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From BpTRU to OMRON: The impact of changing automated blood pressure measurement devices on blood pressure estimates among children and youth

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From BpTRU to OMRON: The impact of changing automated blood pressure measurement devices on blood pressure estimates among children and youth

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ABSTRACT

Background

After six cycles of using the BpTRU (BT) BPM-300 blood pressure (BP) monitor, the Canadian Health Measures Survey (CHMS) introduced the OMRON (OM) IntelliSense HEM-907XL BP monitor in Cycle 7. This study assesses differences between BP values measured by both devices in children and youth aged 6 to 17 years and whether equations could be developed to compare BP measurements taken using the two devices.

Data and methods

In Cycle 6 (2018 to 2019) of the CHMS, BP was measured using BT and OM devices. Between-device estimates of systolic BP (SBP), diastolic BP (DBP), and BP categories were compared for 233 children and youth aged 6 to 17 years. Sex, age, body mass index (BMI), and central obesity categories were examined in linear regression models to predict SBP and DBP values measured with OM based on those measured with BT.

Results

In the study sample, average SBP measured with OM was 9 millimetres of mercury (mmHg) higher than average SBP measured with BT, and average DBP measured with OM was 3 mmHg lower than DBP measured with BT. Normal BP prevalence based on OM measurements was 2.1 to 6.4 percentage points lower than the prevalence based on BT measurements, depending on which pediatric BP guidelines were applied. Between-device BP differences varied in magnitude by sex, age group, and BMI categories. Prediction equations developed using linear regression could not adequately account for the measurement differences between the two devices.

Interpretation

Switching to the OM device in Cycle 7 will substantively affect pediatric BP estimates, preventing comparability with BP data from previous cycles. The impact of changing the BP devices on BP measurement should be acknowledged when reporting estimates of pediatric BP based on the CHMS.

Keywords

blood pressure measurement, crossover study, automated sphygmomanometers, pediatric blood pressure

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What is already known on this subject?

- Children and youth with elevated blood pressure (BP) are more likely to become hypertensive adults and experience cardiovascular disease events in adulthood.
- BP measurement can vary between methods and devices, particularly among children.
- After six cycles of using the BpTRU (BT) BPM-300 BP monitor, the Canadian Health Measures Survey (CHMS) introduced the OMRON (OM) IntelliSense HEM-907XL BP monitor in Cycle 7.

What does this study add?

- This study compares BP measurements taken by the OM and BT devices on a sample of children and youth aged 6 to 17 years during a single visit to the mobile examination centre in Cycle 6 of the CHMS.
- In the study sample, average systolic BP (SBP) measured with OM was 9 millimetres of mercury (mmHg) higher than average SBP measured with BT, and average diastolic BP (DBP) measured with OM was 3 mmHg lower than DBP measured with BT.
- Prediction equations developed using linear regression did not produce estimates that adequately permit comparisons between pediatric BP measurements taken with the two devices.
- Switching to the OM device in Cycle 7 will substantively affect pediatric BP estimates, preventing comparability with BP data from previous cycles. The impact of changing BP devices on BP measurement should be acknowledged when reporting estimates of pediatric BP based on the CHMS.

Children and youth with elevated blood pressure (BP) are more likely to become hypertensive adults¹ and experience cardiovascular disease events, such as heart attack or stroke, in adulthood.² Hypertension affects almost one in four adults,³ heart disease is the second leading cause of death,⁴ and heart failure and heart attack are the number two and number three reasons for hospitalizations (excluding childbirth) in Canada.⁵ Given the connection between childhood BP and lifelong health, ongoing measurement and tracking of pediatric BP levels and changes in the Canadian population are essential.

The Canadian Health Measures Survey (CHMS) has used standardized, automated BP measurement to monitor systolic BP (SBP) and diastolic BP (DBP) in the population aged 6 to 79 years since 2007.⁶ The validated BpTRU (BT) BPM-300 BP monitor was used for cycles 1 to 6 (2007 to 2019) of the CHMS.^{7,8} When BpTRU abruptly ceased operations in 2017,⁹ the OMRON (OM) IntelliSense HEM-907XL BP monitor was selected as the replacement device for Cycle 7 onward after consultation with experts and other national health surveys. Studies have shown that the OM monitor meets validation criteria for measured SBP for individuals aged 7 years and older and for measured DBP for individuals aged 20 years and older.^{10,11}

Because BP measurement can vary between methods and devices at all ages,^{12,13} a crossover study was implemented in Cycle 6 of the CHMS to compare measurements taken by the two devices on the same individuals aged 6 to 79 years. This article focuses on children and youth aged 6 to 17 years who

participated in that study to examine between-device differences in BP values and assess the feasibility of developing equations to compare BP measurements taken with the two devices for this age group. Specifically, the crossover study data are used to estimate SBP, DBP, and BP categories based on measurements from the BT and the OM devices, differences are compared across selected characteristics, and the feasibility of developing prediction equations to compare pediatric BP data from earlier CHMS cycles with data from Cycle 7 onward is assessed. The crossover study data for adults aged 18 to 79 years were analyzed with similar objectives, and the results have been published separately.¹⁴

Data and methods

Data

Data are from Cycle 6 (January 2018 to December 2019) of the CHMS, a cross-sectional survey that collects questionnaire and directly measured health information from community-dwelling individuals aged 3 to 79 years living in the 10 provinces. People living in the three territories or on reserves and settlements in the provinces, the institutionalized population, residents of certain remote regions, and full-time members of the Canadian Forces are excluded (about 4% of the Canadian population). The CHMS involves an in-person household interview and a subsequent visit to a mobile examination centre (MEC). The household interview gathers general demographic and socioeconomic data and detailed

information on health, nutrition, medication use, and lifestyle. At the MEC, direct physical measurements are taken, including BP, height, weight, and waist circumference (WC). Ethics approval for the CHMS was received from the Health Canada Research Ethics Board.¹⁵ Further information about the CHMS is available online.¹⁶

Crossover study protocol

Cycle 6 of the CHMS collected automated digital BP measurements from all respondents using the BT monitor (BpTRU Medical Devices Limited, Coquitlam, British Columbia). The BT monitor takes six readings, with a one-minute interval between the beginning of each consecutive

Table 1
Estimates and differences in systolic and diastolic blood pressure as measured by the OMRON and BpTRU devices, by selected characteristics, crossover study sample aged 6 to 17 years, Canada, excluding territories, 2018 to 2019

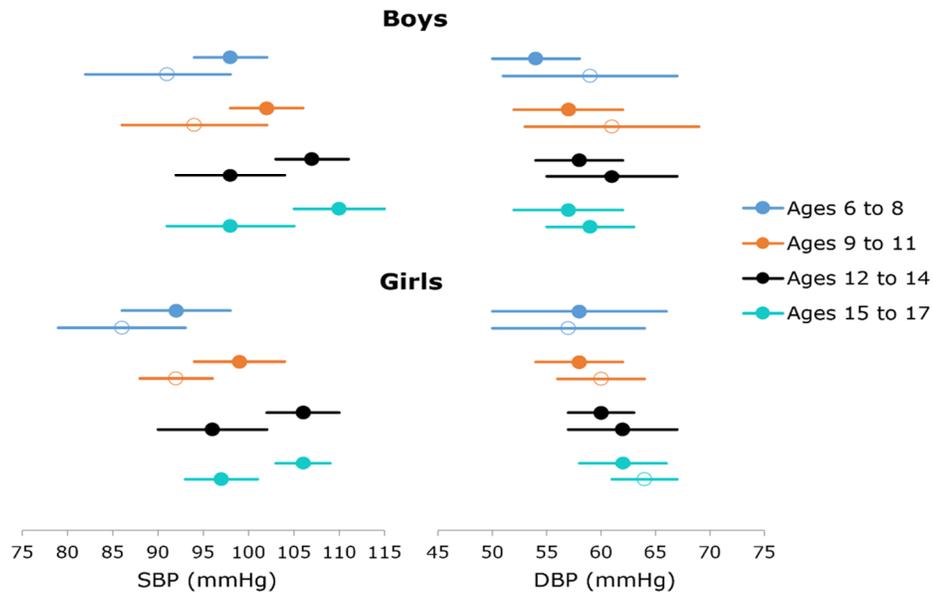
	n	Measured mean SBP (mmHg)					Measured mean DBP (mmHg)				
		OM	BT	Difference (OM - BT)	95% CI		OM	BT	Difference (OM - BT)	95% CI	
					from	to				from	to
Total	233	103	94	9	8	10 [†]	58	61	-3	-3	-2 [†]
Sex											
Male	108	104	95	9	8	11 [†]	56	60	-4	-5	-2 [†]
Female	125	101	93	8	7	9 [†]	59	61	-2	-3	0 [†]
Age group											
6 to 8 years	47	95	88	7	5	9 [†]	56	58	-2	-5	1
9 to 11 years	70	100	93	7	5	9 [†]	58	61	-3	-5	-1 [†]
12 to 14 years	56	106	97	9	8	11 [†]	59	62	-3	-4	-1 [†]
15 to 17 years	60	108	98	11	9	13 [†]	59	61	-2	-4	-1 [†]
Males											
6 to 8 years	25	98	91	7	4	11 [†]	54	59	-5	-9	-1 [†]
9 to 11 years	31	102	94	9	5	12 [†]	57	61	-5	-8	-1 [†]
12 to 14 years	21	107	98	8	5	12 [†]	58	61	-3	-5	-1 [†]
15 to 17 years	31	110	98	12	10	15 [†]	57	59	-3	-4	-1 [†]
Females											
6 to 8 years	22	92	86	7	3	10 [†]	58	57	1	-3	5
9 to 11 years	39	99	92	6	4	9 [†]	58	60	-2	-4	0
12 to 14 years	35	106	96	10	8	12 [†]	60	62	-2	-4	-1 [†]
15 to 17 years	29	106	97	9	6	12 [†]	62	64	-2	-4	0 [†]
Body mass index categories											
Neither overweight nor obese	192	102	93	9	8	10 [†]	57	60	-3	-4	-2 [†]
Overweight	22	108	99	9	7	11 [†]	60	61	-1	-3	1
Obese	19	108	103	5	1	9 [†]	64	64	0	-5	5
Males											
Neither overweight nor obese	82	103	93	10	8	12 [†]	55	60	-5	-6	-4 [†]
Overweight	14	109	99	10	8	12 [†]	61	62	-1	-3	1
Obese	12	108	102	6	0	11	64	62	2	-5	9
Females											
Neither overweight nor obese	110	101	92	8	7	10 [†]	59	60	-1	-3	0 [†]
Overweight	8	107	99	8	3	13 [†]	59	60	-1	-5	2
Obese	7	108	104	4	-4	12	65	68	-3	-10	4
Central obesity category											
Not at risk of central obesity	198	102	93	9	8	10 [†]	57	60	-3	-4	-2 [†]
At risk	19	107	100	7	5	10 [†]	62	63	-1	-4	1
Centrally obese	16	109	104	5	0	10 [†]	64	64	0	-5	5
Males											
Not at risk of central obesity	90	104	94	10	8	12 [†]	55	60	-4	-6	-3 [†]
At risk	9	108	99	9	5	12 [†]	60	63	-3	-6	0
Centrally obese	9	108	104	4	-3	12	64	63	1	-8	10
Females											
Not at risk of central obesity	108	100	92	8	7	10 [†]	59	60	-2	-3	0 [†]
At risk	10	107	100	6	2	11 [†]	63	64	0	-5	4
Centrally obese	7	109	103	6	-2	14	64	66	-2	-9	5

[†] Indicates the difference between BT-measured and OM-measured blood pressure was statistically different from 0 at p < 0.05 (paired t-test).

Notes: SBP = systolic blood pressure, DBP = diastolic blood pressure, OM = OMRON, BT = BpTRU, CI = confidence interval, and n = sample size. Differences were calculated on unrounded means, and all estimates were then rounded to the nearest integer.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

Figure 1
 Mean (plus or minus 1 standard deviation) systolic and diastolic blood pressure, by device, sex and age group, crossover study sample aged 6 to 17 years, Canada, excluding territories, 2018 to 2019



Notes: SBP = systolic blood pressure, DBP = diastolic blood pressure, and mmg = millimetres of mercury. Solid circles represent the mean blood pressure measurements using OMRON, and open circles represent the mean blood pressure measurements using BpTRU. Error bars represent the average ± 1 standard deviation from the mean.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

measurement, and averages the last five to determine SBP and DBP levels.¹⁷ Crossover study respondents also had their BP measured using the OM monitor (OMRON Healthcare Incorporated, Vernon Hills, Illinois). Average mode was used, in which the OM monitor takes three readings, each one minute apart, and averages all three to determine SBP and DBP levels.¹⁸

The last eight sites in Cycle 6 were available for the crossover study. The number of sites and the target sample sizes were selected to ensure that device differences in BP could be measured for each age group independently: ages 6 to 19 years, two sites (n=154); ages 20 to 39 years, four sites (n=210); ages 40 to 59 years, six sites (n=338); and ages 60 to 79 years, eight sites (n=491). Respondents in the crossover study were randomly assigned to have their measurements taken with BT or OM first, based on whether their randomly generated identification number was even or odd.

A health measures specialist (HMS) or medical radiation technologist (MRT) trained in BP measurement explained the crossover study protocol to the respondent at the MEC. The HMS or MRT measured the respondent’s mid-arm circumference for cuff placement and selected the appropriate cuff size for each BP monitor. The BT monitor has five cuff sizes: child (13 to 18 cm), small adult (18 to 26 cm), regular adult (26 to 34 cm), large adult (32 to 43 cm), and extra-large adult (41 to 52 cm).¹⁷ For those aged 6 to 17 years included in

this analysis, the distribution across BT cuff sizes was 6% for the child cuff, 52% for the small adult cuff, 40% for the regular adult cuff, and 2% for the large and extra-large adult cuffs combined. The OM monitor has four cuff sizes: small (17 to 22 cm), medium (22 to 32 cm), large (32 to 42 cm), and extra large (42 to 50 cm).¹⁸ The distribution across OM cuff sizes was 46% for the small cuff, 52% for the medium cuff, and 2% for the large and extra-large cuffs combined. If a respondent’s arm measurement fit two cuff sizes for the same BP monitor, the HMS or MRT was instructed to select the larger sized cuff.

The cuff for the monitor to be used first was placed on the respondent’s arm. If the BT monitor was used first, the respondent was left alone for a five-minute rest period, after which the HMS or MRT returned to the room. The HMS or MRT then pressed start, remained for the first reading, then left the room for approximately five minutes while the BT monitor took the remaining five readings. If the OM monitor was used first, the HMS or MRT pressed start to activate the five-minute timer on the machine then left and returned to the room after approximately nine minutes. During this time, the OM monitor automatically took three readings following the timed five-minute rest period. There was no additional five-minute rest period after the first BP monitor was used, and the HMS or MRT did not speak to the respondent or move the respondent’s position while changing the cuff and starting the protocol for

the second BP monitor. If the child was uncomfortable with staying in the room alone, the parent or guardian was allowed to remain while the child relaxed, but talking and moving around were prohibited.

Age group targets were surpassed during data collection, resulting in 1,341 crossover study respondents with valid BP measurements from the OM and BT devices. Those aged 6 to 17 years were eligible for this analysis, a total of 237 respondents. Less than 2% of eligible respondents were excluded from the analysis for the following reasons: having a difference between their average BP reading from the BT and the OM devices over three standard deviations from the overall mean difference (both SBP and DBP, n=1; DBP only, n=2) or having insufficient data to derive body mass index (BMI) (n=1). The final analytical sample included 233 respondents.

Measures and definitions

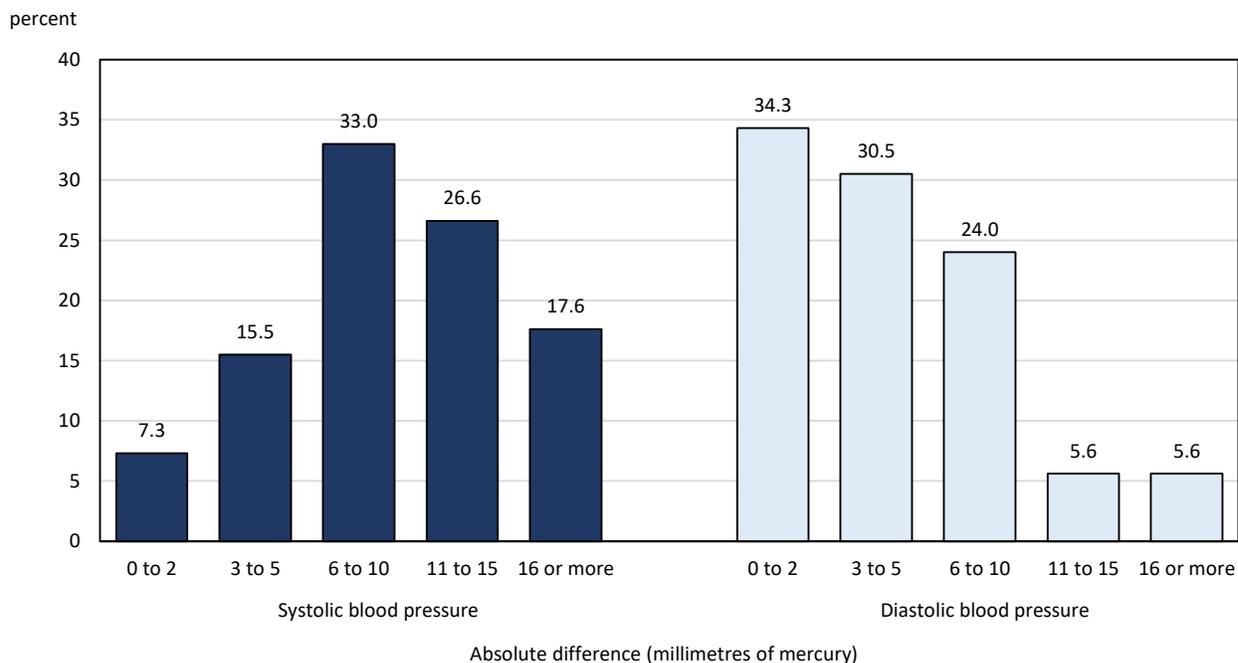
BP: For the BT device, mean SBP and DBP in this study were estimated from at least three and up to five valid measurements. Of the mean SBP and DBP values, 6% were based on three measurements, 16% on four measurements, and 78% on five measurements. For the OM device, mean SBP and DBP were estimated from at least one and up to three valid measurements. Of the mean values, 3% were based on one measurement, 3%

on two measurements, and 94% on three measurements. Of the study respondents, 21% had a parent or guardian present in the room while their BP was being measured.

Measured SBP and DBP were compared with sex-, age-, and height-specific SBP and DBP percentiles to classify respondents into separate BP categories under three sets of pediatric BP guidelines: the National High Blood Pressure Education Program’s *Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents*, published in 2004 (NHBPEP 2004);¹⁹ the American Academy of Pediatrics’ *Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents*, published in 2017 (AAP 2017);²⁰ and Hypertension Canada’s *Comprehensive Guidelines for the Prevention, Diagnosis, Risk Assessment, and Treatment of Hypertension in Adults and Children*, published in 2020 (HC 2020).²¹

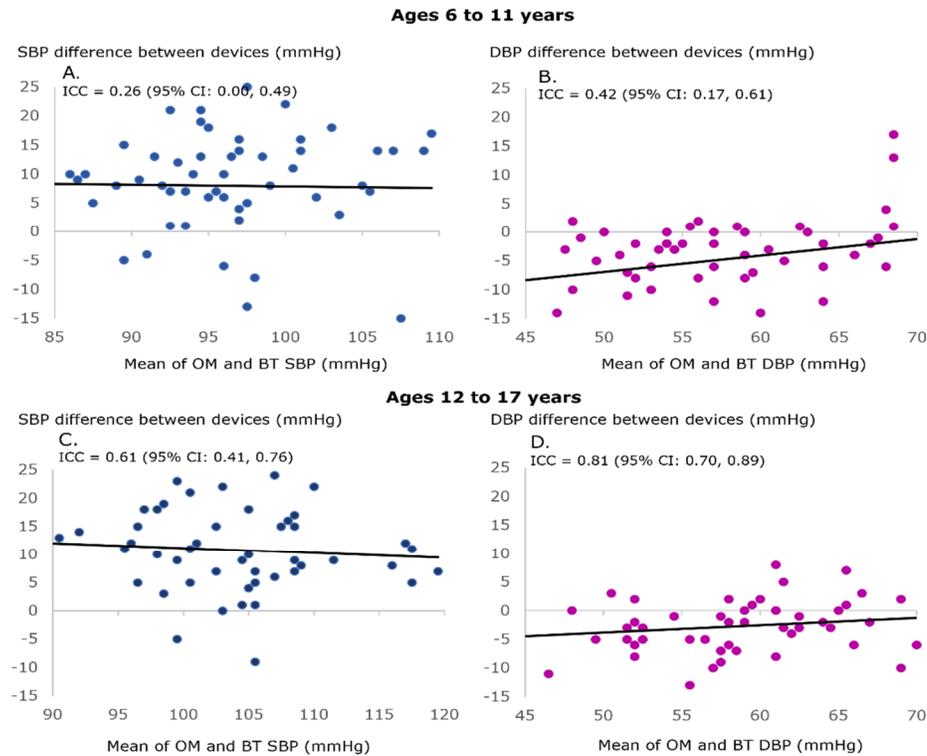
NHBPEP 2004 has the following BP categories: normal, prehypertension, Stage 1 hypertension, and Stage 2 hypertension. This categorization is included in the CHMS data files for cycles 1 to 6 as the variable BpMDBPK. AAP 2017 defines BP categories as normal, elevated BP, Stage 1 hypertension, and Stage 2 hypertension. These categories were derived for this analysis using the childhood BP macro and

Chart 1
Frequency distribution of absolute difference between OMRON and BpTRU for systolic and diastolic blood pressure, crossover study sample aged 6 to 17 years, Canada, excluding territories, 2018 to 2019



Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

Figure 2
Bland–Altman plots of blood pressure differences between devices among boys aged 6 to 17 years, Canada, excluding territories, 2018 to 2019



Notes: SBP = systolic blood pressure, DBP = diastolic blood pressure, OM = OMRON, BT = BpTRU, ICC = intraclass correlation coefficient (A. ICC = 0.26 (95% CI: 0.00, 0.49); B. ICC = 0.42 (95% CI: 0.17, 0.61); C. ICC = 0.61 (95% CI: 0.41, 0.76); D. ICC = 0.81 (95% CI: 0.70, 0.89)), CI = confidence interval, and mmHg = millimetres of mercury.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

accompanying data files—including the updated normative pediatric BP tables—published online by Dr. B. Rosner (available from <https://sites.google.com/a/channing.harvard.edu/bernardrosner/pediatric-blood-press/childhood-blood-pressure>). The updated normative pediatric BP tables used to derive AAP 2017 were also used to derive hypertension under HC 2020. HC 2020 uses percentile criteria to define Stage 1 and Stage 2 hypertension for children and adolescents but does not explicitly define normal and elevated BP, so the AAP 2017 definitions for the latter two categories were applied. The criteria applied under each of the guidelines are summarized in “The impact of updated clinical blood pressure guidelines on hypertension prevalence among children and adolescents.”²²

BP category: The four-level BP categories under all sets of guidelines were grouped into two categories—normal or above normal.

Height: Individuals’ height was measured to the nearest 0.1 cm using a ProScale M150 digital stadiometer (Accurate Technology Incorporated, Fletcher, United States).

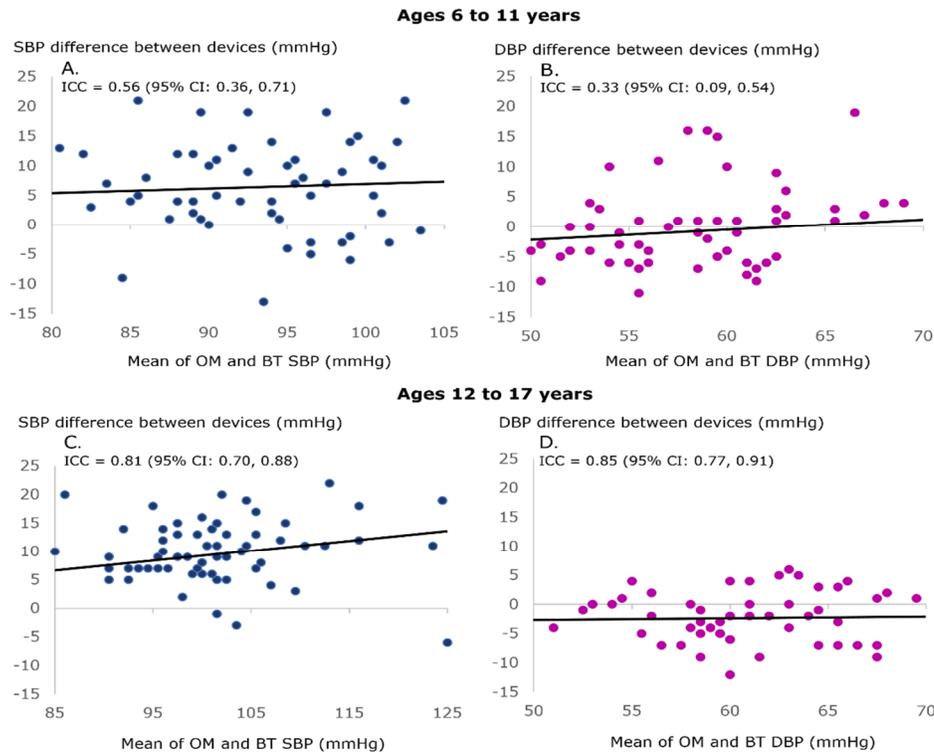
Height category: Individuals’ measured height was compared with sex- and age-specific height percentiles based on the Centers for Disease Control and Prevention Growth Charts²³ in the childhood BP macro provided by Dr. B. Rosner (available from <https://sites.google.com/a/channing.harvard.edu/bernardrosner/pediatric-blood-press/childhood-blood-pressure>).

Weight: Individuals’ weight was measured to the nearest 0.1 kg with a Mettler Toledo VLC with Panther Plus terminal scale (Mettler Toledo Canada, Mississauga, Canada).

BMI: Individuals’ BMI was calculated as their measured weight in kilograms divided by measured height in metres squared. BMI categories were derived from the respondent’s BMI-for-age-and-sex z-score based on a set of cut-offs specified by the World Health Organization.²⁴

WC: Individuals’ WC was measured to the nearest 0.1 cm, directly on the landmarked skin, with a flexible, inelastic measuring tape with an attached tension metre. In keeping with the National Institutes of Health protocol²⁵ that was implemented in Cycle 2, the measure was taken at the highest point of the iliac crest.

Figure 3
Bland–Altman plots of blood pressure differences between devices among girls aged 6 to 17 years, Canada, excluding territories, 2018 to 2019



Notes: SBP = systolic blood pressure, DBP = diastolic blood pressure, OM = OMRON, BT = BpTRU, ICC = intraclass correlation coefficient (A. ICC = 0.56 (95% CI: 0.36, 0.71); B. ICC = 0.33 (95% CI: 0.09, 0.54); C. ICC = 0.81 (95% CI: 0.70, 0.88); D. ICC = 0.85 (95% CI: 0.77, 0.91)), CI = confidence interval, and mmHg = millimetres of mercury.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

Central obesity: Waist-to-height ratio (WtHR) is a measure of fat distribution and primarily identifies those with abdominal obesity.²⁶ It was calculated from individuals’ measured WC in centimetres divided by their measured height in centimetres. Central obesity categories corresponded to not at risk (WtHR below 0.5), at risk (WtHR from 0.50 to less than 0.55), and centrally obese (WtHR at or above 0.55).²⁷

Covariates

Sex at birth (male or female) and age in years were reported at the visit to the MEC.

Analytical techniques

Mean SBP and DBP, mean differences, prevalence across BP categories, and prevalence differences were estimated from BT and OM measurements across selected characteristics, stratified by sex. Mean SBP and DBP estimates were rounded to the nearest integer. The average amount of variability (standard deviation) in the set of measurements from each device used to estimate mean SBP and DBP was estimated by sex and age group. The frequency distribution of absolute between-device differences in SBP and DBP was estimated overall and by sex. Sex-specific Bland–Altman plots illustrated differences

between devices in measured SBP and DBP, stratified by age group. Intraclass correlation coefficients (ICCs) quantified the degree of correlation and agreement between the two sets of measurements for each stratum. ICC estimates and their 95% confidence intervals (CIs) were calculated based on a $k=1$, consistency, two-way mixed-effects model.²⁸

The feasibility of developing prediction equations to compare BP measurements based on BT readings with those based on OM readings was assessed. Overall and sex-specific scatterplots and histograms were used to examine the correlation between, and the distribution of, SBP and DBP from both devices according to age group, BMI category, and central obesity category. The REG procedure in SAS was used to estimate separate SBP and DBP linear regression models with SBP (or DBP) measured with OM as the outcome and SBP (or DBP) measured with BT as the sole independent variable. Sex and an interaction between sex and the BT value were then tested in each model to assess the need for sex-specific models. Age in years, BMI in kg/m^2 , and WtHR and their polynomials (quadratic, cubic) were added sequentially to each base model (BMI and WtHR were tested in separate models as they were intercorrelated, $r=0.84$). Model fit statistics, including likelihood ratio tests of nested models, residual plots, and predicted R-squared values, were evaluated, and linear

Table 2
Proportion distribution across blood pressure categories under three sets of guidelines, crossover study sample aged 6 to 17 years, Canada, excluding territories, 2018 to 2019

	OM			BT			Difference (OM-BT)		
	%	from	to	%	from	to	%	from	to
NHBPEP 2004									
Normal BP	93.6	89.6	96.1	96.6	93.3	98.3	-3.0	-6.7	0.7
Above normal BP	6.4	3.9	10.4	3.4	1.7	6.7
AAP 2017									
Normal BP	89.7	85.1	93.0	96.1	92.7	98.0	-6.4	-10.9	-2.0 [†]
Above normal BP	10.3	7.0	14.9	3.9	2.0	7.3
HC 2020									
Normal BP	93.1	89.0	95.8	95.3	91.6	97.4	-2.1	-6.2	1.9
Above normal BP	6.9	4.2	11.0	4.7	2.6	8.4

... not applicable

[†] OM versus BT McNemar test p-value < 0.05.

Notes: OM = OMRON; BT = BpTRU; BP = blood pressure; NHBPEP 2004 = *Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents*, published by the National High Blood Pressure Education Program in 2004; AAP 2017 = *Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents*, published by the American Academy of Pediatrics in 2017; and HC 2020 = *Comprehensive Guidelines for the Prevention, Diagnosis, Risk Assessment, and Treatment of Hypertension in Adults and Children*, published by Hypertension Canada in 2020. NHBPEP 2004 defines four blood pressure categories: normal, prehypertension, Stage 1 hypertension, and Stage 2 hypertension. AAP 2017 defines four blood pressure categories: normal, elevated, Stage 1 hypertension, and Stage 2 hypertension. HC 2020 does not explicitly define normal and elevated BP but uses percentile criteria to define Stage 1 and Stage 2 hypertension for children and adolescents. "Above normal BP" combines prehypertension or elevated BP, Stage 1, and Stage 2 hypertension into a single category.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

regression assumptions were met. The HPREG procedure with forward selection and the Schwarz Bayesian information criterion specified for model fit were then used to confirm model selection. Two sets of models—base and full (with covariates)—were generated for SBP and DBP. Regression coefficients were truncated to two decimal places, and the predicted R-squared was rounded to three decimal places. Sex-specific probability density plots of predicted versus measured SBP and DBP stratified by age group were generated. Differences between predicted and measured mean SBP and DBP were examined and tested to determine whether the difference between BT and OM measurements was statistically different from 0 ($p < 0.05$, paired t-test) by sex, age group, BMI, and central obesity category. Overall differences between predicted and measured BP categories were also assessed using McNemar tests, with statistical significance set at $p < 0.05$.

Because BP is highly variable²⁹ and consecutive BP measurements tend to regress to the mean,³⁰ device order—whether the BT device was used first or not—was added as a covariate in each final full model in a sensitivity analysis. Model fit statistics and predicted values produced by these adjusted models were assessed.

All analyses were conducted in SAS Enterprise Guide 9.4 and SAS-callable SUDAAN 11.0.3, except for the ICCs and the probability density plots. The psych package³¹ was used to generate the ICCs, and the ggplot2, ggpubr, and scales packages³²⁻³⁴ were used to generate the density plots in RStudio 4.1.3.

Results

OMRON versus BpTRU

About half of the study sample was aged 6 to 11 years ($n=117$). Slightly over half were girls ($n=125$), and most of the sample was neither overweight nor with obesity ($n=192$) (Table 1). Overall mean SBP measured with OM was 9 millimetres of mercury (mmHg) higher than that measured with BT. Mean DBP measured with OM was 3 mmHg lower than that measured with BT. The average between-device difference across characteristics ranged from +4 to +12 mmHg for SBP and -5 to +2 mmHg for DBP. The mean difference in SBP between the two devices was similar for boys (9 mmHg) and girls (8 mmHg), increased for both sexes with increasing age, and was lower among those with obesity and those with central obesity (5 mmHg), compared with those without obesity or not at risk of central obesity (9 mmHg). The mean difference in DBP between devices was -4 mmHg for boys versus -2 mmHg for girls. The pattern of difference in DBP across age groups and increasing BMI or risk of central obesity was not the same for both sexes.

The average amount of variability in the set of measurements from each device used to estimate mean SBP and DBP differed by sex (Figure 1). For boys aged 6 to 14 years, there was higher variability in measurements of SBP and DBP from the BT device, compared with those from the OM device. For girls, the average amount of variability in measurements of SBP and DBP was comparable for both devices, except for girls aged 12 to 14 years.

About 23% of participants had a between-device absolute difference in SBP of 5 mmHg or less, and 65% had an absolute difference in DBP of 5 mmHg or less (Chart 1). Absolute between-device agreement differences in SBP were within 5 mmHg for 27% of girls versus 18% of boys (data not shown). Differences in DBP were within 5 mmHg for 68% of girls versus 61% of boys (data not shown).

For boys, there was a marginal decrease in between-device differences with increasing SBP among those aged 12 to 17 years (Figure 2-C). Conversely, there was a marginal increase in between-device differences with increasing SBP among girls aged 6 to 11 years (Figure 3-A) that was more pronounced for those aged 12 to 17 years (Figure 3-C). Between-device differences decreased with increasing DBP for those aged 6 to 11 years for both sexes (figures 2-B and 3-B) and among boys aged 12 to 17 (Figure 2-D). The ICCs for both sexes aged 6 to 11 years ranged from 0.26 (95% CI: 0.00, 0.49) to 0.56 (95% CI: 0.36, 0.71), indicating poor agreement and correlation between the two devices,²⁸ and from 0.61 (95% CI: 0.41, 0.76) to 0.85 (95% CI: 0.77, 0.91) for those aged 12 to 17 years (indicating poor to good agreement).

Between-device differences in normal BP prevalence varied under the three sets of guidelines. Under AAP 2017, the percentage point difference in normal BP prevalence between the OM and BT devices was -6.4 (Table 2). Under NHBPEP 2004, the difference in normal BP prevalence between OM and BT devices was -3.0 percentage points, while under HC 2020, it was -2.1 percentage points.

Predicted versus measured blood pressure

The regression coefficients of the linear models predicting OM SBP and DBP using BT measurements are presented in Table 3. For the base models, the predicted R-squared was 0.444 for SBP and 0.389 for DBP. For the full models, it was 0.519 for SBP and 0.421 for DBP. The full SBP and DBP models produced predicted values that were slightly lower, on average, than measured values for SBP and DBP (Table 4). Figures 4 and 5 show how predicted BP from the full model compared with measured BP across the BP distribution, stratified by sex and age group. Among boys in both age groups, predicted SBP and DBP were much more likely to follow a normal distribution compared with measured SBP and DBP, resulting in poor

Table 3
Regression coefficients of the linear models predicting OMRON systolic and diastolic blood pressure using BpTRU measurements, crossover study sample aged 6 to 17 years, Canada, excluding territories, 2018 to 2019

	Base model		Full model	
	regression coefficient	SE	regression coefficient	SE
Predicted OM SBP				
Intercept	30.98	5.18	28.43	6.56
SBP measured with BT	0.76	0.05	0.80	0.06
Sex				
Boy	37.36	9.76
Girl [†]
Boy*SBP measured with BT	-0.37	0.10
Age group				
6 to 11 years	-5.16	0.96
12 to 17 years [†]
Model information				
Predicted R ²	0.444	...	0.519	...
Predicted OM DBP				
Intercept	14.95	3.46	9.00	4.12
DBP measured with BT	0.71	0.05	0.66	0.05
Sex				
Boy	-2.53	0.82
Girl [†]
Waist-to-height ratio	0.21	0.06
Model information				
Predicted R ²	0.389	...	0.421	...

... not applicable

[†] reference category

Notes: BT = BpTRU, OM = OMRON, SBP = systolic blood pressure, DBP = diastolic blood pressure, and SE = standard error.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

Table 4
Estimates of and differences in measured and predicted mean systolic and diastolic blood pressure using OMRON, full models, by selected characteristics and sex, crossover study sample aged 6 to 17 years, Canada, excluding territories, 2018 to 2019

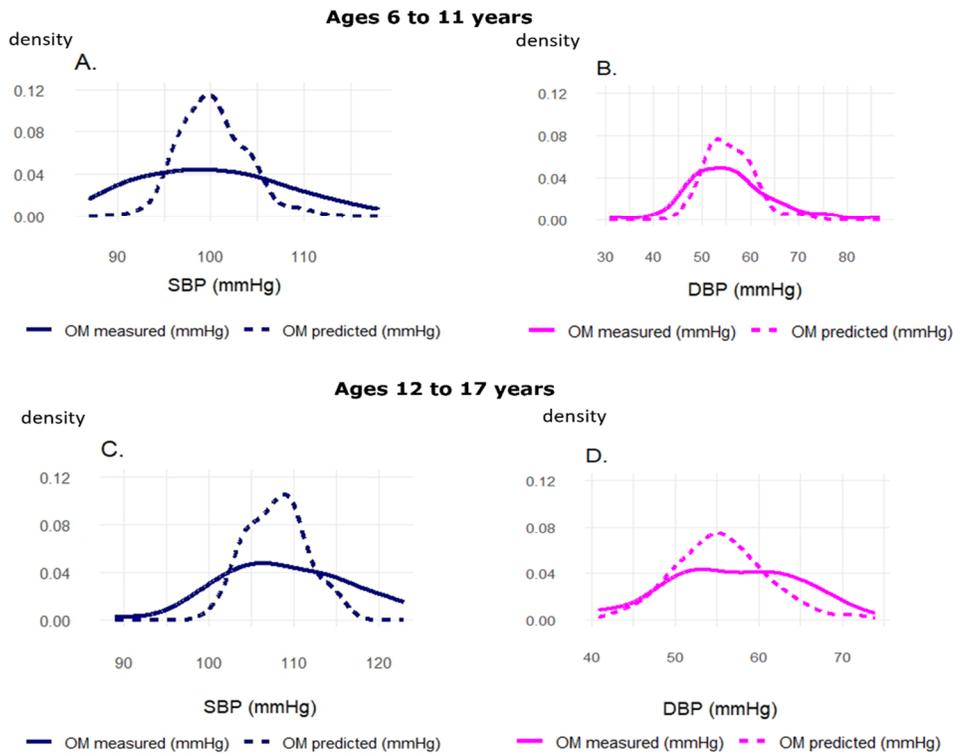
	Mean SBP (mmHg)					Mean DBP (mmHg)				
	OM measured	OM predicted	Difference (OM predicted - OM measured)			OM measured	OM predicted	Difference (OM predicted - OM measured)		
			Difference	95% CI from	95% CI to			Difference	95% CI from	95% CI to
Total	103	102	-1	-1	0	58	57	-1	-2	0 [†]
Sex										
Male	104	104	0	-2	1	56	56	-1	-2	0
Female	101	101	-1	-2	0	59	59	-1	-2	0
Age group										
6 to 8 years	95	96	1	-1	3	56	55	-1	-3	2
9 to 11 years	100	99	-1	-3	0	58	57	-1	-2	1
12 to 14 years	106	106	0	-2	2	59	58	-1	-2	1
15 to 17 years	108	107	-1	-3	1	59	58	-1	-3	0 [†]
Males										
6 to 8 years	98	100	2	-1	5	54	55	1	-3	4
9 to 11 years	102	101	-1	-4	2	57	56	0	-3	2
12 to 14 years	107	108	1	-2	4	58	57	-2	-4	1
15 to 17 years	110	108	-3	-5	-1 [†]	57	55	-2	-3	0 [†]
Females										
6 to 8 years	92	92	0	-4	3	58	56	-2	-5	2
9 to 11 years	99	97	-2	-4	0	58	58	-1	-3	1
12 to 14 years	106	105	-1	-3	1	60	59	0	-2	1
15 to 17 years	106	106	0	-3	3	62	61	-1	-3	1
Body mass index categories										
Neither overweight nor obese	102	101	0	-1	1	57	57	-1	-1	0
Overweight	108	106	-2	-4	0 [†]	60	58	-2	-4	1
Obese	108	108	0	-4	4	64	62	-2	-7	2
Males										
Neither overweight nor obese	103	103	0	-1	2	55	55	0	-1	1
Overweight	109	106	-3	-5	-1 [†]	61	57	-3	-6	0
Obese	108	107	-1	-6	4	64	60	-4	-11	3
Females										
Neither overweight nor obese	101	100	-1	-2	0	59	58	-1	-2	0
Overweight	107	106	-1	-6	3	59	59	1	-4	5
Obese	108	109	1	-6	8	65	66	1	-3	5
Central obesity category										
Not at risk of central obesity	102	101	-1	-2	0	57	56	-1	-2	0
At risk	107	106	-1	-4	1	62	60	-1	-5	2
Centrally obese	109	109	0	-4	5	64	63	-1	-6	4
Males										
Not at risk of central obesity	104	103	0	-2	1	55	55	-1	-2	1
At risk	108	106	-2	-5	1	60	59	-1	-5	3
Centrally obese	108	108	0	-7	7	64	62	-3	-11	6
Females										
Not at risk of central obesity	100	100	-1	-2	0	59	58	-1	-2	0
At risk	107	106	-1	-5	4	63	62	-2	-7	4
Centrally obese	109	109	0	-6	7	64	65	1	-3	5

[†] Indicates the difference between the OM predicted and OM-measured values was statistically different from 0 at p < 0.05 (paired t-test).

Notes: SBP = systolic blood pressure, DBP = diastolic blood pressure, OM = OMRON, BT = BpTRU, CI = confidence interval, and mmHg = millimetres of mercury. Differences were calculated on unrounded means, and all estimates were then rounded to the nearest integer.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

Figure 4
Probability density plots of the full model’s predicted versus measured blood pressure among boys aged 6 to 17 years using OMRON, crossover study sample, Canada, excluding territories, 2018 to 2019



Notes: SBP = systolic blood pressure, DBP = diastolic blood pressure, OM = OMRON, and mmHg = millimetres of mercury.
Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

concordance at all points in the BP distribution (Figure 4). For girls in both age groups, there was better concordance between predicted and measured SBP compared with boys, while concordance for DBP was equally poor for both sexes (Figure 5). For boys and girls, predicted BP tended to be lower than measured BP at higher values. The lower-than-measured predicted BP at higher levels resulted in significantly higher predicted normal BP prevalence, compared with measured BP, under all three sets of BP guidelines (Chart 2). Adjusting for device order in each model had no effect on predicted mean BP values or predicted BP category prevalence and did not alter the underestimation of predicted values at higher levels of BP (data not shown).

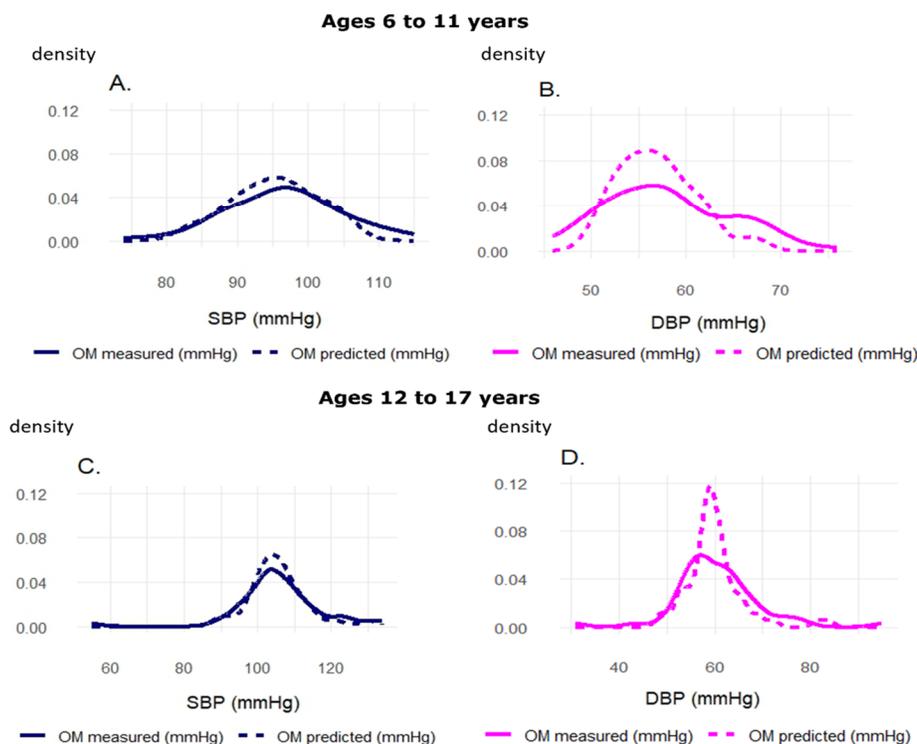
Discussion

This study found significant differences between the OM and BT measurements of SBP and DBP in the CHMS Cycle 6 crossover sample of children and youth aged 6 to 17 years. These between-device differences in BP produced between-device differences in BP categories under three sets of pediatric BP guidelines. The attempt to generate prediction equations to

compare BP measured by both devices did not produce adequate results. It was impossible to account for the measurement differences in the BP data from both devices for this age group. Thus, Cycle 7 pediatric BP data should not be directly compared with pediatric BP data from previous cycles of the CHMS.

In an individual child, the BP difference between the 90th and 95th centile—cut-points differentiating normotensive from prehypertension or elevated BP—is 3 to 6 mmHg for SBP and 2 to 5 mmHg for DBP, depending on the BP reference tables used.^{19,20} To date, cycle-over-cycle absolute differences at the population level in average SBP and DBP among Canadian children and youth have been between 0 to 2 mmHg and 0 to 3 mmHg, respectively,³⁵ and differences in normal BP prevalence under NHBPEP 2004 guidelines have ranged between 0.1 and 1.4 percentage points since Cycle 1 (custom tabulation). In the crossover sample, mean SBP measured with OM was 9 mmHg higher than mean SBP measured using BT, and mean DBP measured with OM was 3 mmHg lower than DBP measured with BT. Furthermore, between-device differences in normal BP prevalence were 3.0 percentage points under NHBPEP 2004 guidelines and 6.4 percentage points

Figure 5
Probability density plots of the full model's predicted versus measured blood pressure among girls aged 6 to 17 years using OMRON, crossover study sample, Canada, excluding territories, 2018 to 2019



Notes: SBP = systolic blood pressure, DBP = diastolic blood pressure, OM = OMRON, and mmHg = millimetres of mercury.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

under AAP 2017 guidelines. These findings suggest that not only will pediatric BP data in Cycle 7 be noticeably different from previous cycles, but the differences will be considered substantive.

Measuring BP in children is challenging. Unlike for adults, all methods—including the gold standard auscultatory method and the use of oscillometric devices such as BT and OM—face obstacles, including small arm dimensions, small and elastic arteries, and difficulties in accurately assessing DBP.³⁶ This can contribute to heterogeneity in BP measurement when comparing methods. Also, different oscillometric devices use different cuff sizes and proprietary algorithms to calculate SBP and DBP, potentially introducing further differences in measurement.³⁷ Properly selecting an appropriate cuff size for measuring pediatric BP is essential,³⁸ and studies have shown that different cuff sizes used on the same person or cuffs that are too small or too large can affect results.^{39,40} In the current study, 6% of the crossover sample—all in the 6-to-11-year age group—had their BP measured by the BT device using the child cuff size (13 to 18 cm). These same respondents were given the smallest cuff size available for the OM device (17 to 22 cm). The cuff size discordance, coupled with smaller arm dimensions, may help explain why the poor agreement between

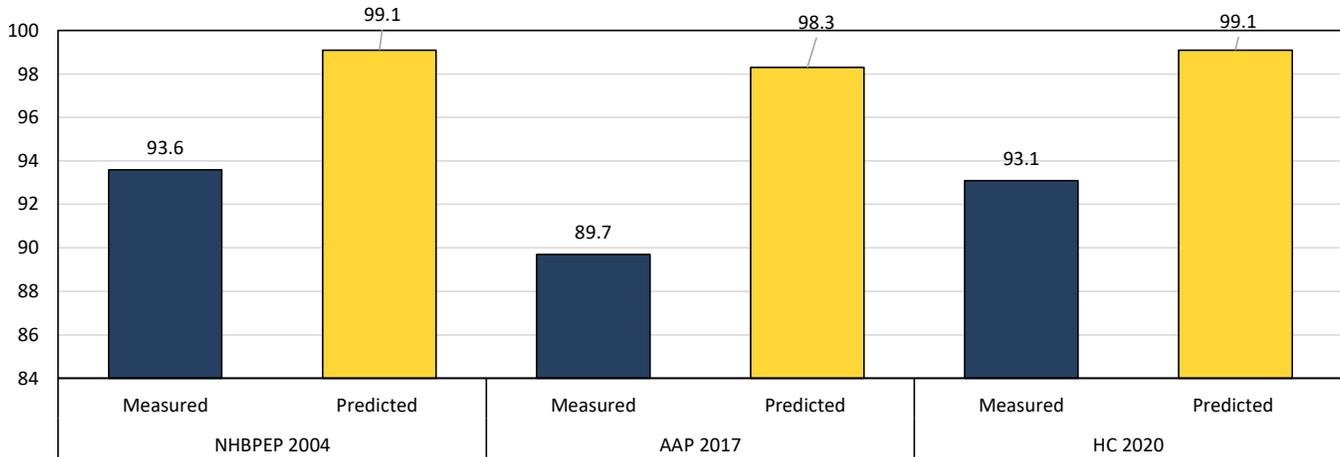
BT and OM measurements was more pronounced among the younger age group.

The attempt to develop equations using linear regression to facilitate data comparability between Cycle 7 pediatric BP and earlier cycles was unsuccessful. The prediction models could not resolve the level of poor agreement and correlation between the two devices for those aged 6 to 17 years. While the average predicted values were within +2 to -4 mmHg of measured values, there was disagreement between the predicted and the measured values at most points along the BP distribution. This disagreement resulted in fewer respondents having predicted values at higher levels of BP, and this in turn produced predicted BP prevalence that overestimated the proportion of respondents with normal BP.

It is unsurprising that the current study found substantive differences in measurement between the OM and BT devices among this sample of 6- to 17-year-olds given the observed differences in BP measurement between these devices among adults;^{14,39} the reported heterogeneity in pediatric BP measurement across methods, devices, and cuff sizes;^{36,37,41} and the OM device not meeting validation criteria for DBP among children and youth.^{10,11} Moreover, the prediction equations could not resolve these differences. Consequently, the Cycle 7

Chart 2

Proportion with normal blood pressure according to measured versus predicted blood pressure using OMRON, under three sets of guidelines, crossover study sample aged 6 to 17 years, Canada, excluding territories, 2018 to 2019



Notes: BP= blood pressure; OM = OMRON; NHBPEP 2004 = *The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents*, published by the National High Blood Pressure Education Program in 2004; AAP 2017 = *Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents*, published by the American Academy of Pediatrics in 2017; and HC 2020 = *Comprehensive Guidelines for the Prevention, Diagnosis, Risk Assessment, and Treatment of Hypertension in Adults and Children*, published by Hypertension Canada in 2020.

Source: Statistics Canada, Canadian Health Measures Survey crossover study, 2018 to 2019.

pediatric BP data should be considered a break from previous cycles and should not be directly compared with pediatric BP data from cycles 1 to 6. This should be acknowledged when reporting estimates of pediatric BP data based on the CHMS. Furthermore, the change in measured SBP, DBP, and BP prevalence resulting from the introduction of the OM device in Cycle 7 should not be interpreted or reported as a genuine change in the BP of Canadian children and youth.

Strengths and limitations

This study has several strengths. BP, height, and weight were measured objectively using systematic methodologies. All respondents had their BP measured by trained staff who followed strict protocols during a single visit to the MEC, and device order was randomly assigned. Nevertheless, the results of this study should be interpreted considering certain limitations. The respondents aged 6 to 17 years included in the crossover study were selected from only two sites. Compared with respondents in the same age group from the other sites, the study participants were slightly older (the average age was 12 years, compared with 11 years for other respondents), were slightly more likely to be female (54% versus 50%), had slightly lower body weight (18% were overweight or with obesity versus 25%), and had slightly lower average BT-measured SBP (94 versus 96 mmHg) and DBP (61 versus 62 mmHg). Because measured arm circumference is not included in the CHMS data, it was impossible to assess how arm circumference relative to selected cuff size may have contributed to between-device differences. The study’s limited sample size reduced statistical

power for examining and interpreting differences in SBP, DBP, and BP categories and constrained the number of variables that could be tested in the predictive equations.

Conclusion

The introduction of the OM monitor in Cycle 7 of the CHMS will result in pediatric BP data that are substantively different from previous cycles. Mean SBP levels will be higher, and mean DBP levels and the prevalence of normal BP will be lower. These changes should not be interpreted or reported as a genuine change in the BP of Canadian children and youth. Cycle 7 BP data for those aged 6 to 17 years should be considered a break from previous cycles and not be directly compared with pediatric BP data from cycles 1 to 6. Also, the impact of switching BP devices on the data should be acknowledged when reporting estimates of pediatric BP based on Cycle 7 of the CHMS.

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