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Youth self-report of child maltreatment in representative surveys: a systematic review

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This evidence synthesis has been peer reviewed.

Abstract

Introduction: This systematic review identified population-representative youth surveys containing questions on self-reported child maltreatment. Data quality and ethical issues pertinent to maltreatment data collection were also examined.

Methods: A search was conducted of relevant online databases for articles published from January 2000 through March 2016 reporting on population-representative data measuring child maltreatment. Inclusion criteria were established a priori; two reviewers independently assessed articles to ensure that the criteria were met and to verify the accuracy of extracted information.

Results: A total of 73 articles reporting on 71 surveys met the inclusion criteria. A variety of strategies to ensure accurate information and to mitigate survey participants' distress were reported.

Conclusion: The extent to which efforts have been undertaken to measure the prevalence of child maltreatment reflects its perceived importance across the world. Data on child maltreatment can be effectively collected from youth, although our knowledge of best practices related to ethics and data quality is incomplete.

Keywords: *abuse, neglect, violence, data quality, ethics, adolescence, teenager, systematic review*

Highlights

- Data on child maltreatment can be collected responsibly and ethically from youth in a way that protects their health and well-being.
- Youth rarely expressed concerns about answering child maltreatment questions on self-report surveys.
- No nationally representative self-report survey focussed on Canadian youth that includes child maltreatment variables was identified from our database search.
- Few reliable and valid self-reported measures of child maltreatment currently exist.

Introduction

The consequences of child maltreatment—a public health issue that poses unique challenges to quantify and study—extend well beyond the immediate harm inflicted. For example, a history of child maltreatment has been shown to interfere with adolescent development and to raise the risk of some of the leading causes of morbidity and mortality.[1] These include alcohol-related injury, drug use, self-harming behaviour, suicide and exposure to violence.[2-5]

A growing body of research is aimed at estimating the extent of child maltreatment, and understanding the dynamics and mechanics of its association with health outcomes.[6] Population-representative surveys provide the opportunity to quantify child maltreatment prevalence and to assess its risk in relation to other health-related and social conditions. Of course, in surveys that address a broad range of health-related content, space limitations and competing interests challenge the inclusion of child maltreatment measures. However, the potential contribution of such surveys in improving our understanding of the prevalence, risk factors and impact of child maltreatment is becoming increasingly appreciated—both in Canada and elsewhere.[7] Population-based data from other countries provide the basis for international comparisons, from which the influence of cultural, social and policy practices on any differences observed can be considered.[8,9]

The ethical aspects of child maltreatment survey research are crucial. The sensitive nature of the subject matter and the consequential risk of emotional distress to respondents call for measures to protect confidentiality, administer questions with appropriate sensitivity, obtain informed consent, and potentially provide follow-up interventions.[10] Procedures to address such matters should be clearly delineated, and included as an elemental component of any survey or research report.

Quality of data is an important consideration and should be evaluated in any survey-based research on child maltreatment. Various factors influence the quality of information a respondent provides, such as age and developmental stage. Surveying young people about experiences of child maltreatment has the advantage of being relatively recent to the exposure, so recall bias is likely lower than it would be in a survey of adults. The reliability of self-reported information from adolescents is greater than that from younger children, by virtue of their more advanced cognitive development.[11] Specifically, research suggests that children under the age of 10 years may not be reliable respondents

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for a survey on experiences of maltreatment.[12] Other potential impediments to the disclosure of accurate information include distress, discomfort and embarrassment generated by the memory of events.[13-16]

A review article published in 2000 addressed methodological and ethical considerations in asking children about their exposure to physical and sexual abuse.[17] The authors identified 14 self-report studies that garnered information directly from children; the approaches used to elicit information varied greatly.[17] While the review provides much worthwhile information, it was limited to surveys conducted before 1999; the surveys focussed on physical and sexual abuse and were not representative of the general population. The authors noted considerable variation in data collection methods, wording and number of maltreatment questions as well as consent procedures. Consequently, the estimates of physical and sexual abuse varied considerably.

This systematic review is aimed at increasing our understanding of child maltreatment data captured in self-reported surveys with youth. The specific objectives are to (1) identify representative surveys that have collected data from youth on child maltreatment and factors influencing prevalence (thus not clinical samples); (2) examine the quality of methods used to measure child maltreatment; and (3) assess practices and procedures undertaken to address ethical issues.

Methods

This systematic review was done according to the PRISMA guidelines.[18] (Protocol is available upon request from the corresponding author).

Identification (search strategy)

A search for peer-reviewed articles published from January 2000 through March 2016 was conducted in the following online databases: Embase, Medline, PsycINFO, Global Health, Social Policy and Practice, ERIC, Social Services Abstracts, Sociological Abstracts, and ProQuest Public Health. Search terms used included: youth, adolescent, young adult, child, abuse, maltreatment, violence, neglect, assault, rape, representative, national, and school surveys. The complete search strings employed are available upon request from the corresponding author. In addition, the reference lists of included articles were examined to identify additional articles for potential inclusion as well as discussions with experts.

The following were the criteria for inclusion of articles in the review:

- published in English;
- primary study (i.e. not review or editorial);
- data collected after 1999;
- data sources limited to school or representative population-based surveys (the latter defined as those which were described that way by the authors of the articles and/or had been sampled and weighted in order to accurately reflect the members of the entire population);
- cross-sectional design;
- age range of respondents was 10 to 18 years (core age group); in some cases, age ranged up to 24 years;
- victim's age at time of exposure to maltreatment was under 18 years;
- reported perpetrator of maltreatment was a parent or other caregiver (except for sexual abuse, for which the perpetrator could be anyone, however articles were still not included if they focused on peer or online victimization);
- analysis was conducted using the entire sample of the specified age group (ages 10 to 18).

It should be noted that we limited the inclusion to cross-sectional studies to ensure the inclusion of the largest numbers of surveys. In addition, since the primary purpose of this article is not to determine associations but instead the feasibility of collecting child maltreatment data from youth to estimate prevalence, cross-sectional studies are appropriate. The benefit of including longitudinal studies would be limited, considering that child maltreatment questions are rarely asked in the first wave of a longitudinal study but rather in the later waves where attrition may be an issue.[19,20]

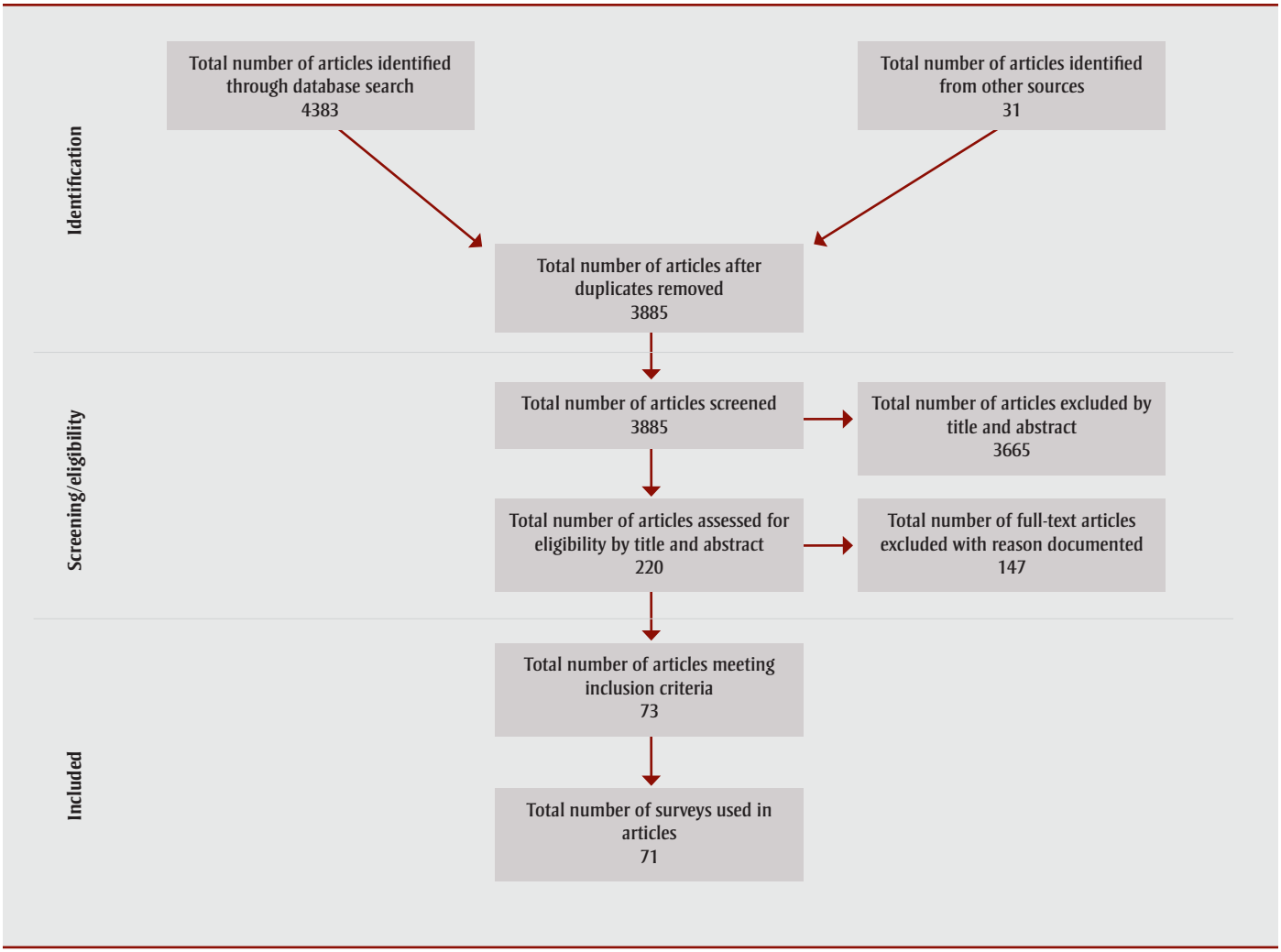
Screening/eligibility (selection process)

Figure 1 shows the process of selecting the articles included in this study. The database search identified 4383 articles; expert consultation and search of reference lists identified another 31 articles. Removing duplicates yielded 3885 articles, and screening by titles and abstracts led to 220 articles to be fully assessed. To these articles, the inclusion criteria noted above were applied by two reviewers independently (J.L., L.T.). The percentage agreement between the coder pairs was 97.9% for titles and abstracts. Articles were excluded when the articles addressed adults' retrospective reports of childhood maltreatment, substance abuse, non-representative samples, newspaper articles, conference abstracts, commentaries, and letters to the editor. Each reviewer also catalogued the reported prevalence of maltreatment by type. Although specific definitions of child maltreatment varied somewhat among the articles, they were conceptually similar enough that the Public Health Agency of Canada's (PHAC) classifications could be applied such as emotional maltreatment (EM), neglect (NG), exposure to intimate partner violence (EIPV), physical and sexual abuse (PA and SA)[21] (Table 1).

We modified a coding key previously used in assessing adults' retrospective exposure to childhood maltreatment.[6] Reliability and validity of the maltreatment measures were noted when reported. Documentation of procedures related to ethics focused on any steps taken to protect confidentiality, offer respondents support, or ease their distress during/following the survey (see Table 2). Information related to survey administration and measures to evaluate data quality were collected from the articles. As well, external sources (e.g. articles or websites) cited in the articles were consulted for information regarding validity and reliability of child maltreatment measures; in some cases, these sources also provided insights into how maltreatment was conceptualized for a survey, or clarified survey procedures. When information in an article included in the review was inconsistent with that provided in an external source, the former took precedence; if information in articles selected for review and pertaining to the same survey conflicted, the article more closely addressing the objectives of the study was used.

As a final step, to verify that the selected articles met the inclusion criteria and to ensure the accuracy of all extracted information, the articles were assessed by two additional reviewers (C.W., S.A., or J.D.);

FIGURE 1
Flow of information through the different phases of the review



any disagreements were discussed until consensus was reached.

Results

From the 3885 articles identified in the online search, 220 were screened in according to the abstract and title. Of these, 73 met the inclusion criteria, representing 71 surveys. Table 3 describes the characteristics of each sample, survey methodology, measures of child maltreatment, reliability and validity, response rates and any steps taken to enhance the response rate, approaches and protocols designed to comfort or reduce the distress of participants, and types of child maltreatment. Schools were most often the place of data collection. Most data were collected via self-administered questionnaire, data were also provided by face-to-face and telephone interviews independent of location. Eleven measures were used and often modified from the original iteration. The Juvenile Victimisation Questionnaire (JVQ) was used most often (eight times), followed by different versions of the Conflict Tactics Scale (CTS) (six times) and the International Society for the Prevention of Child Abuse and Neglect child abuse screening tool—Child (ICAST-CH) (four times). Thirty-seven articles did not provide any information on the specific measures used. In addition, few articles provided information regarding the reliability and validity of measures used. Respondents' response rates ranged from 40.4% to 99.9%. The majority of articles mentioned approaches taken to comfort respondents, although specific information on procedures to reduce distress was scarce.

The most commonly mentioned procedures in place for reducing or dealing with participant distress were as follows: (1) providing respondents with information and telephone numbers of appropriate support services; (2) following up with respondents who disclosed threatening situations; (3) giving focused, sensitivity training to interviewers; (4) alerting appropriate authorities when intervention was deemed necessary. Of course, disclosure to participants of the possibility of alerting authorities could negatively influence participation.

Of the maltreatment types, sexual abuse was captured most frequently in the survey questions (see Table 3). The majority of maltreatment measures specified behaviours, rather than being self-defined; sexual abuse was stipulated with the most detail. Child maltreatment prevalence estimates varied by measure and were not always reported. The heterogeneity of measures and variation in time periods covered precluded meaningful comparisons

TABLE 1
Definition of child maltreatment

Types of maltreatment	Forms of child maltreatment	Questions used to measure child maltreatment
Sexual abuse	Kissing, caressing, fondling and oral sex	How many times has another person touched, grabbed, pinched or brushed against you in a sexual way (which you did not want)?[22]
		Students were asked by their parents to touch the latter's sex organs, or if their own sex organs have been touched by their parents.[23]
		Episodes of unwanted oral sex.[4]
	Attempted rape and rape	Attempts intercourse, completed intercourse and attempts at anal intercourse.[24]
		We define [rape] as someone either having sexual intercourse with you or penetrating your body with a finger or object when you did not want them to, either whether by threatening you, by using force or when you were so small that you didn't know what was happening.[25]
		Somebody tried to undress you in order to have sex with you, had vaginal intercourse [against your will].[26]
	Exposure to pornography, masturbation, flashing	Did anyone show you pornographic material?[27]
		Somebody exposed himself/herself indecently to you [against your will].[26]
		Did anyone make you look at their private parts by using force or surprise, or by "flashing" you?[12]
	Verbal sexual abuse	How many times have you had unwanted sexual comments or jokes directed at you?[22]
		Did anyone hurt your feelings by saying or writing something sexual about your body?[12]
	Online victimization	Did anyone on the Internet ever ask you sexual questions about (himself/herself/yourself) or try to get you to talk online about sex when you did not want to talk about those things?[28]
		Nude photograph(s)/video(s) being uploaded on the Internet against your will.[29]
	Commercial sex	Have you ever experienced that the person/s you met [online] gave you money or a gift in order to have sex with you?[26]
		To be engaged in transactional sex.[30]
	Self-defined	Have you ever been sexually abused?[1]
Physical abuse	Corporal punishment/physical punishment	Your parents spank you on the bottom with their bare hands, hit you on the bottom with something like a belt, ruler, a tick, sweeper or some other hard object, slap you on the hand, arm or leg, pinch you or shake/push you?[31]
		Severe physical punishment resulting in bruises or other forms of injuries.[32]
		Acts traditionally seen as forms of corporal punishment: hair pulling, whipping, smacking.[33]
	Slapped/hit with hand or hard object, punched, beaten	Physical maltreatment and severe physical maltreatment like slapping, hitting […] and […] beating.[34]
		Being beaten […] by a family member.[35]
	Thrown, pushed, knocked down, shaken, kicked	Has any adult ever […] thrown something at you? (followed by question to specify the caregiver).[36]
		Being thrown across the room or against the wall, car, floor or other hard surface by an adult in charge, so that [you] were hurt pretty badly.[4]
	Burned, scalded, choked, head held under water, tied up	"Severe physical maltreatment such as […] burning."[34]
		Being grabbed around the neck or choked by an adult in charge.[4]
		Your parents grab you around the neck and choke you, burn or scald you on purpose.[31]
	Used weapon against	Has any adult […]threatened you with a weapon, such as a knife, stick, a gun?[36]
		Attacked or threatened with a gun, knife, other weapon or other object?[4]
	Self-defined	Having experienced physical violence or having experienced severe physical violence.[15]
Emotional maltreatment	Verbal abuse, belittling	An adult made child scared or feel really bad by name calling, saying mean things.[13]
		Did you get scared or feel really bad because grown-ups in your life called you names, said mean things to you?[37]
	Terrorized, threatened	Threatening to use a gun or knife.[38]
		Your parents threaten to spank or hit you but did not actually do it.[23]
	Inadequate nurturing/affection	Not talking to the child.[39]
		Did you get scared or feel really bad because grown-ups in your life […] say they didn't want you?[37]
	Isolated/confinement	Isolated, confined in a dark room.[32]

Continued on the following page

TABLE 1 (continued)
Definition of child maltreatment

Types of maltreatment	Forms of child maltreatment	Questions used to measure child maltreatment
Neglect	Supervisory	Having inadequate supervision and being required to do age-inappropriate chores.[40]
	Physical	When someone is neglected it means that the grown-up in their life did not take care of them the way they should […] [by] make[ing] sure they have a safe place to stay.[37]
		Not receiving adequate food or clothing.[40]
	Medical	When someone is neglected it means that the grown-up in their life did not take care of them the way they should […] [by] taking them to the doctor when they are sick.[37]
Exposure to intimate partner violence	Physical abuse	The young person witnessed his/her parents physically abusing each other.[41]
		Adolescent observed parents punched, hit or beat up one another, choked one another, hit one another with an object.
	Emotional maltreatment	Asked whether if they had ever […] witnessed severe arguments between their parents.[2]
		Adolescent observed parents […] threatening one another with gun, knife or other weapon.[4]

of prevalence estimates. Summary estimates for lifetime prevalence ranged from 0.3% to 44.3% for sexual abuse, 4.2% to 58.3% for physical abuse, 3.1% to 78.3% for emotional maltreatment, 0.9% to 38.3% for neglect, and 0.6% to 30.9% for exposure to intimate partner violence.

Discussion

The findings of this systematic review reflect the extensive effort that has been made to measure child maltreatment at the population level and thus the perceived importance of this problem across the world. The review identified a variety of strategies employed to enhance data accuracy and mitigate participants' distress. Our findings were similar to those found in the review from 2000.[17] However, both our findings and theirs demonstrate that information on child maltreatment can be collected, albeit the issue of inconsistent definitions remains.

Identifying surveys and factors influencing prevalence estimates

Prevalence estimates of child maltreatment varied widely among the studies examined. In assessing findings across surveys, it is important to consider factors intrinsic to self-reporting that can compromise comparability.[24] Barriers include self-blame, cognitive development and age, stigma, fear of retaliation by the perpetrator, and failure to recognize behaviour as abusive.[16] Regarding the latter, differing perceptions of what constitutes discipline versus abuse can contribute to inconsistencies in response.[8] In some cultures, the use of physical punishment is commonplace and even legally accepted,[31,39] while in others it is considered to be abuse.[109] In some studies, behaviours related to sexual abuse were not assessed because the topic was deemed too culturally sensitive.[50,60]

Variations in prevalence estimates of child maltreatment across studies might also be

TABLE 2
Approaches to increase respondent's comfort and response rate

	Definitions
Approaches to increase comfort	**Assent**: Participants who are legally too young to give informed consent, express willingness to participate in research, since they are old enough to understand the purpose of the research.
	Consent: Voluntary agreement of an individual, or his or her authorized representative, who has legal capacity to give consent.
	Active consent: Parent or legal guardian is required to sign and return a form if they approve their child's participation.
	Passive consent: Parent or legal guardian is required to notify the school or researchers if they refuse to allow their child's participation in the research.
	Confidentiality: Measures undertaken to protect secrecy after the data were collected.
	Privacy: Measures taken to ensure respondent privacy during data collection.
	Anonymity: No identifying information was collected.
	Safe settings: The presence of reassuring figures such as teachers and nurses, and also environmental features to maximize the participant's comfort.
	Voluntary: The choice of participating in the study was left to the participant.
	Withdraw: Participants were notified they could terminate the survey at any time during data collection.
Approaches to increase response rate	**Incentive**: Material reward offered to participate in the study.
	Time to complete questionnaire: Time needed to finish survey was recorded.
	Call-backs: Participants unavailable at the time of data collection were contacted later and given a chance to participate.

TABLE 3
Characteristics of reviewed studies

Country	References	Survey name and year	Method of data collection	Sample characteristics	Child maltreatment measures and reliability and/or validity	Response rate	Approaches										Procedures to deal with participant distress	Child maltreatment types				
							to increase response rate			to increase comfort								SA	PA	EM	NG	EIPV
							Incentive	Time to complete questionnaire	Call-back	Assent	Consent	Confidentiality	Privacy	Anonymity	Safe settings	Voluntary	Withdraw						
Brazil	Horta et al., 2014[42] Malta et al., 2014[43]	National Adolescent School-based Health Survey [PENSE], 2012	Self-administered questionnaire	109 104 students, grade 9		Student: 83%						•				•	•			•			
Canada	Saewyc & Tonkin, 2008[1] Tonkin et al., 2004[44] Tonkin, 2005[45] Saewyc et al.,2006[46]	British Columbia Adolescent Health Survey (BC AHS), 2003	Self-administered questionnaire	≈ 30 500 students grade 7–12		School: 76.3%		< 45 min			P	•	•	•	•			Provided respondents with information of support services; gave sensitivity training to interviewers.	•				
	Saewyc & Chen, 2013[22] Saewyc &Green, 2009[47]	BC AHS, 2008	Self-administered questionnaire	29 315 students age 12–19		School: 84.7% Student: 66%		< 45 min			Y/P	•	•	•	•	•		Provided respondents with information of support services; gave sensitivity training to interviewers.	•				
	Cyr et al., 2013[37]	Quebec, 2009	Telephone interview	1400 youths age 12–17	JVQ (adolescent version)			23 min				•		•					•	•	•	•	•
China	Lau et al., 2005[48]	Survey of Drug Use Among Students, 2000	Self-administered questionnaire	93 060 students age 12–19		Student: 87.3%			•			•	•	•		•			•				
	Chan et al., 2013[29]	2009-2010	Self-administered questionnaire	18 341 students age 15–17 in 6 Chinese cities	JVQ α 0.97 (modified SA)	Student: 95.8%					Y		•	•	•	•	Provided respondents with information of support services; gave sensitivity training to interviewers.	•				
	Chan, 2011[34]	2004	Face-to-face interview	1094 Chinese children age 12–17	CTS EIPV: α 0.76–0.89 CTSPC α 0.82–0.88	Student: 70.0%					Y/P	•						Provided respondents with information of support services.		•	•	•	•
	Leung et al., 2008[31] Wong et al., 2009[23] Tang, 1994 in Tang, 2006[49]	2005	Self-administered questionnaire	6593 students age 12–16	CTSPC α 0.70–0.86	School: 89.0% Student: 99.7%		30 min			Y	•		•	•	•	•		•	•	•		
Croatia	Aberle et al., 2007[32]	2005	Self-administered questionnaire	2140 students age 14 and 18				45 min				•		•	•					•	•		
	Ajdukovic et al., 2013[50]	2011	Self-administered questionnaire	3175 students age 11, 13 and 16	ICAST-CH modified SA: α 0.68			45 min			P/Y	•[a]		•	•			Provided respondents with information and telephone numbers of appropriate support services.	•	•	•		

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TABLE 3 (continued)
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Country	References	Survey name and year	Method of data collection	Sample characteristics	Child maltreatment measures and reliability and/or validity	Response rate	Approaches										Procedures to deal with participant distress	Child maltreatment types				
							to increase response rate			to increase comfort								SA	PA	EM	NG	EIPV
							Incentive	Time to complete questionnaire	Call-back	Assent	Consent	Confidentiality	Privacy	Anonymity	Safe settings	Voluntary	Withdraw					
Denmark	Ellonen et al., 2011[33]	Danish Youth Health Survey, 2008	Self-administered questionnaire	3943 students age 15–16	Danish CTS	School: 35.0% Student: 82.0%							•						•	•		•
	Helweg-Larsen & Larsen, 2006[24] Helweg-Larsen et al., 2011[51] Frederiksen et al., 2008[52]	2002	Self-administered questionnaire	6203 students age 15–16		School: 56.0%					Y	•	•	•	•			Provided respondents with information of support services.	•	•			•
	Van Gastel et al., 2013[53]	Public Health Service School, 2007	Self-administered questionnaire	10 324 students age 11–16		School: 71.0% Student: 84.0%								•	•			Provided respondents with information of support services.	•				•
Finland	Ellonen et al., 2011[33]	The Finnish Child Victim Survey, 2008	Self-administered questionnaire	5762 students age 15–16	Finnish CTS	School: 88.0%							•						•	•		•
	Lepistö et al., 2010[38] Sariola & Uutela, 1992[54]	2007	Self-administered questionnaire	1393 students age 14–17		Student: 78.0%					Y	•	•			•			•	•		•
Ghana	Ohene et al., 2015[55] WHO, 2017[56]	Ghana Global School-Based Student Health Survey (GSHS), 2012	Self-administered questionnaire	1984 senior school students							P			•		•			•			
Germany	Bussmann, 2004[39]	2002	Face-to-face interview	2000 youths age 12–18															•	•		•
Greece	Fotiou et al., 2014[57]	Greek Nationwide School Survey on Substance Use, 2011	Self-administered questionnaire	24 006 students age 15–19		School: 91.0% Student: 86.4%					P/Y			•	•				•			
Haiti	Flynn-O'Brien et al., 2016[58]	Violence Against Children Survey, 2012	Face-to-face interview	2916 youths age 13–24							P/Y	•	•	•				Provided respondents with information of appropriate support services; alerted appropriate authorities.		•			
Iceland	Asgeirsdottir et al., 2011[2]	2004	Self-administered questionnaire	9085 students age 16–19							Y		•			•	•	Provided respondents with information of support services.	•				•
India	Patel & Andrew, 2001[59]	General Health Questionnaire (GHQ), 2000	Self-administered questionnaire	811 students grade 11				90 min						•	•			Provided respondents with information of support services.	•				
Iran	Mahram et al., 2013[60]	2011	Self-administered questionnaire	1028 students age 9–13	α 0.83–0.98		Gift					•								•	•	
Kenya	Seedat et al., 2004[35]	2000	Self-administered questionnaire	901 students grade 10	LEQAV			45–60 min		P				•	•	•			•	•		•
	Okech, 2012[61]	2009-2010	Self-administered questionnaire	430 students age 10–16	My Worst Experiences Scale	Student: 71.6%				Y	P				•				•			

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TABLE 3 (continued)
Characteristics of reviewed studies

Country	References	Survey name and year	Method of data collection	Sample characteristics	Child maltreatment measures and reliability and/or validity	Response rate	Approaches												Procedures to deal with participant distress	Child maltreatment types				
							to increase response rate			to increase comfort										SA	PA	EM	NG	EIPV
							Incentive	Time to complete questionnaire	Call-back	Assent	Consent	Confidentiality	Privacy	Anonymity	Safe settings	Voluntary	Withdraw							
Mexico	Borges et al., 2008[25]	Mexican Adolescent Mental Health Survey, 2005	Face-to-face interview	3005 youths age 12–17		Youth: 71%		150 min		Y	P							Provided respondents with information of support services.	•	•			•
	Pineda-Lucatero et al., 2009[27]	2002	Self-administered questionnaire	1067 students age 11–20		Student: 89.1%					Y,P,T,S	•		•	•			Alerted appropriate authorities.	•				
	Frias & Erviti, 2014[62]	National Survey on Exclusion, Intolerance and Violence in Public High School Level Education, 2007	Self-administered questionnaire	13 440 students age 15–18															•	•			•
Malaysia	Ahmad et al., 2014[63]	Malaysia Global School-Based Student Health Survey-2012	Self-administered questionnaire	25 174 students age 12–17		Student: 99.1%					P/Y			•					•	•	•		
	Ahmed et al., 2015[64]	2011	Self-administered questionnaire	3509 students age 10–12	ICAST-CH: Child Exposure to Domestic Violence Scale	Student: 88.9%					S/P	•	•	•	•	•		Provided respondents with information of support services.		•	•	•	•
Nether-lands	Klein et al., 2013[65]	Questionnaire on experience and events in high school students in Curaçao	Self-administered questionnaire	545 students age 11–17				45 min			P	•		•	•	•			•	•	•	•	
New Zealand	Denny et al., 2011[66] Fleming et al., 2007[67] Adolescent Health Research Group, 2008[68]	Youth'01 and Youth'07	Self-administered questionnaire	2001: 9699 students age 13–17 2007: 9107 students age 13–18		School: 2001: 86.0% 2007: 84.0% Student: 2001: 64.0% 2007: 62.0%					S/P/Y	•		•		•	•		•				•
Peru	Fry et al., 2016[69]	National Survey on Social Relations, 2013	Face-to-face interview	1498 youths age 12–17		Youth: 99.9%					Y	•	•			•	•	Alerted appropriate authorities; gave sensitivity training to interviewers; provided respondents with information of support services.	•	•	•		•
Saudi Arabia	Al-Quaiz & Raheel, 2009[70]	2008	Self-administered questionnaire	419 female students age 11–21		Student 80.0–90.0%		15 min				•			•				•				
	Al-Eissa et al., 2016[71] ISPCAN, no date [72]	2012	Self-administered questionnaire	16 939 students age 15–19	ICAST-CH α 0.69–0.86					Y	P	•		•		•	•	Gave sensitivity training to interviewers; provided respondents with information of support services.	•	•	•	•	•
Sri Lanka	Rajindrajith et al., 2014[73]		Self-administered questionnaire	1792 youths age 13–18							P/Y			•	•				•	•	•		

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TABLE 3 (continued)
Characteristics of reviewed studies

Country	References	Survey name and year	Method of data collection	Sample characteristics	Child maltreatment measures and reliability and/or validity	Response rate	Approaches to increase response rate: Incentive	Approaches to increase response rate: Time to complete questionnaire	Approaches to increase response rate: Call-back	Approaches to increase comfort: Assent	Approaches to increase comfort: Consent	Approaches to increase comfort: Confidentiality	Approaches to increase comfort: Privacy	Approaches to increase comfort: Anonymity	Approaches to increase comfort: Safe settings	Approaches to increase comfort: Voluntary	Approaches to increase comfort: Withdraw	Procedures to deal with participant distress	Child maltreatment types: SA	Child maltreatment types: PA	Child maltreatment types: EM	Child maltreatment types: NG	Child maltreatment types: EIPV
South Africa	Seedat et al., 2004[35]	2000	Self-administered questionnaire	1140 students grade 10	LEQAV			45–60 min		P				•	•	•			•	•			•
	Andersson & Ho-Foster, 2008[74]	2002	Self-administered questionnaire	126 696 male students age 10–19									•	•	•	•	•		•				
	Pettifor et al., 2005[30]	National Household Survey, 2003	Face-to-face interview	11 904 youths age 15–24		Youth: 77.2%					P/Y		•						•				
	Waller et al., 2014[75] Young Carers Project South Africa, 2016[76]	Teen Talk 2010-2011	Self-administered questionnaire	3515 youths age 10–17	UNICEF Scales for Sub-Saharan Africa: Child Exposure to Community Violence Checklist	Youth: 97.2%	Refreshment	40–60 min			P/Y	•[a]	•			•	•	Alerted appropriate authorities.	•	•	•		•
Swaziland	Breiding et al., 2013[36]	2007	Face-to-face interview	1292 females age 13–24		Youth: 96.3%					P/Y	•	•		•		•	Provided respondents with information of support services; gave sensitivity training to interviewers.	•	•			
Sweden	Priebe & Svedin, 2012[26] Mossige et al., 2007[77]	2009	Self-administered questionnaire	3432 students age 18		School: 60.5%	School compensated				Y			•		•		Provided respondents with information of support services.	•				
Taiwan	Yen et al., 2008[78]	Project for Health of Adolescents, 2003	Self-administered questionnaire	1684 students age 13–18	Abuse Assessment Screen Questionnaire	Student: 81.0%	Gift				Y		•			•			•	•			
Turkey	Sofuglu et al., 2014[79]	2012	Self-administered questionnaire	7540 students age 11, 13 and 16	ICAST-CH EM: α 0.86; PA: 0.86; NG: 0.81	Student: 85.3%		45 min					•	•						•	•	•	•
UK	Jackson et al., 2016[80]		Self-administered questionnaire	730 students age 13-16	Modified JVQ α 0.51 JVQ correlated to TSC $r = 0.29–0.37$, $p < 0.01$	School: 22.0% Student: 52.0%					P/Y		•						•				
	Radford et al., 2013[81]	2009	Self-administered questionnaire	2275 youths age 11–17	Modified JVQ	Youth: 64%					P/Y	•[a]	•	•				Provided respondents with information of support services; alerted appropriate authorities.	•	•	•	•	•
United States	Finkelhor, Ormrod et al., 2005[12]	Developmental Victimization Survey, 2002-2003	Telephone interview	1000 youths age 10–17	JVQ	Youth: 79.5%	10 $		•		P/Y	•	•					Followed up with respondents who disclosed threatening situations.	•	•	•	•	•

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United States (cont.)	Finkelhor et al., 2011[82] Finkelhor et al., 2009[28] Mitchell et al., 2011[83] Finkelhor et al., 2005[84] Hamby et al., 2013[85]	National Survey of Children's Exposure to Violence (NatSCEV), 2008	Telephone interview	2095 youths age 10–17	JVQ CM: α 0.39; SA: α 0.35–0.51 Test-retest CM: κ 0.52; 91% agreement (3–4 weeks after); EIPV: κ 1.0; 100% agreement (3–4 weeks after) JVQ correlated to TSC CM: $r = 0.14–0.35$, $p < 0.01$; SA: $r = 0.11–0.34$, $p < 0.01$	Youth: 54%	20 $	45 min	•		P/Y	•							Followed up with respondents who disclosed threatening situations; gave sensitivity training to interviewers; alerted appropriate authorities.	•	•	•	•	•
	Finkelhor et al., 2013[13] Hamby et al., 2005[86] Finkelhor et al., 2014[87]	NatSCEV II, 2011	Telephone interview	N not provided youths age 14–17	Validity: JVQ compared with other CM data	Youth: 40.4%	20 $	55 min										Followed up with respondents who disclosed threatening situations; provided respondents with information of support services.	•	•	•	•	•
	Finkelhor et al., 2015[88] Finkelhor et al., 2015[89]	National Survey of Children's Exposure to Violence, 2014	Telephone interview	N not provided youths age 14–17 1949 youths age 10–17	JVQ	Varied by recruitment 15.1%–67.0% Youth: 14.2%–67.0%	5 $, 20 $				P/Y	•						Followed up with respondents who disclosed threatening situations.	•	•	•	•	•
	McLaughlin et al., 2012[40] Strauss, 1979[90] McLaughlin et al., 2013[91] McChesney et al., 2015[92] Merikangas et al., 2009[93]	National Comorbidity Survey – Adolescent Supplement, 2001-2004	Face-to-face interview	6483 youths age 13–17	CTS (modified), Composite International Diagnostic Interview (modified) and Child Welfare Questionnaire	School: 86.8% Student: 82.6%	50 $	≈ 2h30		Y	P								•	•	•	•	•
	Begle et al., 2011[4] Danielson et al., 2010[94] Hawkins et al., 2010[95] McCauley et al., 2010[96] McCart et al., 2011[97] Andrews et al., 2015[98]	National Survey of Adolescents Replication, 2005	Telephone interview	3614 youths age 12–17	SA: α 0.99; PA: α 0.72; EIPV: α 0.64[73]	Youth: 52.2%	10 $	•	•	Y	P	•		•	•	•	•	Provided respondents with information of support services; followed up with respondents who disclosed threatening situations; alerted appropriate authorities .	•	•			•

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TABLE 3 (continued)
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Country	References	Survey name and year	Method of data collection	Sample characteristics	Child maltreatment measures and reliability and/or validity	Response rate	Approaches												Procedures to deal with participant distress	Child maltreatment types				
							to increase response rate			to increase comfort										SA	PA	EM	NG	EIPV
							Incentive	Time to complete questionnaire	Call-back	Assent	Consent	Confidentiality	Privacy	Anonymity	Safe settings	Voluntary	Withdraw							
United States (cont.)	Haley et al., 2010[99] Oregon Teen Survey, 2005[100]	Oregon Healthy Teen Survey, 2005	Self-administered questionnaire	16 289 students age 13–17								•				•				•				
	Alriksson-Schmidt et al., 2010[101] Eaton et al., 2006[102]	National Youth Risk Behavior Survey (YRBS), 2005	Self-administered questionnaire	7181 female students age 15–18		Student: 52.2%		•				•	•	•		•				•				
	Basile et al., 2006[3] Brener et al., 2004[103]	YRBS, 2003	Self-administered questionnaire	13 080 grade 9–12 students		School: 67.0–100.0% Student: 60.0–94.0%					P		•	•	•	•				•				
	Howard & Wang, 2005[104]	YRBS, 2001	Self-administered questionnaire	13 601 students age 14–18		School: 75.0% Student: 83.0%					P			•		•				•				
	Lippe et al., 2008[105]	YRBS, 2007	Self-administered questionnaire	Samoa: 3625 Northern Mariana Islands: 2292 Marshall Islands: 1522 Guam: 1716 Palau: 732 students age 14–18		School: 100.0% Student: 78.0%–90.0%					P			•		•				•				
	Peleg-Oren et al., 2013[106]	Florida YRBS, 2005	Self-administered questionnaire	4564 students grade 9–12		School × Student: 66.0%		50 min		Y	P		•	•	•	•	•		•				
Namibia, Swaziland, Uganda, Zambia, Zimbabwe	Brown et al., 2009[107] WHO, 2017[56]	GSHS, 2003-2004	Self-administered questionnaire	22 656 students age 13–15		School: 90.0–100.0% Student: 75.0–99.0%							•			•				•				
European Union	Kassis et al., 2013[41] Kassis & Puhe, 2009[108]	Germany, Austria, Slovenia, Spain, 2009	Self-administered questionnaire	5149 students age 13–15	Family Violence Inventory EIPV: α 0.88; EIPV (EM): α 0.85; PA: α 0.83						S/P/Y			•		•		•	Provided respondents with information of support services.		•			•

Abbreviations: CM, child maltreatment; CTS, Conflict Tactics Scale; CTSPC, Parent Child Conflict Tactics Scale; EIPV, exposure to intimate partner violence; EM, emotional maltreatment; ICAST-CH, ISPCAN child abuse screening tool-child; ISPCAN, International Society for the Prevention of Child Abuse and Neglect; JVQ, Juvenile Victimization Questionnaire; LEQAV, Life Event Questionnaire – adolescent version; NG, neglect; P, parent; PA, physical abuse; S, school; SA, sexual abuse; T, teacher; TSC, Trauma Symptoms Checklist for Children; Y, youth.

[a] Confidentiality was maintained, except when child was at risk of significant harm, in which case referral was made to the appropriate authorities.

attributable to differences in measures. For example, with the objective of encouraging disclosure of sexual abuse, some surveys stipulate specific behaviours,[3] while others use more generally-worded questions.[101] Some measures of maltreatment are dichotomous (yes-no), in contrast to others that ask for details on severity and frequency.

Dissimilarities in conceptual scope can also influence prevalence estimates. For example, some but not all surveys explicitly include online victimization as a component of sexual abuse. Finally, the particular vocabulary used to describe specific behaviours may also impact comparability. For example, the expression, "forced sex without consent," might be interpreted more broadly than "rape," and thus be more apt to elicit a positive response (and increase apparent prevalence). Neglect was measured in only a few surveys—perhaps reflecting the challenges inherent to capturing it in population surveys. In some communities, relatively lower estimates of neglect were attributable to close social networks and living arrangements.[65] Efforts to improve the collection of data on neglect in population-based surveys and from young respondents are currently under way.[110,111]

Quality of data

The majority of the articles examined provided no detailed information on the reliability or validity of measures used within surveys. Statements such as "the reliability of the scale has been well-documented," or indicating that validity had been determined by the authors, were common but not fully informative. Unfortunately, only three articles reported validity.[80,84,87] In terms of reliability, internal consistency assessed by Cronbach alpha was documented most often followed by interrater reliability assessed as percentage agreement.

Internal consistency may have limited use given that some maltreatment behaviours may not be related. For example, some forms of neglect may not relate to other forms of neglect nor with other types of child maltreatment. Due to these complexities of internal consistency, this measure must be interpreted with caution.[84,112] In general, surveying youth yields data that are only minimally affected by recall bias.[113] Of course, validity may still be compromised by social desirability bias, due to the delicate nature of maltreatment questions. However, research revealed few difficulties arising from the sensitivity of the questions.[24,53,61] The different developmental stage of the reviewed measures may partially explain why few psychometric properties of child maltreatment measures were reported. Newer measures were often adjusted for cultural and language adaptations; continued testing should lead to improvements in data accuracy.

Data quality and response rate are also affected by technical aspects of data collection and the setting in which it takes place. Most of the studies reviewed were based on surveys conducted within schools—where all students were responding to the same survey at the same time—and thus obtained high response rates. However, willingness to participate was not universal among schools, for reasons unrelated to child maltreatment questions.[33,53,57] Research suggests that among students, maximizing privacy and guaranteeing anonymity are effective in ensuring high response rates.[45] The importance of privacy was also underscored in a study in which younger participants (age 10 years) found responding to a survey more upsetting in the presence of the caregiver than when they were alone.[114]

The means by which consent for survey participation is obtained can also affect the response rate; the requirement for consent from parents may discourage participation, especially among youth who have experienced child maltreatment.[47,51,115] Parental passive consent was used in multiple surveys to increase response rate and avoid sampling bias potentially related to active parental consent.[65,80,106] In one study, researchers designed and used a modified consent procedure in case any of the participants were being maltreated by a primary caregiver.[58]

Ethical considerations

Eliciting information about experience with child maltreatment is a delicate matter; the manner in which questions are worded is an important consideration. Even a survey's name can potentially evoke anxiety and may lead to unwillingness to participate (e.g. stronger emotions may be triggered by reference to a survey on "child maltreatment" than to one on "child health"). Similarly, the language used in questions about experience with child maltreatment can affect the respondent. Sensitivity to the potential for adverse reactions is critical, as is a clear statement assuring the anonymity and confidentiality of the survey. However, the review found that some researchers included a confidentiality breach procedure in the consent form if a youth was in need of protection, which allowed automatic referral of participants to appropriate authorities.[50,75,81] This strategy did not negatively affect response rate.[75,81]

This review suggests that youth are generally comfortable in answering questions about their experience with child maltreatment.[12,14,71,116] One study showed that 4.6% of youth reported being upset when answering a child maltreatment survey, but of these, 95.3% said they would nonetheless participate in a similar survey.[116] Interestingly, from the 17.3% of participants who had reported experiences classified as high-risk, only 2% were referred for counselling services[116]. In addition, one article mentioned that sexual abuse questions were not answered by 11% of respondents, but did not offer adequate information to assess if non-responses were higher for sexual abuse questions than for others.[2] However, several researchers concluded that the potential benefits from the information obtained from child maltreatment questions exceed the potential respondent distress.[7,116,117] An earlier study in adolescents comparing stress produced by child maltreatment questions with that arising from questions about school marks found no differences.[118]

Limitations

Several limitations affect this review. First, inconsistencies in child maltreatment measures across surveys—and sometimes even within different cycles of the same survey—made classification challenging. Second, some articles that otherwise met the criteria for inclusion in the review were excluded on the basis of insufficient methodological information. For instance, papers failing to identify the relationship of the perpetrator to the victim or to distinguish between exposure to family violence and community violence were not included. Third, prevalence estimates were not provided in a standardised way. Fourth, steps taken to increase the response rate could often not be distinguished from those taken to increase the comfort of the respondent, so they were considered in

combination. Fifth, measures had often been modified from their original version, and results of validity and reliability testing of the modified versions were not usually provided. Sixth, certain segments of the population were excluded either because they do not attend school or were absent the day of data collection. Seventh, the exclusion of articles in languages other than English limited the international scope of the review. Eighth, only peer-reviewed articles have been included in the review, which may introduce publication bias. Finally, limiting the review to the articles without examining the underlying surveys likely resulted in the exclusion of some relevant information.

Implications

This review shows that child maltreatment is a common concern across a range of societies and cultures although Canadian national data were missing. As evidenced by the large number of self-report surveys and studies asking youth about their level of comfort, data on child maltreatment can be collected responsibly and ethically from youth in a way that protects their health and well-being.[14,116] Surveillance and research on child maltreatment would benefit greatly from the routine inclusion of questions on the subject in population-based self-report health surveys. Hovdestad and Tonmyr[119] stressed the importance of setting the stage for inclusion of child maltreatment questions in surveys by a) preparing for early resistance, b) building a broad base of support, c) having knowledge of the current literature (including issues addressed in this article), and d) being willing to compromise and showing determination. Data collected on a regular basis would provide the opportunity for enhancing our understanding of the burden and the factors that are correlated with child maltreatment.[120] Schools could be an excellent venue for data collection due to high participation in these surveys and high enrolment among youth. After required discussions and agreements with the appropriate school authorities, it is easy to have procedures in place to obtain youth consent to participate and parents/caregivers passive consent. To maximize the quality of the data, measures used in collection should undergo reliability and validity testing, and all aspects of the survey methodology should be sound. Behaviour-based questions with response options capturing severity and frequency are also recommended.

Protocols to address potential participant distress should be established, and interviewers should be trained to conduct research sensitively and appropriately. Effective means of evaluating participant distress should be refined and applied, and the results of such evaluations should inform questionnaire design and language. Surveys should be conducted according to a strict code of ethics, the overarching goals of which should be the protection of privacy and confidentiality, and respect for respondents.

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Conflicts of interest

There is no conflict to declare.

Authors' contributions and statement

L.T. conceived and designed the study. C.W., L.T., and J.L. wrote the paper: L.T. wrote the protocol, with input from the others. J.L., L.T., C.W., J.D., and S.A. extracted and categorized the data. L.T. led the evaluative component.

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Effectiveness of the CANRISK tool in the identification of dysglycemia in First Nations and Métis in Canada

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Abstract

Introduction: First Nations/Métis populations develop diabetes earlier and at higher rates than other Canadians. The Canadian diabetes risk questionnaire (CANRISK) was developed as a diabetes screening tool for Canadians aged 40 years or over. The primary aim of this paper is to assess the effectiveness of the existing CANRISK tool and risk scores in detecting dysglycemia in First Nations/Métis participants, including among those under the age of 40. A secondary aim was to determine whether alternative waist circumference (WC) and body mass index (BMI) cut-off points improved the predictive ability of logistic regression models using CANRISK variables to predict dysglycemia.

Methods: Information from a self-administered CANRISK questionnaire, anthropometric measurements, and results of a standard oral glucose tolerance test (OGTT) were collected from First Nations and Métis participants (n = 1479). Sensitivity and specificity of CANRISK scores using published risk score cut-off points were calculated. Logistic regression was conducted with alternative ethnicity-specific BMI and WC cut-off points to predict dysglycemia using CANRISK variables.

Results: Compared with OGTT results, using a CANRISK score cut-off point of 33, the sensitivity and specificity of CANRISK was 68% and 63% among individuals aged 40 or over; it was 27% and 87%, respectively among those under 40. Using a lower cut-off point of 21, the sensitivity for individuals under 40 improved to 77% with a specificity of 44%. Though specificity at this threshold was low, the higher level of sensitivity reflects the importance of the identification of high risk individuals in this population. Despite altered cut-off points of BMI and WC, logistic regression models demonstrated similar predictive ability.

Conclusion: CANRISK functioned well as a preliminary step for diabetes screening in a broad age range of First Nations and Métis in Canada, with an adjusted CANRISK cut-off point for individuals under 40, and with no incremental improvement from using alternative BMI/WC cut-off points.

Keywords: *CANRISK, Type 2 Diabetes, First Nations and Métis, screening, sensitivity, specificity*

Highlights

- Data from First Nations and Métis participants aged 18 and older in the CANRISK studies were analyzed; 69% of participants were under 40 years old, and 15% had either prediabetes or diabetes.
- Though the standard CANRISK score cut-off point of 33 points achieved expected accuracy in this First Nations and Métis sample aged 40 or over, a lower cut-off point of 21 was shown to be more sensitive for individuals under 40.
- Alternative ethnicity-specific BMI/WC cut-off points did not improve the predictive ability of a logistic regression model using the CANRISK variables.

Introduction

From the 2011 National Household Survey, 4.3% of the Canadian population identified themselves as Aboriginal (First Nations, Inuit, or Métis), with 28% aged 14 years or under and 18.2% aged 15 to 24 years[1]. Studies have demonstrated that the Canadian Aboriginal population is at a higher risk for developing diabetes due to many factors including lifestyle, environmental and genetic.[2]

Over the past century, the Canadian Aboriginal population has been affected by westernized nutritional and lifestyle changes.[3] Traditional foods (game, fish, seafood, edible wild plants) which are high in animal protein and low in fat[4] have been replaced by store-bought foods, which are higher in refined carbohydrates and fat with less protective fiber; all of which have been implicated as major factors in increased diabetes rates in First Nations.[5] Moreover, procurement of store-bought foods reduces physical activity, as it results in less fishing, hunting, trapping and growing of foods.[4,6]

These are all in addition to environmental factors which include less access to

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healthcare[7] and healthy food[8] in many First Nations communities that may contribute to the development of diabetes and its complications, in addition to a delay in diagnosis and preventative treatment.[2] Researchers have suggested that some Indigenous peoples may have genes that promote caloric conservation during times of food shortage.[9] Particular polymorphisms linking obesity and diabetes in small groups of First Nations people have been found to support this hypothesis.[10-12]

The cumulative effects of these factors have resulted in an increased prevalence of diabetes in a variety of First Nations and Métis communities, with an average age standardized prevalence of 21% in individuals 25 years or older in 2012.[13] Diabetes is also becoming more prevalent among younger individuals in First Nations populations compared to the general Canadian population.[2,14] Higher complication rates among First Nations, particularly nephropathy and neuropathy, are also exacerbated by the earlier onset of diabetes compared to other Canadians.[15,16] These factors highlight the importance of developing a low-cost and simple screening tool for dysglycemia to address First Nation and Métis populations who are at high risk for type 2 diabetes at an earlier age.[17]

In Canada, a Canadian Diabetes Risk Questionnaire (CANRISK) was developed from a similar tool developed in Finland (FINDRISC).[17] To take into account Canada's multi-ethnic population and other correlates of diabetes, CANRISK included questions about parental ethnicity, education, sex and large birth-weight babies (macrosomia). The published CANRISK tool presents three risk groups: low risk (scores lower than 21), moderate risk (scores 21 to 32), and high risk (scores 33 and higher). CANRISK was developed and validated in a study of 6223 Canadians, the majority of whom were 40 years or older, and 12% of whom were Aboriginal people based on the mother's ethnicity.[17]

While Aboriginal people were overrepresented in this initial sample, the effectiveness of CANRISK in identifying dysglycemia (prediabetes and diabetes) has not been ascertained specifically for the First Nations and Métis population. Furthermore, data from several studies indicate that body mass index (BMI) and waist circumference (WC) are important predictors of diabetes[15,18,19], and First Nations and Métis people in Canada have high rates of obesity[15] and similar distributions of serum glucose at significantly lower body mass index (BMI) values compared with Europeans.[20] A similar serum glucose level is associated with a BMI level of 30 kg/m^2 for a European and as low as 21.8 kg/m^2 for a First Nations person.[20] Since CANRISK was developed using the World Health Organization (WHO) standard cut-off points for WC and BMI, it is prudent to examine whether lower BMI and/or WC cut-off points may provide a more accurate risk assessment specific to First Nations and Métis. Interestingly, the Australian diabetes risk assessment tool (AUSDRISK) includes alternative WC cut-offs points validated for the Australian Aboriginal population.[21] Additionally, alternative BMI cut-offs recommended by the WHO for Asians were found to have better accuracy in identifying obesity within this population.[22,23]

Primary and secondary aims

The primary aim of this paper was to assess the effectiveness of the current CANRISK tool and cut-off points in detecting dysglycemia in both older (40 years and older) and younger (under 40 years old) First Nations and Métis participants. A secondary aim was to compare the predictive ability of logistic models using CANRISK variables, with alternative WC and BMI cut-off points, for assessing the odds of dysglycemia in a First Nations and Métis sample.

Methods

As part of the validation of CANRISK, the Public Health Agency of Canada (PHAC) collected data from a large sample of Canadians across Canada over two phases of data collection. The current study comprises a sub-sample from this data set, pooled over both phases of data collection, by specifically including only First Nations and Métis participants (n = 1469).

In Phase 1 (2007 to 2011) and Phase 2 (2013 to 2014) of the CANRISK study, residents aged 18 and over, from seven provinces (British Columbia, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia and Prince Edward Island) and two territories (Yukon and Nunavut) in Canada, of unknown diabetes status, were invited to participate in a dysglycemia risk assessment study. In Phase 1, most participants were over 40 years and recruited during their visits at community health centres, although some were recruited via mailouts from community health centres and regional health authorities.[17] Phase 2 of recruitment was specifically aimed at younger participants aged 20 to 39 among some high-risk ethnic populations including First Nations and Métis. In Phase 2, radio announcements, social media, posters, brochures and pamphlets were added to advertise participant recruitment. Local public health nurses could be contacted for recruitment questions. Those who already had a diagnosis of diabetes or were pregnant, or were unable to complete the CANRISK questionnaire in English or French were excluded. Participants in Phase 2 received a $50 food voucher for local grocery stores as compensation in Nunavut, Yukon, and Saskatoon data collection sites, and $50 cash compensation at the Vancouver site.

In order to ensure participants of First Nations and Métis heritage, data were collected in several communities with a high proportion of First Nations and Métis residents in conjunction with local health authorities. The highest numbers of First Nations and Métis participants were recruited through collaboration with the Yukon Department of Health and Social Services and the Saskatoon Health Region. In accordance with the Tri-Council requirements of conducting research in Aboriginal communities, ethics approvals were granted by the Health Canada/PHAC Research Ethics Board and by each local research ethics office or board. The First Nations and Métis subgroup of the CANRISK study population was used for this analysis. Participants who identified one or more parents of First Nations or Métis origin were retained in the analysis. In Phase 1, the data collection grouped those of First Nations, Métis and Inuit heritage into a single variable of Aboriginal heritage, which we were unable to separate. We ascribed First Nations and Métis ethnicity to all participants from Phase 1 who were recruited from the Saskatoon site and who self-identified as having Aboriginal heritage. As less than 1% of the Aboriginal population identifies as Inuit in Saskatoon[24], we are confident that the number of Inuit participants that misclassified as First Nations and Métis is minimal.

Risk assessment and data gathering procedures

There were two different data gathering procedures, depending on the data collection

phase (first or second). During the first phase, data gathering began at the time of recruitment with informed consent and instructions to arrive at the data collection site on a different day in a fasting state. Once at the data collection site, CANRISK was self-administered, and anthropometric measurements and two venous blood samples were collected on-site to determine glycemic status (see details below, the oral glucose tolerance test or OGTT); both of which were performed by nurses or health professionals. During the second data collection phase, however, informed consent was collected, as well as CANRISK scores and anthropometric measurements, all during the initial visit. Participants were then instructed to arrive at the blood collection site on a different day in a fasting state in order to collect the same two venous blood samples (to determine glycemic status by OGTT). Anthropometric measurements were taken in a standardized way after all project staff had received training. Participants were weighed using a digital standing scale without shoes and dressed in indoor clothing. A standardized tape measure attached to the wall was utilized for height and the minimum circumference between the umbilicus and xiphoid provided the WC measurements.

The CANRISK tool collected information on sex, age, mother and father's ethnicity, self-reported physical activity (such as brisk walking for at least 30 minutes each day), self-reported daily fruit and vegetable consumption, history of high blood pressure, history of high blood glucose, family history of diabetes, and education.[17] The full CANRISK tool can be found here: http://healthycanadians.gc.ca/en/canrisk?utm_source=VanityURL&utm_medium=URL&utm_campaign=publichealth.gc.ca/canrisk. Individual CANRISK scores were generated for each participant according to the publicly available CANRISK tool.[25] Since the CANRISK tool was intended for participants over the age of 40, the reference group (zero points) for age was 40 to 44 years. As such, the participants in the present study under the age of 40 were also assigned zero points for age-related risk.

Participants' glycemic status was determined using a standard oral glucose tolerance test (OGTT) procedure, which includes fasting plasma glucose (FPG) and a plasma glucose 2 hours after a 75-g glucose challenge (2hPG), as recommended by the WHO and Canadian Diabetes Association (CDA) 2013 guidelines.[26,27] An individual was classified as having pre-diabetes if they had a FPG level of 6.1 to < 7.0 mmol/L, and/or a 2hPG of 7.8 to 11.0 mmol/L. An individual was classified as having diabetes if they had a FPG level of 7.0 mmol/L or higher, and/or a 2hPG of higher than 11.0 mmol/L. Dysglycemia, a positive OGTT, referred to an individual having a FPG level ≥ 6.1mmol/L and/or a 2hPG of ≥ 7.8 mmol/L.

Data analysis

Descriptive analyses were conducted in order to describe participant characteristics. Glycemic status according to their OGTT results was also described. Logistic regression with all covariates from CANRISK was performed using SAS 9.3, with presence or absence of dysglycemia as the outcome variable. Reference categories were based on the previously validated CANRISK model which best represented good health.[27] Four logistic regression models were conducted using CANRISK standard and alternative [28-30] WC and BMI cut-off points as described below. Models were then compared for model fit using a Receiver Operator Characteristic (ROC) Curve measuring the area under the curve (AUC) and the Hosmer Lemeshow Goodness of Fit test.[31]

In the CANRISK tool, standard BMI cut-off points were < 25 kg/m^2 (underweight and normal weight; reference), 25 to 29.9 kg/m^2 (overweight), 30 to 34.9 kg/m^2 (obesity class 1) and 35+ kg/m^2 (obesity classes 2 and 3)[17]; standard WC cut-off points were small (male < 94 cm and female < 80 cm; reference), medium (male 94 to 102 cm and female 80 to 88 cm) and large (male > 102 cm and female > 88 cm).[17] The alternative Aboriginal cut-off points for BMI from AUSDRISK[17] were: < 23 kg/m^2 (underweight and normal weight; reference), 23 to < 27.5 kg/m^2 (overweight) and 27.5 kg/m^2 or higher (obese). Alternative WC cut-off points recommended for Asians by the WHO[22,23] were: small (male < 90 cm, female < 80 cm; reference), medium (male 90 to 100 cm, female 80 to 90 cm) and large (male > 100 cm, female > 90 cm).

The sensitivity, specificity, positive predictive value and accuracy rates were determined using the original CANRISK score risk categories ("Slightly Elevated Risk" cut-off point ≥ 21, and "High Risk" cut-off point ≥ 33)[24] for the whole sample, for those under 40 years, and those 40 years or older. Sensitivity was defined as the proportion of people who had a positive CANRISK score among those with a positive OGTT result. Specificity was the proportion of people who had a negative CANRISK score among those with a negative OGTT result. The positive predictive value (PPV) was defined as the probability that subjects with a positive CANRISK result truly had dysglycemia as determined by a positive OGTT. The negative predictive value (NPV) was the probability that subjects with a negative CANRISK result truly did not have dysglycemia as determined by a negative OGTT result. Both positive and negative predictive values are affected by the underlying prevalence of the condition, while sensitivity and specificity scores are independent of prevalence. The accuracy rate was the number of confirmed positive CANRISK scores and the number of confirmed negative CANRISK scores out of the total number of participants. These measurements were calculated to identify if the current CANRISK cut-off points could be used in a primarily younger First Nations and Métis population.

Results

A total of 1479 First Nations and Métis individuals participated in the CANRISK study; 834 individuals from phase 1 and 645 from phase 2. The study sample was 57% female, and 69% were aged 18 to 39 years (see Table 1). Less than 10% had obtained a college or university degree, and 46% had some high school education or less. Using CANRISK BMI and alternative cut-off points, 73% and 80% were considered overweight or obese, respectively. Likewise, 68% and 69% were in the highest CANRISK WC and alternative cut-off point category, respectively. Fifteen percent of participants had pre-diabetes or diabetes according to standard cut-off points applied to their OGTT results (see Table 2).

Table 3 provides the odds ratios from four adjusted logistic regression models using CANRISK variables. The sample size for the logistic regression models was reduced from 1479 to 1373, as 7% of the sample had a missing value on at least one of the variables. Model A used the CANRISK standard BMI and WC cut-off points. Model B used original BMI but alternative WC cut-off points based on the alternative Aboriginal cut-off points used in the AUSDRISK.[28] Model C used original WC

TABLE 1
Study sample characteristics

Characteristics	Sample	Proportion (%)	Missing
Sex			
Female	847	57.3	0
Male	632	42.7	
Age			
18–29	536	36.2	0
30–39	479	32.4	
40–44	140	9.5	
45–54	206	13.9	
55–64	88	6.0	
65+	30	2.0	
BMI (kg/m²) – CANRISK cut-off points			
Normal/Underweight (< 25)	400	27.1	0
Overweight (25–29.9)	474	32.1	
Obese, non-morbid (30–34.9)	350	23.7	
Obese, morbid (≥ 35)	255	17.2	
BMI (kg/m²) – Alternative cut-off points			
Normal/Underweight (< 23)	300	20.3	0
Overweight (23 to < 27.5)	357	24.1	
Obese (≥ 27.5)	822	55.6	
WC – CANRISK cut-off points			
Male < 94, Female < 80	263	18.0	16
Male 94–102, Female 80–88	209	14.3	
Male > 102, Female > 88	991	67.7	
WC – Alternative cut-off points			
Male < 90, Female < 80	195	13.3	16
Male 90–100, Female 80–90	261	17.8	
Male > 100, Female > 90	1007	68.8	
Daily brisk physical activity			
Yes	1061	71.9	4
No	414	28.1	
Daily consumption of fruit/vegetable			
Yes	778	52.6	1
No	700	47.4	
High blood pressure			
Yes	252	17.1	4
No	1223	82.9	
High blood sugar			
Yes	172	88.3	5
No	1302	11.7	

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but alternative BMI cut-off points based on WHO recommendations for Asians.[29,30] Finally, Model D used both alternative WC and BMI cut-off points. All four logistic regression models passed the Hosmer-Lomeshow goodness of fit test with p values ranging from 0.35 to 0.75 (see Table 3). Each model also showed good predictive ability for dysglycemia, with similar AUCs of approximately 0.75. In other words, using alternative BMI and/or WC cut-off points did not improve the predictive ability of the model as the AUC was no different than the Model with original BMI and WC cut-off points.

Predictive ability statistics of CANRISK by age group, including sensitivity and specificity are presented in Table 4. Using the "high risk" cut-off point of 33, the sensitivity and specificity were 68% and 63% in those aged 40 or over; and in those aged under 40, it was 27% and 87%, respectively. However, when using the "slightly elevated risk" CANRISK cut-off point of 21, the sensitivity was improved to 77%, and the specificity was reduced to 44%, in those aged below 40 years.

For those 40 and older, the PPV was 38% and the NPV was 86% at the original cut-off point of 33. For those under 40, the PPV was 18% and the NPV was 92% with an overall accuracy of 81% at the original CANRISK cut-off point of 33, whereas the PPV was 13% and NPV 95% with an overall accuracy of 47% using the alternative, more sensitive, CANRISK cut-off point of 21.

Discussion

In order to determine if ethnicity-specific cut-off points for BMI and WC model would better predict dysglycemia risk among First Nations and Métis Canadians, three logistic regression models using alternative BMI and/or WC cut-off points, in addition to a model using the original CANRISK cut-off points, were performed. However, contrary to what was hypothesized, alternative BMI and/or WC cut-off points did not improve model fit. Though each model had good predictive ability (75%), the alternative models did not more accurately predict dysglycemia risk beyond what was found in the original model. Our results suggest that current BMI and WC cut-off points used in the CANRISK tool are appropriate for use in a Canadian First Nations and Métis population.

TABLE 1 (continued)
Study sample characteristics

Characteristics	Sample	Proportion (%)	Missing
Number of primary relatives with diabetes			
0	685	49.1	
1	424	30.4	
2	217	15.6	85
3	63	4.5	
4	5	0.4	
Positive family history of diabetes			
No relatives with DM	282	19.1	
Secondary relative has DM (sibling or other)	448	30.3	0
Primary relative has DM (mother, father, or child)	620	41.9	
No confirmed cases, but suspected cases[a]	129	8.7	
Education			
Some high school or less	686	46.4	
High school diploma	279	18.9	0
Some college or university	371	25.1	
College or university degree	143	9.7	
History of macrosomia (% of female)	**228**	**26.9**	**0**

Abbreviations: BMI, body mass index; DM, diabetes mellitus; m, metre; WC, waist circumference.
Note: Total N = 1479.
[a] No relatives marked as yes, but some relatives marked as "unsure."

Among participants aged 40 years and over, using the CANRISK score of 33 as a cut-off point for high risk of dysglycemia, we found similar sensitivity and specificity to that reported in the original CANRISK validation paper:[17] sensitivity of 68% versus 66%; specificity of 63% versus 70%, respectively. Using the same threshold scores for younger adults yielded lower sensitivity (27%) and higher specificity (87%). However, using a lower CANRISK score threshold of 21 points for younger adults, a sensitivity of 77% and specificity of 44% was achieved. In other words, in order to achieve comparable predictive ability, a lower CANRISK score threshold of 21 points is needed for First Nation and Métis Canadians adults below the age of 40 years.

TABLE 2
Blood test results for prediabetes and diabetes

	Proportion (%)	Sample
Prediabetes		
A) FPG only (6.1 to < 7.0 mmol/L)	2.7	40
B) 2hPG only (7.8–11.0 mmol/L)	5.3	78
C) Both FPG and 2hPG	1.6	24
D) Total prediabetes (A+B+C)	9.6	142
Diabetes		
E) FPG only (≥ 7.0 mmol/L)	1.7	25
F) 2hPG only (> 11.0 mmol/L)	1.4	21
G) Both FPG and 2hPG	2.0	30
H) Total diabetes (E+F+G)	5.1	76
Total prediabetes and diabetes	**14.7**	**218**

Abbreviations: 2hPG, plasma glucose after 2-hour glucose challenge; FPG, fasting plasma glucose.
Note: Total N = 1479.

The need for a lower score threshold for younger participants is logical. Age is a key unmodifiable variable in the CANRISK score with 0 points attributed to ages 40 to 44 years up to 15 points attributed to those 65 to 74 years old, out of the highest possible score of 93 points. The maximum CANRISK score is therefore lower for participants under 44 years of age than for participants over 44 years of age. To compensate, in practice, this would mean using a threshold of 21 points for younger First Nations and Métis people (age 18 to 39) and 33 points for participants 40 and older. This does, however, have implications for the positive predictive value (PPV) of the test and its accuracy. For those under 40, given the relatively low prevalence of dysglycemia at younger ages, the PPV is only 13% at a cut-off of 33 and 18% at a cut-off of 21, whereas for those 40 and over, the PPV is 29% and 38%, at cut-offs of 33 and 21 points, respectively. The higher PPV at both cut-offs among the older age group reflects the higher underlying prevalence of dysglycemia with increasing age. For those under the age of 40, while accuracy was reduced from 81%, at the 33-point cut-off, to 47%, at the 21-point cut-off, the sensitivity was sufficiently increased to a more ideal level, compensating for the decrease in accuracy. The increase in sensitivity ensures that potentially affected young individuals do move on to clinical diabetes testing, which is more important than having the highest accuracy. Using cut-off points that balance sensitivity and specificity in both age groups ensures that potentially affected individuals from either age group do move on to clinical diabetes testing, while reducing the need for expensive and cumbersome screening of low-risk participants.

Strengths and limitations

In this paper we investigated the effectiveness of the CANRISK tool in screening for dysglycemia risk in a relatively large sample size of First Nations and Métis people from across Canada. We also investigated whether alternative BMI and WC cut-off points improved the predictive ability of the CANRISK model for dysglycemia in this population. To our knowledge, this is the first paper to examine the impact of using alternative BMI and WC categorizations in

TABLE 3
Logistic regression model comparison predicting dysglycemia status

Variable	Model A with CANRISK cut-off points			Model B with alternative WC cut-off points			Model C with alternative BMI cut-off points			Model D with alternative WC and BMI		
	OR	95% CI		OR	95% CI		OR	95% CI		OR	95% CI	
Age (years)												
18–29	0.44	0.25	0.77	0.43	0.24	0.77	0.46	0.26	0.81	0.45	0.25	0.80
30–39	0.61	0.36	1.05	0.61	0.35	1.04	0.62	0.36	1.06	0.61	0.36	1.05
40–44	Ref			Ref			Ref			Ref		
45–54	1.18	0.66	2.12	1.16	0.65	2.08	1.14	0.64	2.04	1.12	0.62	2.00
55–64	2.24	1.15	4.36	2.21	1.13	4.32	2.16	1.11	4.20	2.12	1.09	4.13
65+	3.28	1.24	8.71	3.31	1.24	8.83	2.91	1.10	7.67	2.92	1.10	7.77
BMI (kg/m²) – CANRISK cut-off points												
Normal/ underweight (< 25)	Ref			Ref								
Overweight (25–29.9)	1.21	0.69	2.12	1.12	0.62	2.01						
Obese, non-morbid (30–34.9)	1.57	0.84	2.94	1.38	0.73	2.63						
Obese, morbid (≥ 35)	3.08	1.64	5.79	2.71	1.42	5.16						
BMI (kg/m²) – Alternative cut-off points												
Normal/ underweight (< 23)							Ref			Ref		
Overweight (23 to < 27.5)							1.07	0.57	2.00	1.01	0.52	1.95
Obese (≥ 27.5)							1.78	0.94	3.36	1.54	0.78	3.04
WC – CANRISK cut-off points												
Male < 94, Female < 80	Ref						Ref					
Male 94–102, Female 80–88	0.94	0.46	1.92				0.91	0.45	1.87			
Male > 102, Female > 88	1.34	0.68	2.63				1.42	0.72	2.80			
WC – Alternative cut-off points												
Male < 90, Female < 80				Ref						Ref		
Male 90–100, Female 80–90				0.66	0.31	1.40				0.65	0.31	1.40
Male > 100, Female > 90				1.36	0.66	2.83				1.46	0.68	3.10
Daily brisk physical activity												
Yes	Ref			Ref			Ref			Ref		
No	1.50	1.06	2.14	1.51	1.06	2.15	1.56	1.10	2.21	1.56	1.10	2.21
Daily consumption of fruit/vegetable												
Yes	Ref			Ref			Ref			Ref		
No	1.06	0.76	1.47	1.05	0.76	1.45	1.04	0.75	1.44	1.03	0.75	1.43

Continued on the following page

TABLE 3 (continued)
Logistic regression model comparison predicting dysglycemia status

Variable	Model A with CANRISK cut-off points			Model B with alternative WC cut-off points			Model C with alternative BMI cut-off points			Model D with alternative WC and BMI		
	OR	95% CI		OR	95% CI		OR	95% CI		OR	95% CI	
High blood pressure												
Yes	1.13	0.76	1.68	1.10	0.74	1.64	1.18	0.79	1.75	1.15	0.77	1.70
No	Ref			Ref			Ref			Ref		
High blood sugar												
Yes	2.73	1.78	4.21	2.75	1.79	4.23	2.72	1.78	4.18	2.75	1.79	4.22
No	Ref			Ref			Ref			Ref		
Positive family history of diabetes												
None	Ref			Ref			Ref			Ref		
Primary relative	1.26	1.06	1.51	1.26	1.06	1.50	1.28	1.07	1.52	1.27	1.07	1.51
Gender												
Female	Ref			Ref			Ref			Ref		
Male	1.77	1.21	2.59	1.79	1.24	2.60	1.69	1.16	2.47	1.71	1.18	2.48
Education												
Some high school or less	1.18	0.81	1.72	1.17	0.81	1.71	1.19	0.82	1.73	1.18	0.81	1.71
High school diploma	1.27	0.80	2.02	1.28	0.80	2.04	1.30	0.82	2.06	1.31	0.82	2.07
Some/graduated college or university	Ref			Ref			Ref			Ref		
History of macrosomia												
No/NA	Ref			Ref			Ref			Ref		
Yes	0.93	0.57	1.51	0.92	0.57	1.50	0.92	0.57	1.49	0.92	0.57	1.48
AUC	0.7412			0.7448			0.7296			0.7332		
Hosmer Lemeshow goodness of fit	p = 0.6602 (DF = 8)			p = 0.6148 (DF = 8)			p = 0.3453 (DF = 8)			p = 0.7490 (DF = 8)		

Abbreviations: AUC, area under the curve; BMI, body mass index; CI, confidence interval; DF, degrees of freedom; kg, kilogram; m, metre; NA, not available; OR, odds ratio; Ref, reference group; WC, waist circumference.

Note: Total N = 1373.

the Canadian First Nations and Métis population in predicting dysglycemia risk.

Additionally, this study supports the use of the CANRISK tool among young adults of First Nations and Métis in Canada to identify dysglycemia risk, provided that a lower CANRISK score threshold of 21 points is used. Though specificity at this threshold was low, the improved sensitivity is a sensible compromise when implementing CANRISK among those aged under 40 years as it is more important to identify high-risk individuals in this population. This is important as diabetes rates are high in the First Nations and Métis population with a greater incidence rate among younger individuals.[2,10] Using the CANRISK tool will facilitate diabetes screening among young First Nations and Métis people, providing initial convenient screening without having to offer expensive clinical screening to young low-risk First Nations and Métis individuals. Until future research can determine the optimal model for young First Nations and Métis individuals, our results show acceptable predictive ability for this population using the "Slightly Elevated Risk" original CANRISK cut-off point. In the future, it may also be useful to create separate risk algorithms for men and women.

Considering this study relied on a convenience sample of English or French speaking volunteers who self-identified as either First Nations or Métis by their parents' ethnic background, it was not possible to fully investigate dysglycemia risk in a fully representative sample of the general First Nations and Métis population in

TABLE 4
Predictive ability of CANRISK by age group

Age group	All ages	Under 40 years	40 years or over
n	1479	1015	464
Minimum CANRISK Score	3.0	3.0	3.0
Maximum CANRISK Score	65.0	56.0	65.0
Median CANRISK Score	25.0	22.0	31.0
Mean CANRISK Score	25.7	23.1	31.3
CANRISK (%) – Using a cut-off point of 33 (high risk as specified in original CANRISK instructions)			
Sensitivity	49.1	26.7	68.4
Specificity	80.2	86.8	62.8
Positive predictive value	30.0	18.2	38.3
Negative predictive value	90.1	91.5	85.5
Accuracy	75.6	80.8	64.2
CANRISK (%) – Using a cut-off point of 21 (slightly elevated risk as specified in original CANRISK instructions)			
Sensitivity	86.2	77.2	94.0
Specificity	37.7	43.8	21.6
Positive predictive value	19.3	13.2	28.8
Negative predictive value	94.1	94.6	91.5
Accuracy	44.8	47.1	39.9

Canada. It is possible that our two separate recruitment strategies resulted in some group differences in the participating individuals between Phases 1 and 2. In addition, the fact that those with a pre-existing diabetes diagnosis were excluded from the current analysis makes it impossible to compare rates of diabetes and its risk factors between the current study and the general First Nations and Métis population.

Conclusion

The CANRISK tool functions well in a sample of Canadian First Nations and Métis as the primary step of diabetes screening for not only those aged 40 years or over but also for those under 40, with an adjustment of CANRISK score cut-off point. Our study found that alternative First Nations and Métis specific BMI and WC cut-off points did not improve the predictive ability of a logistic regression model using the CANRISK variables. Using CANRISK in the First Nations and Métis population can effectively support the early detection of type 2 diabetes and help promote awareness of its risk factors.

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Conflict of interest

Dr. Gina Agarwal was contracted to lead this project by the Science Integration Division of the Public Health Agency of Canada. Research ethics board approval was obtained from each of the regions in which data were collected and from the Health Canada/Public Health Agency of Canada Research Ethics Board.

The authors declare no conflict of interest.

Authors' contributions and statement

G.A., Y.J., H.M. and Y.M. contributed substantially to the study design and drafted the paper. H.O. provided methodological advice for data analysis. S.R.V.K. and C.L. analysed the data. B.H., K.D., and L.L. developed site collection protocols and completed data acquisition. Y.J., C.L., and H.O. reviewed and revised the paper. All authors read and gave final approval of this version to be published and agreed to be guarantors of the work.

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Effects on patients of variations in the implementation of a cardiometabolic risk intervention program in Montréal

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Abstract

Introduction: In 2011, the Agence de la santé et des services sociaux de Montréal (ASSSM), in partnership with the region's Centres de santé et de services sociaux (CSSS), coordinated the implementation of a program on cardiometabolic risk based on the Chronic Care Model. The program, intended for patients suffering from diabetes or hypertension, involved a series of individual follow-up appointments, group classes and exercise sessions. Our study assesses the impact on patient health outcomes of variations in the implementation of some aspects of the program among the six CSSSs taking part in the study.

Methods: The evaluation was carried out using a quasi-experimental "before and after" design. Implementation variables were constructed based on data collected during the implementation analysis regarding resources, compliance with the clinical process set out in the regional program, the program experience and internal coordination within the care team. Differences in differences using propensity scores were calculated for HbA1c results, achieving the blood pressure (BP) target, and two lifestyle targets (exercise level and carbohydrate distribution) at the 6- and 12-month follow-ups, based on greater or lesser patient exposure to the implementation of various aspects of the program under study.

Results: The results focus on 1185 patients for whom we had data at the 6-month follow-up and the 992 patients from the 12-month follow-up. The difference in differences analysis shows no clear association between the extent of implementation of the various aspects of the program under study and patient health outcomes.

Conclusion: The program produces effects on selected health indicators independent of variations in program implementation among the CSSSs taking part in the study. The results suggest that the effects of this type of program are more highly dependent on the delivery of interventions to patients than on the organizational aspects of its implementation.

Keywords: *chronic disease, diabetes, hypertension, primary health care*

Highlights

- The six CSSSs in the study implemented a program with moderate local variations.
- Local variations between the CSSSs with regard to program implementation do not appear to have had an impact on patient health outcomes.
- The results seem to indicate that the program's impact is more dependent on the patient's progress through the clinical process, which is based on aspects of the Chronic Care Model, rather than on the program's organizational aspects.

Introduction

The steady increase in prevalence of diabetes mellitus and high blood pressure (HBP) among Canadians is worrisome. Because the diseases share an etiology—and this is a major risk factor for heart disease[1,2]—it is logical to consider them jointly as part of a prevention and management approach.

The Chronic Care Model (CCM) is a chronic disease care model that can be used to guide health care reform to optimize the management of chronic disease.[3] In 2011, the Agence de la santé et des services sociaux de Montréal (ASSSM), in partnership with the region's Centres de santé et services sociaux (CSSS), coordinated the implementation of an integrated interdisciplinary cardiometabolic risk prevention and intervention program. The duration of the program was two years; it was inspired by the CCM and was aimed at making lifestyle changes, restoring biological indicators, preventing complications, and empowering patients with diabetes or hypertension (additional information on the program and the eligibility criteria is available from the authors).

A number of studies have shown that CCM-based interventions not only improve the process and health outcomes, but also reduce costs and service use among patients with chronic diseases,[4] particularly in the case of diabetes.[5] Although we attempted to assess the

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impact of the CCM's implementation on effects on patients in order to determine which specific elements or combination thereof yielded the best results, none have been identified to date.[6,7] In addition, to our knowledge, no studies have focused on implementation context and variations in implementation of a CCM-inspired intervention among various local settings as regards the effects on patients.

The purpose of this study is to assess, as part of the implementation of the program in the various CSSSs, the effects of variations in the implementation of certain aspects of the program on patient health indicators.

Methods

Study design

Our study is a secondary analysis carried out as part of the assessment of the cardiometabolic risk program in Montréal.[8] A quasi-experimental approach was taken to assessing the effects of variations in the implementation of certain aspects of the program on patient health outcomes.[9]

Six of the 12 CSSSs in Montréal took part in the evaluation. They were selected on a voluntary basis, as well as on their willingness to comply with the general program implementation framework suggested by the Agency. Patient recruitment was carried out by CSSS staff and took place from March 2011 to August 2013. The objective was to have each CSSS in the study recruit 300 patients per year for a total of 1500 patients per year, with anticipated attrition of approximately 15%.

Data sources and definition of variables

Data on program implementation were taken from the implementation analysis, whose purpose was to provide an overall assessment of the program. It was based on the program's logic model and the conceptual framework of factors that explain the degree of implementation. They are qualitative in nature and were collected in three phases (at the outset of program implementation in March 2011, or implementation T0; 20 months later, in November 2012, or implementation T20; and in June and July 2014, 40 months after implementation, or implementation T40) using a variety of methods: semi-formal interviews with local and regional officers, collection of official documents, questionnaires for the managers in charge and stakeholders involved in the program in each territory.

Independent variables

The study's independent variables are variations in the implementation of four aspects of the program between participating CSSSs at T40, i.e. once the implementation analysis was complete. We selected the variables that had the greatest likelihood of affecting patient health outcomes: resources, program compliance to the planned regional clinical process, internal coordination of the health team, and program experience. These "implementation variables" were dichotomized in order to compare results for two groups of patients: the group of patients exposed to the program in CSSSs where the characteristic under study had been implemented more strongly (which we will call the "high implementation variable exposure" group), and the group of patients exposed to the program in CSSSs where the characteristic was less strongly implemented (which we will call the "low implementation variable exposure" group). The resources are the number of patients seen per CSSS based on full-time staff (or their equivalent) on the core team (nurses, nutritionist and kinesiologist). Compliance with the clinical process means compliance with individual follow-ups, group classes and adherence to the calendar set out in the regional program. Internal coordination means team integration in terms of collaboration with other stakeholders and patient referrals among stakeholders. Program experience means the number of years since the implementation of the first program component (diabetes), but also greater stakeholder experience with the program as noted in the qualitative implementation analysis carried out prior to this study.

CSSS 1 was weak in its implementation of the four program components. CSSS 2 had more extensive program compliance. CSSS 3 was the strongest in implementing internal coordination. CSSSs 4, 5 and 6 were those that invested the most resources in the program and whose internal coordination was implemented most extensively. In addition, CSSS 6 had high compliance with the prescribed clinical process, and CSSS 5 distinguished itself with its program experience.

Each of the implementation variables was analyzed individually, as it was impossible to compare CSSSs that implemented all the variables with high intensity to those that implemented all the variables with lesser intensity (Table 1).

The conversion of implementation variables into dichotomous variables was done while taking into account their distribution, implementation analysis findings, the small number of CSSSs, moderate variability among CSSSs with regard to the extent of implementation of the program aspects studied and, lastly, choice of analysis method. The description of data sources and the variable construction details (including dichotomization) are set out in Table 2. The "high exposure to the implementation variable" and "low exposure to the implementation variable" groups differ for each of the implementation variables. Details of patient characteristics for each group are available upon request from the authors.

Dependent variables

The four dependent variables correspond to four health indicators: two clinical indicators, namely glycosylated hemoglobin (HbA1c) and blood pressure (BP); and two lifestyle indicators, i.e. exercise (EX) level and carbohydrate distribution. Data on the biological parameters (HbA1c and BP) and lifestyle (EX level and carb distribution) for each patient taking part in the assessment were extracted from the regional computerized chronic disease

TABLE 1
Distribution of the four implementation variables for each CSSS

Implementation variables	CSSS 1	CSSS 2	CSSS 3	CSSS 4	CSSS 5	CSSS 6
Resources	Low	Low	Low	High	High	High
Compliance with clinical process	Low	High	Low	Low	Low	High
Internal coordination	Low	Low	High	High	High	High
Program experience	Low	Low	Low	Low	High	Low

Abbreviation: CSSS, Centre de santé et de services sociaux.

TABLE 2
Implementation variables: definition, data sources and construction

Implementation variables	Variable composition	Data source	Measure	Variable construction
Resources	Number of patients seen per CSSS based on full-time employees (or full-time equivalents) on the core team (nurse, nutritionist and kinesiologist)	Manager questionnaires (T40)	• For each type of job below, indicate the number of FTEs for each status (nurse, nutritionist and kinesiologist) included.	Step 1: Calculate the "number of patients seen per CSSS / FTE" ratio for each professional. Step 2: Dichotomization of the ratio calculated in step 1 for each type of professional (lower ratio = high resources for this professional). Step 3: Create a dichotomous variable combining the three ratios: at least 2/3 "high" ratios mean "high" resources.
Compliance with clinical process	Compliance with individual follow-up and group classes and compliance with the prescribed program timetable	Manager questionnaires (T40) and interviews with local and regional officers (T40)	• Generally speaking, is the program timetable for the sample collection sequence and individual and group meetings in your CSSS identical to the regional program timetable? • For each individual and group meeting, indicate whether the description of activities and themes addressed in each meeting, as described in the regional program, generally applies to your CSSS. If the answer is no, give a brief description of the main differences and the reasons for these. • In your CSSS, apart from the exercise assessment carried out by the kinesiologist during the group classes, are any other exercise sessions offered as part of the program?	Step 1: Analyze the changes made to the basic program template for each CSSS. Step 2: Confirm the construction of a dichotomous variable for program compliance with the research officer who carried out the implementation analysis.
Internal coordination	Team integration: collaboration with other stakeholders and patient referrals among stakeholders	Team stakeholder questionnaires (T40)	• How would you rate the achievement of each of the following elements related to interdisciplinary team integration and care coordination under the program? Use a scale of 1 to 5 where 5 is "very high" and 1 is "very low." • Collaboration with other CLSC stakeholders. Referrals of patients among team professionals.	Step 1: Analyze the distribution of frequency of each subquestion and identify stakeholders who rate the achievement of these elements by grouping together 4 and 5 as high. Step 2: Categorize the level of achievement of each of the subquestions where stakeholders answered 4 or 5 (low meaning 50% or less, average 51 to 69%, and high 70% or more). Step 3: Create a dichotomous variable, with 1 average + 1 high or 2 high being equivalent to high, with other combinations equivalent to low.
Program experience	Year of implementation of the diabetes component of the program[a]	Manager questionnaires (T20)	• Indicate the year and, if possible, the month in which the diabetes clinic opened.	Step 1: Analyze the distribution of the program opening years in 6 CSSSs. Step 2: Create a dichotomous variable with high for before 2008 and low for after 2008.

Abbreviations: CLSC, Centre local de services communautaires; CSSS, Centre de santé et de services sociaux; T20, implementation follow-up at 20 months; T40, implementation follow-up at 40 months.

[a] The cardiometabolic risk program is the product of a diabetes prevention and management program put in place in Montreal's CSSSs between 2007 and 2010. This variable represents the time elapsed between the implementation of the program's diabetes component and the start of cardiometabolic risk program implementation in spring 2011.

registry created by the ASSSM and implemented in the CSSSs as part of the project. Sociodemographic and health characteristics were drawn from a self-administered questionnaire that took approximately 20 minutes to fill out, which was given to patients taking part in the assessment at the time of their entry into the program (T0).

Glycemic control was measured using HbA1c, which is expressed as a percentage and represents the proportion of glycosylated hemoglobin as compared to total hemoglobin.[10] Achieving the BP target means the achievement (yes or no) of the treatment target (below 140/90 mm Hg for non-diabetics and below 130/80 mm Hg for diabetics). Achievement of the EX target, assessed by means of a brief questionnaire adapted from Enquête québécoise sur l'activité physique et la santé[11] and administered to the patient at each visit, occurs when the EX level is 3 or 4 on a scale of 1 to 4, which corresponds to the number of days the patient did at least 30 minutes of EX, weighted by activity intensity. Achievement of the balanced carbohydrate distribution (BCD) is determined by the nutritionist's determination, following an assessment at each visit, of whether or not the patient achieved balanced carbohydrate distribution as determined by the patient's personalized food plan. Food plans are based on the document *Meal Planning for People with Diabetes at a Glance.*[12]

Data analysis

The intervention unit is the same as the analysis unit: the patient exposed to implementation variables in his/her CSSS.

Prior to the analyses, missing data at T0 regarding the studied health indicators, or 10% to 15% of the data, underwent imputation using the Hot Deck[13] method in order to reduce bias associated with non-responses[14].

Difference in differences (DID) were calculated to measure the impact of implementation variables on the studied health indicators.[15] A separate analysis model was constructed for each of the implementation variables studied, for each of the health outcomes studied, and for each analysis period.

Propensity scores were used in the DID analyses by including the following individual variables: age; sex; origins (Canadian or other); language spoken in the home (French or other); highest completed level of education (no high school diploma, high school diploma, college studies, university); professional activity in the past six months (working, unemployed, retired); number of comorbidities (none, one, two or more of the following: heart disease, asthma or COPD, bone and joint problems, history of stroke, mental health problems, and cancer); body mass index (BMI) on entry into the program; and type of front-line clinic of the general practitioner treating the patient for diabetes or HBP (family medicine group [FMG]; network clinic [NC]; FMG-NC; local community service centre [CLSC]; family medicine unit [FMU]; non-FMG, non-NC group clinic; solo practice; or orphaned patient). The propensity score, or the conditional likelihood of being a member of the "high exposure to the implementation variable" group based on individual characteristics, makes it possible to distribute these characteristics among the groups. Subject matching was done using the kernel matching[16] method, which allows for almost complete matching by associating each subject with a fictitious counterpart representing the average weighted propensity scores of subjects with similar characteristics. A different propensity score was calculated for each analysis model. Our analyses have shown that this strategy has effectively made the "high exposure to the implementation variable" and "low exposure to the implementation variable" groups comparable on the basis of these characteristics. We can thus conclude that the effect observed between two different times in the "low exposure to the implementation variable" group would be comparable to the effect observed in the "high exposure to the implementation variable" if the group's subjects had had a lower exposure to the studied implementation variable.

The DID analyses, performed using the STATA-diff[17] module, were carried out on all patients and the various patient subgroups based on their comorbidity profile (with or without comorbidities), each taken separately. Because the program aims to manage (pre)diabetic and hypertensive patients, we can assume that the implementation impact is different for patients with comorbidities that do not fall within the program's specific focus.

Ethical approval

This research project received the approval of the ASSSM ethics research committee.

Results

Sample description

The initial sample was made up of the 1689 patients registered in the program who consented to take part in the evaluation (evaluation participation rate of 60%). At the 6-month (T6) and 12-month (T12) follow-ups from their individual date of entry into the program, 1185 and 992 patients, respectively, had provided data. The difference in the size of the cohorts available for analysis at the three moments can be explained by both withdrawals and delays in patient follow-up.

At T0, the majority (77%) of patients suffered from diabetes (or prediabetes) or high blood pressure (HBP). Patients in the samples from the 6-month and 12-month follow-ups did not differ from those in the initial sample as regards their characteristics (Table 3), except for the proportion of patients suffering from both chronic diseases on which the program focuses. This proportion was higher in the follow-up samples.

Descriptive findings

Generally speaking, the average of each health result appeared to improve over the course of the program follow-up for all patients. This was more marked between T0 and T6 (Figure 1). However, the study design did not make it possible to draw conclusions as to the program's impact on patient health outcomes, and that impact is not the subject of this study.

Impact of implementation variables on findings: results of the difference in differences analysis

Overall, most analyses showed no effect of implementation variables on the studied results (Table 4). Tables 5 and 6 show the difference in differences (DID) analysis results carried out on patient subgroups by comorbidity profile.

Significant DIDs ($p < 0.05$) are in dark grey and accompanied in the tables by a "+" symbol when positive, i.e. favourable to the "high exposure to the implementation variable" group, and a "−" symbol in

TABLE 3
Characteristics of the samples studied

Time		Sample at T0		Sample at T6		Sample at T12	
Sociodemographic characteristics		**n = 1689**	**%**	**n = 1185**	**%**	**n = 992**	**%**
Average age (years)		**57.6**		**58.3**		**58.5**	
Sex	Male	755	45	517	44	428	43
Nationality	Canadian	1183	72	840	72	706	72
Primary language	French	1323	80	944	81	796	81
Education	No diploma	250	15	156	14	124	13
	Secondary school diploma	745	46	518	45	441	46
	Diploma of college studies	222	14	163	14	132	14
	University degree	413	25	312	27	266	28
Income (divided into quartiles)	Very low	411	28	275	27	230	27
	Low	319	22	221	21	182	21
	High	402	27	288	28	244	28
	Very high	331	23	248	24	204	24
Occupational activity	Working	720	44	504	44	418	43
	Retired	348	21	215	19	175	18
	Unemployed	575	35	439	38	376	39
Person living alone		645	41	476	42	399	42
State of health on entry into the program		**n = 1689**	**%**	**n = 1185**	**%**	**n = 992**	**%**
Diagnosis(es)	Diabetes or prediabetes	614	18	413	9	340	8
	Hypertension	79	5	51	4	44	4
	Both conditions	996	77	721	87	608	88
Average HbA1c of (pre)diabetics (%)		1485	7.15	1111	7.10	933	7.11
Average BP	Systolic (mm Hg)	1570	129.9	1125	130.0	945	129.9
	Diastolic (mm Hg)		75.8		75.5		75.3
Proportion of patients achieving the BP target	%	1625	41.5	1173	40.5	983	41.0
Number of comorbidities[a]	0	544	32	401	34	337	34
	1	611	36	435	37	371	37
	2 or more	534	32	349	29	284	29
Receiving primary care		**n = 1689**	**%**	**n = 1185**	**%**	**n = 992**	**%**
Type of primary care clinic	FMG/NC	517	31	373	32	310	32
	FMG	356	21	247	21	212	22
	NC	81	5	65	6	54	6
	CLSC/FMU	269	16	178	15	150	15
	Group	251	15	187	16	154	16
	Solo	97	6	65	6	53	5
	Orphaned patients	92	6	56	5	50	5

Abbreviations: CLSC, centre local de services communautaires; FMG, family medicine group; FMU, family medicine unit; NC, network clinic; T6, patient follow-up at 6 months; T12, patient follow-up at 12 months.

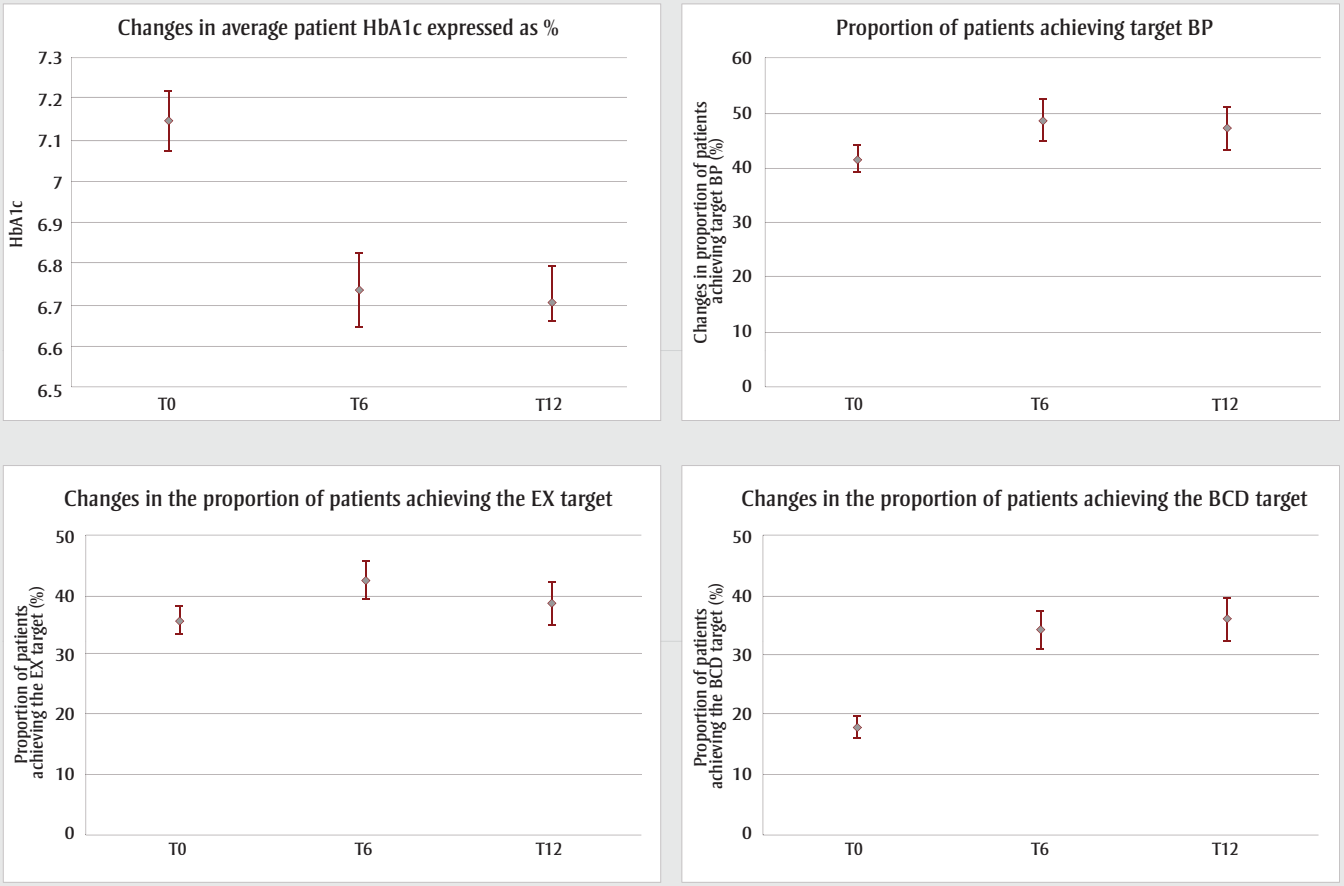
Note: The T0 sample consists of the 1689 for whom data is available upon their entry into the program; the T6 sample is the 1185 patients for whom we have data from the 6-month follow-up; and the T12 sample is the 992 patients for whom we have data from the 12-month follow-up.

[a] The included comorbidities are: heart disease, asthma or chronic obstructive pulmonary disease, bone and joint conditions, history of stroke, mental health problems, and cancer.

the opposite case, when negative. DIDs with a significance threshold between 0.05 and 0.10 are in white and are considered trends, with a "(+)" or "(−)" symbol to indicate direction.

Table 5 shows that the clinical results specific to the program, namely improvements in HbA1c and achievement of the BP targets, are influenced by implementation variables only for the subgroup of patients with no comorbidities and that this influence only involves the program experience variable. This has a positive impact on HbA1c at T12 (−0.72 percentage points). This impact is also present at

FIGURE 1
Changes in the four health outcomes studied in all patients at 0, 6 and 12 months, with 95% confidence intervals



Abbreviations: BCD, balanced carbohydrate distribution; BP, blood pressure; EX, exercise; T0, patient entry into the program; T6, 6-month patient follow-up; T12, 12-month patient follow-up.

the 6-month follow-up in the form of a trend. At that moment, the two groups ("high exposure to the implementation variable" and "low exposure to the implementation variable") show improvements in their HbA1c. Program experience appears to have a negative impact on the proportion of patients achieving the BP target. The scope of this trend is substantial (−23.7%), with the "high exposure to the implementation variable" group deteriorating and the "low exposure to the implementation variable" improving.

Table 6 shows that the proportion of patients achieving lifestyle targets is also little dependent on implementation variables. Achievement of the EX target is only influenced in patients with no comorbidities. The two significant effects are associated with the "resources" and "program experience" variables and are positive, but only at T6: the "low exposure to the implementation variable" group deteriorated, while the "high exposure to the implementation variable" group improved. The scope of the effect was substantial (+20.7% for resources and +26.3% for program experience).

Achievement of the BCD target is influenced negatively by certain implementation variables (resources and program experience), for both the subgroups of patients with and without comorbidities. These negative effects, detected at T12, are substantial (from −12.6% to −21.3%). In addition, in terms of the proportion of patients achieving the BCD target, the "high exposure to the implementation variable" group linked to the resources effect remained unchanged, while the "low exposure to the implementation variable" group improved among patients without comorbidities. The "high exposure to the implementation variable" linked to program experience deteriorated, while the "low exposure to the implementation variable" group improved among patients with comorbidities. The variable with the greatest influence appears to be program experience.

Discussion

Low impact of implementation on patient outcomes

The main objective of our study was to assess the influence of variations in the implementation of four program components on patient outcomes. The expected effects for at least three aspects ranged from neutral to positive for each of the studied health indicators. Greater compliance with the clinical process initially set out in the regional program might have generated more varied effects if we assume that adapting the program to patient needs, which would likely result in improved health outcomes, might not follow the prescribed clinical process.

TABLE 4
Synthesis of statistically significant results ($p < 0.05$) and trends ($p < 0.10$) in analysis of difference in differences

Patient categories and health indicators	Implementation variables															
	Resources				Clinical process compliance				Internal coordination				Program experience			
	T6		T12		T6		T12		T6		T12		T6		T12	
	DID	*p*	DID	*p*	DID	*p*	DID	*p*	DID	*p*	DID	*p*	DID	*p*	DID	*p*
All patients																
Average patient HbA1c																
Proportion of patients achieving the target BP (%)																
Proportion of patients achieving the EX target (%)																
Proportion of patients achieving the BCD target (%)			−9.6	0.040											−18.7	< 0.001
0 comorbidity																
Average patient HbA1c													−0.42	0.085	−0.72	0.034
Proportion of patients achieving the target BP (%)															−23.7	0.096
Proportion of patients achieving the EX target (%)	20.7	0.020											26.3	0.002		
Proportion of patients achieving the BCD target (%)			−18.3	0.038									−13.0	0.090		
1+ comorbidity(ies)																
Average patient HbA1c																
Proportion of patients achieving the target BP (%)																
Proportion of patients achieving the EX target (%)																
Proportion of patients achieving the BCD target (%)															−21.3	< 0.001

Abbreviations: BCD, balanced carbohydrate distribution; BP, blood pressure; DID, difference in differences; EX, exercise; T6, 6-month patient follow-up; T12, 12-month patient follow-up.

Notes: HbA1c is expressed as a percentage.
Data on personnel included in each of the analysis models and propensity scores are available from the authors upon request.
Statistically significant $p < 0.05$ results are illustrated in grey (pale for a positive DID threshold and dark for a negative DID threshold) and $p < 0.10$ are indicated in white.

The results of the DID analyses show that clinical indicators (HbA1c and achievement of the BP target) and lifestyle indicators are not much influenced by implementation variables when we consider all the patients taking part in the study.

In addition, some variables seem to negatively influence the proportion of patients achieving the BCD target. In the case of program experience, particularly with regard to the diabetes component, it is reasonable to assume that the CSSS nutritionists with the most experience have more experience in managing and monitoring diabetic patients, which may make them more conservative in their assessment of achievement of the BCG indicator in such patients. In the case of resources, some of these may be used for other purposes than the cardiometabolic risk program. CSSSs providing the fewest visits to patients may be providing potentially longer or higher-quality interventions. And lastly, barriers to service delivery may exist, particularly with regard to the complexities of managing appointments that follow the clinical process schedule.

Apart from a number of mitigated effects of implementation variables on the carbohydrate distribution indicator, very few effects of these variables were brought to light overall as regards health impacts for all patients. This is consistent with the results of systematic reviews showing that no CCM component has, to date, been demonstrated as being solely responsible for the CCM's positive effects.[6,7] It is highly likely that the implementation variables used in our study had a synergistic effect when taken together.

Effects in patients with no comorbidity

More significant effects of implementation variables were observed in the subgroup of patients without comorbidities than in the subgroup with comorbidities, particularly with respect to the "program experience" and "resources" variables.

It is possible that as part of the program, patients with comorbidities are given particular attention to meet their specific needs, regardless of variations in the implementation of certain aspects of the program.

The positive impact of program experience on HbA1c in patients with no

TABLE 5
Clinical results (disease control): average patient HbA1c and proportion of patients achieving the BP target at the 6- and 12-month follow-ups, according to their comorbidity profile and exposure to the implementation variables

Patient subgroups and health outcomes	Implementation variables											
	T6							T12						
	Baseline		Follow-up		DID			Baseline		Follow-up		DID		
	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction
Resources														
0 comorbidity														
Average patient HbA1c	7.24	7.18	6.93	6.68	−0.19	0.480		7.04	7.14	6.69	6.74	−0.05	0.850	
Proportion of patients achieving the target BP (%)	33.1	33.8	41.9	47.9	5.2	0.627		32.5	41.4	40.8	48.3	−1.4	0.904	
1+ comorbidity(ies)														
Average patient HbA1c	6.87	7.18	6.65	6.84	−0.12	0.527		6.84	7.25	6.50	6.95	0.04	0.832	
Proportion of patients achieving the target BP (%)	41.3	34.6	51.8	43.4	−1.7	0.808		43.3	39.7	48.6	48.8	3.7	0.606	
Compliance with the clinical process														
0 comorbidity														
Average patient HbA1c	7.04	6.80	6.58	6.59	0.25	0.273		6.93	6.83	6.52	6.54	0.13	0.613	
Proportion of patients achieving the target BP (%)	33.2	45.8	41.7	51.8	−2.5	0.814		40.8	45.7	41.1	52.9	6.8	0.543	
1+ comorbidity(ies)														
Average patient HbA1c	6.92	6.98	6.72	6.59	−0.19	0.272		6.95	6.95	6.62	6.59	−0.04	0.796	
Proportion of patients achieving the target BP (%)	28.8	50.0	44.3	58.4	−7.1	0.302		40.0	50.8	42.6	54.2	0.7	0.920	

Continued on the following page

TABLE 5 (continued)
Clinical results (disease control): average patient HbA1c and proportion of patients achieving the BP target at the 6- and 12-month follow-ups, according to their comorbidity profile and exposure to the implementation variables

Patient subgroups and health outcomes	Implementation variables												
	T6							T12					
	Baseline		Follow-up		DID			Baseline		Follow-up		DID		
	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction
Internal coordination														
0 comorbidity														
Average patient HbA1c	7.03	7.36	6.90	6.81	−0.42	0.120		7.14	7.34	6.77	6.87	−0.1	0.759	
Proportion of patients achieving the target BP (%)	32.1	40.0	40.3	50.0	1.8	0.877		39.5	40.0	45.4	41.3	−4.6	0.684	
1+ comorbidity(ies)														
Average patient HbA1c	6.86	7.17	6.55	6.84	−0.02	0.897		6.86	7.23	6.50	6.86	−0.01	0.945	
Proportion of patients achieving the target BP (%)	41.3	36.7	58.8	45.0	−9.2	0.183		41.2	39.6	55.2	44.3	−9.3	0.197	
Program experience														
0 comorbidity														
Average patient HbA1c	7.15	7.44	6.77	6.64	−0.42	0.085	(+)	7.08	7.61	6.99	6.79	−0.72	0.034	+
Proportion of patients achieving the target BP (%)	38.1	18.2	48.3	22.7	−5.7	0.573		35.1	40.0	52.1	33.3	−23.7	0.096	(−)
1+ comorbidity(ies)														
Average patient HbA1c	6.94	7.04	6.8	6.82	−0.08	0.644		6.99	6.89	6.64	6.76	0.22	0.244	
Proportion of patients achieving the target BP (%)	43.4	20.6	52.9	28.6	−1.6	0.819		41.7	29.8	50.6	44.7	6.0	0.469	

Abbreviations: BP, blood pressure; DID, difference in differences; T6, 6-month patient follow-up; T12, 12-month patient follow-up.

Notes: HbA1c is expressed as a percentage.

Patients' clinical disease control results are measured by average patient HbA1c and the proportion of patients achieving the BP target at the 6- and 12-month follow-ups.

Statistically significant $p < 0.05$ results are indicated in dark grey and $p < 0.10$ trends are in white.

A (+) or (−) symbol indicates the direction of the change.

Data on personnel included in each of the analysis models and propensity scores are available from the authors upon request.

TABLE 6
Intermediate results (lifestyle improvement): proportion of patients achieving exercise and balanced carbohydrate distribution targets at the 6- and 12-month follow-ups, by comorbidity profile and exposure to implementation variables

Patient subgroups and health outcomes	Implementation variables												
	T6							T12					
	Baseline		Follow-up		DID			Baseline		Follow-up		DID		
	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction
Resources														
0 comorbidity														
Proportion achieving the EX target (%)	49.3	35.9	41.2	48.5	20.7	0.020	+	44.5	30.3	52.3	40.8	2.8	0.784	
Proportion of patients achieving the BCD target (%)	21.4	14.0	41.4	35.5	1.4	0.857		25.0	15.9	43.4	15.9	−18.3	0.038	−
1+ comorbidity(ies)														
Proportion achieving the EX target (%)	30.3	31.6	39.4	38.3	−2.3	0.688		34.0	32.2	35.5	34.9	1.3	0.846	
Proportion of patients achieving the BCD target (%)	24.2	10.9	34.7	25.4	4.0	0.439		25.8	9.2	42.6	20.9	−5.0	0.377	
Compliance with clinical process														
0 comorbidity														
Proportion achieving the EX target (%)	37.9	54.2	40.0	55.1	−1.1	0.899		30.9	51.4	39.1	52.8	−6.8	0.506	
Proportion of patients achieving the BCD target (%)	14.6	31.7	34.4	48.5	−2.9	0.717		12.2	32.9	30.8	44.7	−6.8	0.466	
1+ comorbidity(ies)														
Proportion achieving the EX target (%)	33.8	37.0	38.7	39.6	−2.2	0.707		33.8	39.3	38.0	36.2	−7.3	0.272	
Proportion of patients achieving the BCD target (%)	17.5	26.3	25.9	39.0	4.3	0.423		21.2	25.0	32.9	42.9	6.1	0.330	

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TABLE 6 (continued)
Intermediate results (lifestyle improvement): proportion of patients achieving exercise and balanced carbohydrate distribution targets at the 6- and 12-month follow-ups, by comorbidity profile and exposure to implementation variables

Patient subgroups and health outcomes	Implementation variables												
	T6							T12					
	Baseline		Follow-up		DID			Baseline		Follow-up		DID		
	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	Group with low exposure to the implementation variable	Group with high exposure to the implementation variable	DID	*p*	Direction
Internal coordination														
0 comorbidity														
Proportion achieving the EX target (%)	53.6	37.2	49.2	45.3	12.4	0.158		51.2	30.7	56.1	36.6	1.1	0.913	
Proportion of patients achieving the BCD target (%)	22.9	17.3	50.2	33.8	−10.8	0.177		18.8	18.9	32.7	28.8	−3.9	0.652	
1+ comorbidity(ies)														
Proportion achieving the EX target (%)	29.7	31.8	37.5	38.7	−0.9	0.872		33.8	33.1	28.7	36.0	8.1	0.199	
Proportion of patients achieving the BCD target (%)	23.4	16.9	28.9	30.2	7.7	0.143		22.5	18.6	34.0	36.8	6.7	0.259	
Program experience														
0 comorbidity														
Proportion achieving the EX target (%)	48.1	22	43.8	43.9	26.3	0.002	+	44.8	29.7	49.1	37.8	3.9	0.702	
Proportion of patients achieving the BCD target (%)	21.0	15.0	41.5	22.5	−13.0	0.090	(−)	30.8	17.6	30.4	14.7	−2.5	0.775	
1+ comorbidity(ies)														
Proportion achieving the EX target (%)	31.7	25.5	40.0	34.0	0.2	0.979		37.4	25.4	39.6	29.9	2.2	0.742	
Proportion of patients achieving the BCD target (%)	20.5	11.7	35.1	19.1	−7.1	0.160		22.1	12.5	38.7	7.8	−21.3	< 0.001	−

Abbreviations: BCD, balanced carbohydrate distribution; DID, difference in differences; EX, exercise; T6, 6-month patient follow-up; T12, 12-month patient follow-up.

Notes: Intermediate results in terms of lifestyle improvement are measured by the proportion of patients achieving the EX and BCD targets.
Statistically significant $p < 0.05$ results are indicated in dark grey and $p < 0.10$ trends are in white.
A (+) or (−) symbol indicates the direction of the change.
Data on personnel included in each analysis model and propensity scores are available from the authors upon request.

comorbidities indicates that those patients, when exposed to a more experienced program, are more inclined to improve their diabetes control than patients who have comorbidities. Program experience, which corresponds to the duration of the program since the implementation of the diabetes component, doubtless reflects characteristics pertaining to expertise, particularly with regard to managing diabetic patients. Our results suggest that this expertise is perhaps better adapted to the management of diabetic patients with no comorbidities. Although the proportion of patients achieving the BCG target in the most experienced CSSS appears to have dropped by the 6-month follow-up, nutritionists in the program appear to contribute to the final program objective of diabetes control as measured by improvements in the average HbA1c of patients without comorbidities.

Resources, like program experience, have the expected positive impact on the EX target at the 6-month follow-up. Patients without comorbidities doubtless tend to increase their exercise levels in response to increased access to health care professionals who provide support and encouragement in their efforts to make changes, as well as the program expertise developed if it is more extensive in their CSSS. Patients with comorbidities benefit less from resource availability, particularly if they are dealing with physical or mental obstacles to exercise related to the number and nature of the other health problems from which they suffer.[18]

Moderate variations in implementation

The implementation analysis showed a few differences among the six participating CSSSs with regard to the program aspects implemented, but overall, the program was implemented fairly similarly across the board. The moderate variation observed can be explained by the fact that the program was very clearly defined and that the CSSSs agreed to follow the general implementation framework suggested by the Agency. Our analyses therefore compared a group with a low level of implementation to a group with a high level of implementation for each variable, but on the basis of variations that proved to be modest. This may in part explain why the variations observed had little effect on patient outcomes and, in some cases, even had unexpected impacts.

Program experience is probably the implementation variable that caused the greatest variations. A single CSSS was in the "high" category for this variable, which may explain its more substantial impact on patient results.

Strengths and limitations

Our study has a number of limitations. First, this is an exploratory study, involving post-hoc analyses. Also, the large number of analyses increases Type I errors. Since the purpose of the study was not to assess the program's effectiveness, we cannot make any determination in that regard but can only reach conclusions as to the impact of variations in the implementation of the characteristics studied. There is no control group, given the fact that the study was carried out in an actual program implementation context, which limits the interpretation of results. Moreover, the quasi-experimental design involves limitations with regard to its assumption that results for the "high exposure to the implementation variable" would have mirrored those of the "low exposure to the implementation variable" group had it not had such high exposure.

To our knowledge, there were no changes in practice in any of the CSSSs that may have affected the study's results, but we were unable to assess this component directly. We were also unable to assess the program's effectiveness on cardiometabolic risk across all program participants, since we used a non-probability sample, which prevents us from gauging its representativeness. However, according to the analysis of the data at our disposal, the patients who agreed to take part in the evaluation are identical in terms of age and sex to the patients participating in the program. We do not have any data characterizing the program's target population in the various CSSS territories.

The sample size was smaller than anticipated owing to the program's low coverage, which limited the breadth of our analyses. We did not use any interaction terms in the analyses (whose purpose was exploratory), which allowed us to gauge the impact of each variable on each of the subgroups but prevented us from comparing the impact of implementation variables between the two patient subgroups (patients with and without comorbidities). Measures linked to lifestyle indicators have more limited reliability than those associated with clinical indicators. The lack of a blind for assessing health indicators may generate information bias, but in our study neither the patients nor the health care professionals collecting information on the health indicators were aware of the group to which they belonged, as these were defined after the fact. Lastly, data collection proved more difficult than anticipated early in the project's implementation phase, as this period was mainly devoted to training new teams and learning new work methods, which affected the quality of the collected data (entry errors, missing data). Imputation of missing data nonetheless allowed us to enhance the quality of all the data and reduce the non-response bias.[14]

The type of analysis selected is one of this study's major strengths. The analysis of difference in differences, with the use of propensity scores, is a method that did indeed make it possible to test causal relationships by comparing two groups over time: one group exposed to a program with a more strongly implemented aspect and another group where the implementation of that same program aspect was weaker. The groups were therefore comparable to one another because the effect of the exposure was isolated.

Another of the study's strengths is that it attempted to draw a connection between the variations related to local environments in the implementation of certain aspects of the program to patient impacts, while also linking them to contextual elements stemming from the implementation analysis conducted at the time of the program's implementation. Quantification of qualitative variables is rarely found in the literature, and this is an innovative practice. However, the identification of variables that, when taken independently, may have a direct impact on patient results is a challenge[19] and it is likely that the aspects selected in our analyses as being more likely to directly influence patient outcomes acted synergistically.

The patients taking part in the evaluation entered the program at different times throughout the assessment period. We elected to consider implementation T40, or the evaluation conclusion, as the best approximation of program implementation levels for each of the aspects under study. This strategy may, however, have caused a certain underestimation of the

association between variations in aspects of program implementation and patient impacts. The implementation analysis showed that changes under way mid-program (implementation T20) were heading toward the program's status at implementation T40, justifying this methodology choice.

As mentioned previously, the implementation analysis showed differences among the CSSSs as regards program implementation, but those differences remained fairly modest. Consequently, for each dichotomized implementation variable, the difference between categories is moderate, limiting our ability to draw connections between implementation variables and patient outcomes.

Lastly, it should be mentioned that the implementation variables each carry wording that represents the aspect on which the CSSSs varied and that the groups were divided on this basis for analysis purposes. We must bear in mind that, for each implementation variable, the two CSSS groups can also differ in other characteristics than those indicated in the wording. This means that we cannot state that the effect of an implementation variable observed via our analysis is exclusively due to the concept reflected in the wording of the variable and not, at least in part, due to another, unmeasured characteristic that varies among CSSSs in a manner similar to the selected variable.

Linking variations in cardiometabolic risk program implementation to patient health outcomes is one of the study's great strengths. It allows us to gauge the extent to which variations in program implementation in the field, related to differing local contexts, have an impact on patient results. The combination of results presented in this study with the information on the contextual elements collected during the implementation analysis make it possible to enhance the external validity of the results and the possibility that they can be used in similar contexts, in whole or in part. These results can guide decision-making with regard to the implementation of future CCM-based projects addressing other chronic diseases in populations in Montréal, in Quebec, or elsewhere in Canada.

Conclusion

The results of this study show that some variations in the implementation of various aspects of the cardiometabolic risk program have little influence on patients' health outcomes, particularly on the clinical indicators of HbA1c and the achievement of blood pressure treatment targets.

Generally speaking, knowing that 6 CSSSs in the study implemented a program that was fairly similar, the moderate differences observed in this study do not appear to have had an impact on patient outcomes.

These results are an incentive to continue research to assess with greater accuracy the impact of variations in program implementation in various settings. The integration of qualitative and quantitative methods is a contribution that enriches the interpretation of our results and is a research direction to be pursued and improved. In that respect, greater cohesion between the qualitative and quantitative processes, particularly with regard to collecting data on the implementation of the intervention and on patient outcomes, is needed in conducting this type of research, in order to be able to better assess the impact of implementation extent on patient health outcomes.

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Conflicts of interest

The authors have no conflicts of interest to declare.

Authors' contributions and statement

All authors took part in designing and drafting the manuscript and interpreting the data. All authors also took part in the critical review and read and approved the final manuscript.

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