from baseline						
Yes	42 (40.0%)	8 (18.2%)	84.0	36.4	40.0	81.8
No	63 (60.0%)	36 (81.8%)	(70.9-92.8)	(26.9-46.6)	(35.5-44.7)	(69.4-89.9)
Increase in dmfs score from baseline						
Yes	66 (62.9%)	8 (18.2%)	89.2	48.0	62.9	81.8
No	39 (37.1%)	36 (81.8%)	(79.8-95.3)	(36.3-59.9)	(57.3-68.1)	(69.2-90.0)

Table 7. Analysis of Canadian Caries Risk Assessment form questions with regards to sensitivity/specificity and positive predictive/negative predictive value for new caries formation

Variable Baseline	New caries clinically noted at follow-up		Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
	Yes	No				
Q1. Teeth cleaned with brush (or cloth if infant) at least twice daily by parent or caregiver						
Yes	40 (45.5%)	48 (54.5%)	55.6	37.7	45.5	47.5
No	32 (52.5%)	29 (47.5%)				
Q2. Daily exposure to fluoride?						
Yes	63 (48.5%)	67 (51.5%)	87.5	13.0	48.5	52.6
No	9 (47.4%)	10 (52.6%)				
Q3. Feeding practices						
Yes	41 (51.9%)	38 (48.1%)	56.9	50.7	51.9	55.7
No	31 (44.3%)	39 (55.7%)				
Q4. Family income is low						
Yes	49 (51.6%)	46 (48.4%)	68.1	40.3	51.6	57.4
No	23 (42.6%)	31 (57.4%)				
Q5. Visible plaque and/or food debris on teeth						
Yes	27 (60.0%)	18 (40.0%)	37.5	76.6	60.0	56.7
No	45 (43.3%)	59 (56.7%)				
Q6. Visible caries (incl. white spot lesions) and/or past evidence of dental treatment for caries (e.g., fillings, stainless steel crowns, extracted teeth)						
Yes	61 (64.9%)	33 (35.1%)	84.7	57.1	64.9	80.0
No	11 (20.0%)	44 (80.0%)				

Background

As healthcare providers, dentists have the important responsibility of educating and advocating for the oral health of their patients regardless of nationality, ethnicity, or socioeconomics. This includes accountability to their pediatric population for creating a childhood that is free of pain and dental disease. Historically, pediatric care focused around the tripartite mission of formation of a dental home, establishing a prevention protocol to prevent dental caries and periodontal disease, and treatment with restorative or surgical techniques as required. While these principles continue to be a cornerstone of dental care, the continual epidemic of early childhood caries (ECC) and severe ECC (S-ECC) and their impact on disadvantaged communities has resulted in a more multidimensional model of pediatric care. Evidence from the United States demonstrates a decline in prevalence of caries among school aged-children, adolescents, and adults, and an increase in prevalence of ECC in preschool populations[1]. Children living in poverty, residing in isolated rural and remote communities, immigrants, refugees, and of an Indigenous background are all recognized as being more likely to be affected by ECC than other children in Canada[2-7]. However, while ECC may be concentrated in children from these groups, it does not discriminate and can affect individuals from all cultural and socioeconomic backgrounds.

Dental procedures completed under general anesthesia may be the only restorative and surgical option for children with ECC, this is dependent on the age of the child and extent of treatment required[8]. The Canadian Institute of Health Information has reported hospital costs for surgeries to treat S-ECC exceeds $21 million/year with and the average rate of surgery to be 12.5/1000 children 1-5 years of age[9]. Higher rates of individuals requiring dental surgery were noted in children from rural regions of Canada, from less affluent homes, and residing in neighbourhoods with a high percentage of Indigenous residents[9]. While surgical management provides immediate treatment, it fails to address the underlying risk factors associated with disease formation as noted in children who acquire new caries or experience failure of treatment months after their initial surgery[8]. It is not uncommon for many children to require repeat surgical intervention under general sedation to correct treatment failures and recurrent

caries[8]. This demonstrates the importance of implementing an individually tailored preventive protocol, based on underlying risk factors, as a complement to restorative and surgical management.

ECC has been shown to be multifactorial in origin. Besides the basic etiological triad (i.e., teeth, bacteria, and sugars) there are other oral, social, economic, and personal factors and lifestyle behaviours at play[10,11]. Caries is shaped by a broad range of determinants of health, as such, prevention needs be tailored specifically to meet the needs and circumstances of the individual patient. The Fisher-Owens conceptual model describes the various child (e.g., biological and genetic endowment, physical and demographic characteristics, use of dental care, etc.), family (e.g., socioeconomic status and family finances, health practices and behaviours, culture, family make-up, etc.), and community (e.g., health and dental care systems, physical and social environments, culture, etc.) level factors that shape a child's dental health[10]. Identifying and recognizing the multiple factors that contribute to the formation of ECC is what makes prevention so difficult in young children. The Canadian Dental Association (CDA) recognizes the role that these non-biomedical factors have in caries development that it has gone so far as to specifically mention that ECC is heavily influenced by the social determinants of health in their formal position statement on ECC (12).

The objective of caries risk assessment (CRA) is to identify individual risk factors associated with disease formation and develop and implement patient-centered preventive and management strategies. CRA differs from traditional restorative management for dental caries by placing on emphasis on intervention before irreversible damage to teeth occurs[13, 14]. CRA assists dental practitioners by tailoring clinical care decisions unique to the individual[15]. Over the past several years there have been numerous well conducted systematic reviews and commentaries about CRA16-28. Through the course of these studies there were a considerable number of caries risk indicators that were identified. These included, clinical evidence of previous disease (i.e., past caries experience), sociodemographic, parental influence, dietary habits, microbiological factor, saliva, oral hygiene and plaque control, and use of fluorides[16-28]. It is essential that

dental professionals familiarize themselves with the numerous indicators that influence CRA and how to utilize this knowledge when screening their young patients. In addition, the implementation of CRA by non-dental primary healthcare providers would aid in their identification of at-risk individuals, recommendation and delivery of preventative practices, and appropriate referral to professional dental services.

Several dental and pediatric organizations have created CRA tools that can aid practitioners in their determination of an individual's likelihood for caries development. Proper implementation of risk assessment is an important starting point in reducing risk for ECC[12]. It can help identify whether a child is at low, moderate, or high likelihood of developing caries and can serve as a guide to choosing appropriate preventive interventions and practices that can help minimize the risk for decay. These tools help guide the conversation between dental provider and the parent or caregiver so that key information is obtained to assist in identifying many of the protective and caries-causing factors that are at play in a child's life. Involving non-dental primary healthcare providers in CRA has the potential to improve access to needed primary oral health care for children.

Well designed and contemporary CRA tools can facilitate clinical dental examinations as they specifically identify risk factors on a regular basis. This allows clinicians to review and inquire parents regarding several factors that are recognized to contribute to caries risk and more effectively individualize oral health supervisions and preventive strategies[29]. One limitation of current CRA tools is that they are not validated. The validity of a tool can be determined by assessing the sensitivity and specificity of the instrument [18,19,23]. When analyzing the validity of a CRA tool sensitivity refers to the capability to predict future caries formation in individuals who go on to develop caries. Specificity refers to the capability to predict the absence of caries in those who does not develop caries. An ideal CRA tool should have a combined sensitivity and specificity score of at least 160% and is relatively well-balanced between these two measures[19]. The purpose of this pilot study was to determine the sensitivity and specificity of a newly

developed Canadian Caries Risk Assessment Tool for children < 6 years to predict caries development in a cohort of individuals followed in community-based dental clinics.

Methods

This prospective observational cohort study was approved by the University of Manitoba's Health Research Ethics Board in Winnipeg, Canada. This pilot study's main aim was to test the Canadian Caries Risk Assessment Tool (Figure 1) and determine its preliminary sensitivity and specificity to predict future caries in preschool children. Children were recruited from January 2019 to October 2021 and were followed for a 12-month period on the day of their scheduled first dental exam or recall dental exam visit. Participants included children < 72 months of age and their parent or main caregiver and residing in Winnipeg or within one hour drive of Winnipeg to minimize loss-to-follow-up. Participation was restricted to children attending community-based dental clinics (Access Downtown, Mount Carmel Clinic, and the Children's Hospital Dental Clinic) in Winnipeg, Manitoba. Exclusion criteria included children with existing chronic disease and those not accompanied by a parent or primary caregiver to their dental appointment at the time of recruitment. The Canadian Caries Risk Assessment Tool was developed following a systematic review of the literature and accompanying assessment of the level of evidence, a comprehensive review of existing CRA tools for children, and informed by Canadian evidence of risk factors for ECC[30]. Research staff members asked parents and caregivers if they were interested in participating in the study.

After providing informed consent, the Canadian Caries Risk Assessment Tool was administered via interview to parents or primary caregivers of preschool children recruited into this study. Interviewing was performed in a private space to ensure confidentiality. A dental exam, performed by dentists familiar with the Canadian Caries Risk Assessment Tool, at baseline reviewed the clinical factors domain of past caries experience and treatment history along with the presence of visible plaque. The sociodemographic/biological factors section asked about the socioeconomic status of the family, infant feeding practices associated with increased caries risk and snacking between meals. Lastly, the protective factors domain posed questions on fluoride exposure and tooth brushing frequency. Children's caries status and oral health status

will be recorded at baseline. The child's total number of decayed, missing due to caries, and filled primary teeth (dmft score) and tooth surfaces (dmfs score) will be recorded at baseline. Twelve months after recruitment, participating children returned for their recall examination at which time a follow-up Canadian Caries Risk Assessment Tool was completed and changes in their oral health, including dental caries activity was determined. The study staff attended the child's follow-up dental examination at the community-based dental clinic or reviewed the child's chart following the child's recall examination to determine whether there have been any new caries lesions that developed during the study period and determine the child's dmft and dmfs scores. Radiographs were also used, if available, to determine caries lesion activity at baseline and follow-up. A 12-month follow-up period was selected to provide sufficient time for new caries lesions to appear and become clinically apparent.

Members of the research team reviewed all clinical patient records to determine if new caries has been documented during the observation period. Data were entered into an Excel (Microsoft Office, Redmond, Washington) spreadsheet database and saved on the secure server at the Children's Hospital Research Institute of Manitoba. Data were analyzed using standard descriptive (e.g., frequencies, means ± standard deviations (SD)), bivariate statistics (chi square, t test and McNemar's) using NCSS (Version 2021, Kaysville, Utah). A p value ≤ 0.05 was significant. Odds ratio (OR) were calculated. Sensitivity, specificity, and positive/negative predictive values were calculated using MedCalc's diagnostic test evaluation calculator (https://www.medcalc.org/calc/diagnostic_test.php).

Results

A total of 173 preschool children were initially enrolled into the study, 96 males and 77 females (Table 1). The average age was 39.9 ± 7.0 months (table 1). Children were recruited from Access Downtown (108, 62.4%), Children's Dental Clinic (23, 13.3%), and Mount Carmel Clinic (42, 24.3%) (Table 1). Baseline CRA enrollment and follow up occurred between January 2019 and October 2021 with an average time between assessments of 13 ± 4 months. Overall, 122 (70.5%) children were assigned a high CRA rating at their baseline appointment and 106 (61.3%) were found to have active caries or past evidence of dental treatment for caries (Table

2). Additionally, 57.8% had their teeth cleaned at least twice daily, 87.9% had daily exposure to fluoride either from toothpaste or drinking water, and 53.2% had feeding practices that are associated with higher risk for caries.

Of the 173 initial enrollments, 24 were lost to follow-up, and five children returned for a follow-up examination without the completion of a 12-month CRA form. Analysis of responses to the baseline and follow-up CRA found a significant change ($p= 0.0002$) with 86.8% of individuals responding yes to Question 2 (Fluoride exposure) at baseline, and 97.9% responding yes at follow-up (Figure 2). A significant change ($p = 0.0009$) in presence of caries or evidence of past dental treatment (Question 6) was also noted in individuals who responded yes at baseline (62.5%) and yes at follow up (70.1%). There were no significant changes noted between brushing/feeding practices, family income, or presence of visible plaque between baseline and follow-up assessments. Individuals rated as high or low risk at baseline and follow up were also found to be statistically significant ($p= 0.0016$) with 69.4% high risk at baseline and 78.5% high risk at follow up (Figure 3).

From the six questions analyzed in the Canadian Caries Risk Assessment Tool, an individual's response to question number 6 (Table 3). Visible caries and/or past evidence of dental treatment) was found to be statistically significant ($p <0.0001$) with new caries noted at their follow up assessment (OR= 7.39). Of the remaining five questions in the CRA form, there were no statistically significant associations between an individual's response to the question and the formation of new dental caries noted at their follow up appointment (Table 3). Sex of the individual was also found to not be statistically significant with new caries noted at follow up examination (Table 3).

Individuals assigned to a high risk CRA rating were found to be significantly associated ($p= 0.0001$) with formation of new caries noted at their follow up assessment (Table 3/Table 4) (OR= 4.9). Increases in dmft and dmfs scores from baseline were also found to be statistically

significant (p= 0.01 & <0.0001) based on an individual's base line CRA rating (Table 4) with odds ratios of 3.0 and 7.6, respectively.

The mean average CRA score was found to be 3.9 ± 2.0 at baseline and 3.9 ± 1.9 at follow-up with an average baseline dmft/dmfs of 3.8 ± 4.7; 7.7 ± 11.0 and a follow up dmft/dmfs of 4.7 ± 4.9; 12.2 ± 16.5. The average change in dmft/dmfs scores were found to be 0.83 ± 1.9; 4.2 ± 8.3 respectively (Table 4). Individuals who experienced an increase in dmft score from baseline (50, 33.6%) were found to be significantly associated (p value 0.01) with a high-risk baseline CRA rating (42, 40.0%) and an odds ratio of 3.0. In addition, an increase in dmfs score from baseline (74, 49.7%) was also found to be significantly associated with a high-risk baseline CRA rating (66, 62.9%) and an odds ratio of 7.6 (Table 5).

Sensitivity and specificity for baseline CRA rating and new caries noted at clinical follow-up was determined to be 86.1% and 44.2% with a positive predictive value of 59.1% and a negative predictive value of 77.3% (Table 6). For increase in dmft scores from baseline, the sensitivity and specificity were 84.0%/36.4% and a positive and negative predictive value of 40.0%/81.8% (Table 6). For increase in dmfs scores from baseline, the sensitivity and specificity were 89.2%/48.0% and a positive and negative predictive value of 62.9%/81.8% (Table 6). From the six questions on the Canadian Caries Risk Assessment Tool, the following was noted for sensitivity/specificity and positive/negative predictive values with regards to new caries being noted at follow-up examination; Question 1 (Teeth cleaned 2x/daily) sensitivity/specificity 55.6%/37.7%, and positive/negative predictive values of 45.5%/47.5%; Question 2 (Fluoride exposure) sensitivity /specificity 87.5%/13.0% and positive/negative predictive value 48.5%/52.6%; Question 3 (Feeding practices) sensitivity /specificity 56.9%/50.7% and positive/negative predictive value 51.9%/55.7%; Question 4 (Family income) sensitivity /specificity 68.1%/40.3% and positive/negative predictive value 51.6%/57.4%; Question 5 (Visible plaque) sensitivity /specificity 37.5%/76.6% and positive/negative predictive value 60.0%/56.7%; And Question 6 (Visible caries and/or past evidence of dental treatment) had a

sensitivity of 84.7%, specificity of 57.1%, and positive/negative predictive values of 64.9%/80.0% (Table 7).

Discussion

Utilization of caries risk assessment in young children aims to identify individuals most likely to experience the disease and provide patient centered prevention and management strategies. Through the identification of risk factors and behaviours associated with the formation of caries, dental practitioners can recommend appropriate protective measures and individually tailor clinical care decisions to the patients' needs. Ultimately these interventions would aim to reduce the risk of irreversible damage and need for traditional surgical/restorative techniques[13-14]. This pilot study intended to evaluate the sensitivity and specificity of a newly developed Canadian Caries Risk Assessment Tool for children < 6 years to predict caries development. From the clinical indicators assessed in the Canadian Caries Risk Assessment Tool, only baseline evidence of active caries and history of treatment related to caries was found to be significantly associated with evidence of new decay onset at follow-up (Table 3). With an odds ratio of 7.39, this clinical factor was significantly higher than the others when it came to associating a baseline finding with the risk of developing new caries in the future. This finding is consistent with other evaluations of pediatric CRA systems, in which baseline disease status was the most reliable predictor for future caries formation in preschool children[17,19,20,24,31]. This finding does not imply that the other measured CRA items 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[24,26,31]. As such, this present study is consistent with past evidence that CRA promotes dental providers to incorporate multiple patient variables in assigning risk status; with the goal of identifying potentially modifiable factors in an individualized caries management strategy[10,22]. Of note, the clinical presence of dental plaque was very close to being significantly associated with formation of future caries (p= 0.06 Table 3) and an odds ratio of 1.97; as further follow up and increase in study participants takes place into analyzing the Canadian Caries Risk Assessment

Tool, this clinical factor may become more statistically significant. To date, there have been no randomized control trials which have examined 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 being high risk for caries development had significantly more dental work done compared to those identified as low or moderate risk[31]; another suggested that the use of CAMBRA CRAT, with low specificity scores in Victoria (AUS) children, could potentially be driving over treatment for individuals seen in public dental services[32]. This demonstrates 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 preventative and restorative actions. As such if the interventions are successful the accuracy of any CRA tool will decrease[33]. 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.

The current assessment of the Canadian Caries Risk Assessment Tool revealed a sensitivity of 86.1% and a specificity of 44.2% (Table 6) when predicting new caries formation in preschool children. Overall, for a CRA tool to be useful, it should have a combined sensitivity and specificity score of at least 160% and should be relatively well-balanced between these two measures[19]. With a combined score of 130.3% the Canadian Caries Risk Assessment Tool in this pilot falls slightly below the ideal of 160% but demonstrates excellent sensitivity yet low specificity. In addition, a positive predictive value of 59.1% and negative predictive value of 77.3% reveals that the Canadian Caries Risk Assessment Tool has a higher probability of identifying low risk individuals who truly do not develop future caries. Similar findings were noted with respect to high and low risk individuals experiencing an increase in dmft score (sensitivity/specificity; 84.0%/36.4%) and dmfs score (sensitivity/specificity; 89.2%/48.0%). The results of this pilot study show promising potential for the Canadian Caries Risk Assessment Tool with further evaluation required into increasing the specificity of the tool. An evaluation and possible refinement of the CRA questions and their weighting contribution to the overall CRA score may produce a better caries predictive outcome for sensitivity and specificity. To

date, some of the most notable and commonly recognized pediatric caries risk assessment tools include 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 regrading risk factors for ECC is vast, the accuracy of CRA's has rarely been investigated and thus an uncertainty remains regarding their validity in predicting dental caries[20,32]. The results from a CAMBRA CRAT study to predict caries formation on young children in Victoria (AUS), ages 36 and 48 months, determined a sensitivity of 74% and 70% for each age group; however, their specificity was determined to only be 35% and 36%[32]. As such the conclusion was reached that in its current form, CAMBRA CRAT was not a good predictor for future caries prediction in the Victoria children population and in fact may be overestimating the proportion of high-risk children at risk of future disease[32]. Similar findings demonstrating satisfactory sensitivity but low specificity for CAMBRA CRAT have also been observed in other studies[19, 31]. Another study examined the predictability, sensitivity and specificity of the American Academy of Pediatric Dentistry's Caries Risk Assessment Tool, Caries Management by Risk Assessment (CAMBRA), Cariogram, and the National University of Singapore caries risk assessment program (NUS- CRA)[19]. Overall, their findings suggested that algorithm-based software programs like the NUS-CRA and Cariogram had a better balance of sensitivity and specificity over the checklist style caries risk assessment tools, with the NUS-CRA performing better than the Cariogram (Sensitivity/Specificity of its screening and comprehensive models were 82%/73% and 81%/85%)[19]. Assessment of Cariogram has also been validated in other populations and demonstrated acceptable accuracy when caries increment was taken into consideration with respect to impact on cavity levels[21, 34]; However, this same CRA approach performed less well when initial caries was incorporated into the study model[35]. This diverse reporting of predictive values demonstrates the limitations of these studies being more valid towards their populations studied and with regards to the different Cariogram settings in which their information was gathered. Furthermore, the application of Algorithm based CRA programs is complex and requires expensive and time-consuming laboratory results, as such they are not practical for use in screening situations. From these studies Cariogram has shown limited and mixed data in assessing its efficacy in predicting caries

development, while other standardized CRA models are completely lacking in research. As such, these limited findings make it difficult to draw conclusions about their effectiveness and cannot yet be generalised to individual patients from different populations[18]. Overall, the NUS-CRAT studies have been found to report the most information in terms of the assessment of its measurement properties[31, 36]. While limited in evidence to support a specific type of CRA to be utilized, these studies lend support and justify the notion that a comprehensive CRA should be carried out at a child's first dental visit[37]. Furthermore, as researchers have not reported any negative side effects for performing a CRA assessment in 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-centered 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.

A key follow-up to this study will be the implementation of the Canadian Caries Risk Assessment Tool in different health care settings and evaluation by non-dental health professionals. Primary care providers often utilize structured checklists to aid in the application of clinical practice guidelines[38], the Canadian Caries Risk Assessment Tool would provide the necessary guidance for healthcare 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 as well as the promptness for booking their first appointment[39,40]. Among the factors affecting low dental referral rates among physicians, confidence in identifying the need for a referral, availability of dentists, and practices with a high patient volume of pediatric patients were noted[41]. The Canadian Caries Risk Assessment Tool would not only provide the guidance necessary for a proper caries risk evaluation, but also provide the opportunity for proper referral to an appropriate dental clinic as well as recommendations for caries prevention and risk reduction.

Limitations of this study would be the patient demographic that is usually seen at the ACC, CDC, and MCC clinics. Individuals who attend these clinics typically come from regions of the city of

Winnipeg the have a lower socio-economic demographic. In addition, their behaviour, preventive practices, and presence of existing caries may have been an indication for a general dentist to refer them for care at a pediatric centered clinic. As such there could be an unintended bias towards screening more individuals who have a predisposition to the high-risk caries risk assessment category. Language barriers experienced by parents in the community clinics also may have affected comprehension and response to the CRA questions, resulting in potential for response and recall bias. Implementing the Canadian Caries Risk Assessment Tool into additional clinics, both pediatric specific and general based, and even beyond into more Canadian cities could aid in removing this bias for screening only one specific population. Another important limitation in the evaluation of CRA tools is the fact that individual with an estimated risk level would be managed by specific preventative and restorative actions. If these interventions are successful in preventing caries progression and formation the accuracy of any CRA tool will decreased[33]. Thus, an important follow up investigation for the Canadian Caries Risk Assessment Tool would be to address the benefits and harms of CRA in preschool children with their categorization of caries risk and associated management. The 2020 COVID-19 pandemic, which occurred roughly mid-way through the study period, is another important limitation of this study. Closure of clinics, limited access to dental care, and loss of household income all could have impacted proper access to professional preventative care as well as proper utilization of home oral hygiene practices for the study participants. In addition, the ability to follow-up and screen individuals using the Canadian Caries Risk Assessment Tool was also delayed due to provincial restrictions about types of individuals who could be seen in the dental clinic, sometimes beyond the study protocol 12-month timeframe. This delayed follow-up screening and limited access to preventative and restorative care may have resulted in individuals reporting higher numbers for new caries formation and increases in dmft/dmfs scores. Fortunately, even with these exceptional circumstances, very few individuals were lost to follow-up due to COVID and majority of participants were still seen within the ideal 12-month follow-up period.

Conclusion

Caries risk assessment is unique over traditional restorative approaches to managing caries, with emphasis on intervention before irreversible damage, and focuses on development of patient-centered prevention and management strategies. The purpose of this pilot study was to determine the sensitivity and specificity of a newly developed Canadian Caries Risk Assessment Tool for children <6 years to predict caries development in a cohort of individuals followed in community-based dental clinics. The current assessment of the Canadian Caries Risk Assessment Tool revealed a sensitivity of 86.1% and a specificity of 44.2% (total 130.3%) when predicting new caries formation in preschool children with a CRA rating of high or low risk at baseline evaluation.

References:

1. Dye BA, Tan S, Smith V, Lewis BG, Barker LK, Thornton-Evans G, Eke PI, Beltran-Aguilar ED, Horowitz AM, Li C. Trends in oral health status: United States, 1988-1994 and 1999-2004. *Vital Health Stat 11.* 2007;(248):1-92.
2. Schroth RJ, Harrison RL, Moffatt ME. Oral health of indigenous children and the influence of early childhood caries on childhood health and well-being. *Pediatr Clin North Am.* 2009;56(6):1481-1499.
3. Schroth RJ, Moore P, Brothwell DJ. Prevalence of early childhood caries in 4 Manitoba communities. *J Can Dent Assoc.* 2005;71(8):567.
4. Parker EJ, Jamieson LM, Broughton J, Albino J, Lawrence HP, Roberts-Thomson K. The oral health of Indigenous children: a review of four nations. *J Paediatr Child Health.* 2010;46(9):483-486.
5. Phipps KR, Ricks TL, Manz MC, Blahut P. Prevalence and severity of dental caries among American Indian and Alaska Native preschool children. *J Public Health Dent.* 2012;72(3):208-215.
6. Harrison RL, Veronneau J, Leroux B. Effectiveness of Maternal Counseling in Reducing Caries in Cree Children. *J.Dent Res.* 2012;91(11):1032-1037.
7. Amin MS, Perez A, Nyachhyon P. Parental Awareness and Dental Attendance of Children Among African Immigrants. *J Immigr Minor Health.* 2015;17(1):132-138.
8. Schroth R, Smith W. A review of repeat general anesthesia for pediatric dental surgery in Alberta, Canada. *Pediatr Dent* 2007;29(6):480-487.
9. Canadian Institute for Health Information. Treatment of Preventable Dental Cavities in Preschoolers: A Focus on Day Surgery Under General Anesthesia. Ottawa, ON: CIHI, 2013:1-34.
10. Fisher-Owens SA, Gansky SA, Platt LJ, Weintraub JA, Soobader MJ, Bramlett MD, Newacheck PW. Influences on children's oral health: a conceptual model. *Pediatrics.* 2017;120(3):e510-e520.
11. Selwitz RH, Ismail AI, Pitts NB. Dental caries. *Lancet.* 2007;369(9555):51-59.
12. Canadian Dental Assoc. CDA Position on Early Childhood Caries. *Canadian Dental Association.* 2010.
13. Fontana M, Gonzalez-Cabezas C. Evidence-Based Dentistry Caries Risk Assessment and Disease Management. *Dent Clin North Am.* 2019;63(1):119-128.
14. Quinonez R, Crall JJ. Caries-risk assessment. In: Berg JH, Slayton RL, eds. *Early Childhood Oral Health.* Vol First. Ames, Iowa: Wiley-Blackwell; 2009:170-197.
15. American Academy of Pediatric D. Guideline on caries-risk assessment and management for infants, children, and adolescents. *Pediatr Dent.* 2015;37(6):132-139.
16. Divaris K. Predicting Dental Caries Outcomes in Children: A "Risky" Concept. *J Dent Res.* 2016;95(3):248-254.
17. Mejare I, Axelsson S, Dahlen G, Espelid I, Tranaeus S, Twetman S. Caries risk assessment. A systematic review. *Acta Odontol Scand.* 2014;72(2):81-91.
18. Twetman S, Fontana M, Featherstone JD. Risk assessment - can we achieve consensus? *Community Dent Oral Epidemiol.* 2013;41(1):e64-e70.

19. 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):787-795.
20. 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.
21. Carson SJ. Limited evidence for existing caries assessment systems. *Evid Based Dent.* 2013;14(1):10- 11.
22. Twetman S, Fontana M. Patient caries risk assessment. *Monogr Oral Sci* 2009;21:91-101.
23. Slayton RL. Clinical Decision-making for Caries Management in Children: An Update. *PediatrDent.* 2015;37(2):106-110.
24. Diagnosis and management of dental caries throughout life. National Institutes of Health Consensus Development Conference statement, March 26-28, 2001. *J Dent Educ* 2001;65:1162-1168.
25. Swedish Council on Technology Assessment in Health Care. Caries diagnosis, risk assessment and non-invasive treatment: a systematic review. Summary and conclusions. 2007:1-13.
26. Scottish Intercollegiate Guidelines Network (SIGN). Dental interventions to prevent caries in children. Edinburgh: SIGN, 2014:1-45.
27. Zero D, Fontana M, Lennon AM. Clinical applications and outcomes of using indicators of risk in caries management. *J Dent Educ.* 2001;65(10):1126-1132.
28. Pienihakkinen K, Jokela J, Alanen P. Assessment of caries risk in preschool children. *Caries Res.* 2004;38(2):156-162.
29. Fisher-Owens SA. Broadening perspectives of pediatric oral health care provision: social determinants of health and behavioural management. *Pediatr Dent.* 2004;26(2):115-120.
30. Schroth R, Rothney J, Sturym M, Dabiri D, Dabiri D, Dong C, Grant C, Kennedy T, Sihra R. A systematic review to inform the development of a Canadian caries risk assessment tool for use by primary healthcare providers. *Int J Paediatric Dent*. 2021;00: 1-25.
31. Chaffee B, Featherstone J, Gansky S, Cheng J, Zhan L. Caries risk assessment item importance. Risk designation and caries status in children under Age 6. *JDR Clin Trans Res*. 2016 Jul;1(2):131-142.
32. Christian B, Calache H, Adams Geoff, Hall M, Dashper S, Gibbs L, Gussy, M. A methodological study to assess the measurement properties (reliability and validity) of a caries risk assessment tool for young children. *J Dent*. 2020;95:1-8.
33. Jorgensen M, Twetman S. A systematic review of risk assessment tools for early childhood caries: is there evidence? *Eur Arch Paediatr Dent*. 2020 Apr;21(2):179-184.
34. Garg A, Madan M, Dua P, Saini S, Mangla R, Singhai P, Dupper A. Validating the usage of Cariogram in 5- and 12-year-old school children in Paonta Sahib, Himachal Pradesh, India: a 12-month prospective study. *Int J Clin Pediatr Dent.* 2018;11(2):110-5.
35. Birpou E, Agouropoulos A, Twetman S, Kavvadia K. Validation of different Cariogram settings and factor combinations in preschool children from areas with high caries risk. *Int I Paediatr Dent.* 2019;29(4):448-455.

36. Christian B, Armstrong R, Hanny C, Carpenter L, Gibbs L, Gussy M. A systematic review to assess the methodological quality of studies on measurement properties for caries risk assessment tools for young children. *Int J Paediatric Dent*. 2018;29(2):106-116.
37. Tinanoff N, Baez R, Guillory C, Donly K, Feldens C, McGrath C, Phantumvanit P, Pitts N, Seow W, Sharkov N, Songpaisan Y, Twetman S. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: Global perspective. *Int J Paediatr Dent.* 2019. May; 29(3):238-248.
38. Grimshaw J, Winkens R, Shirran L, Cunningham C, Mayhew A, Thomas R, Fraser C. Interventions to improve outpatient referrals from primary care to secondary care. *Cochrane Database of Systematic Reviews*. 2005. Jul;(3):CD005471.
39. Beil H, Rozier RG. Primary Health Care Providers' Advice for a dental check-up and dental use in children*. Pediatrics*. 2010;126(2):e435–441.
40. Pahel B. Effectiveness of preventive dental treatments by physicians for young Medicaid enrollees. *Pediatrics*. 2011;127(3):e682-689.
41. Dela Cruz G, Rozier R, Slade G. Dental screening and referral of young children by pediatric primary care providers. *Pediatrics*. 2004;114(5):e642–e65.