Effect of South Africa’s interim mandatory salt reduction programme on urinary sodium excretion and blood pressure

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A B S T R A C T

South Africa implemented legislation in June 2016 mandating maximum sodium (Na) levels in processed foods. A pre-post impact evaluation assessed whether the interim legislative approach reduced salt intake and blood pressure. Baseline Na intake was assessed in a nested cohort of the WHO Study on global AGEing and adult health (WHO-SAGE) Wave 2 (Aug-Dec 2015). 24-hour urine samples were collected in a random subsample (n = 1,299; of which n = 750 were considered valid (volume ≥ 300 mL and creatinine ≥ 4 mmol/day (women) or ≥ 6 mmol/day (men))). Follow-up urine samples were collected in Wave 3 (Jun 2018-Jun 2019), with replacements included for those lost to follow-up (n = 1,189; n = 548 valid). In those aged 18 to 49y, median salt intake was 7.8 (4.7, 12.0) g/day in W2 (n = 274), remaining similar in the W3 sample (7.7 (4.9, 11.3) g salt/day (n = 92); P = 0.569). In older adults (50 + y), median salt intake was 5.8 (4.0, 8.5) g/day (n = 467) in W2, and 6.0 (4.0, 8.6) g/day (n = 455) in W3 (P = 0.721). Controlling for differences in background characteristics, overall salt intake dropped by 1.15 g/day (P = 0.028). 24hr urinary Na concentrations from a countrywide South African sample suggest that salt intakes have dropped during the interim phase of mandatory sodium legislation. Further measurement of population level salt intake following stricter Na targets, enforced from June 2019, is necessary.

1. Introduction

In low-income and middle-income countries (LMIC), a disproportionately rapid increase in hypertension is occurring with little evidence of adequate strategies to halt this growth or mitigate the impact on CVDs and death (Yusuf et al., 2014). South Africa is a country with a particularly high prevalence of hypertension, with an estimated age standardised prevalence of 35.1% in those aged 15 years and older (Berry et al., 2017), and poor management of the condition once diagnosed (Lloyd-Sherlock et al., 2014; Day et al., 2014).

In order to reduce the burden of hypertension, the World Health Organization (WHO) and World Health Assembly recommend 30% reduction in population salt/sodium intake by 2025 (WHO, 2020). Population salt reduction efforts are underway in many countries, with a major focus on sodium reduction in processed foods within national salt reduction strategies (Trieu et al., 2015). The most common interventions include engaging with the food industry for product reformulation, more informative front-of-pack nutrition labelling, and setting voluntary sodium reduction targets (Charlton et al., 2015).

Few countries have opted for legislative approaches but, in June 2016, the South African government was one of the first to implement legislation for mandatory maximum sodium levels permitted in a wide range of processed food categories (bread; breakfast cereal; butter and margarine; potato crisps; salty snacks; raw sausage; processed meat; instant noodle mix; dry soup powder; and stock cube concentrate) (South African Department of Health, 1972). The sodium targets were

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introduced in two phases, with further reductions in sodium levels required by June 2019. Modelling of salt reductions achieved in bread, margarine, stock cubes and seasoning in a randomised clinical trial conducted in South African hypertensives (Charlton et al., 2008) was predicted to decrease salt intake by 0.85 g per person per day; and thereby reduce annual CVD deaths by 11% (Bertram et al., 2012).

The effectiveness of legislative approaches to population salt reduction has not yet been widely demonstrated (Charlton et al., 2014), and mechanisms to monitor and enforce such legislation remain challenging (Cappuccio and Capewell, 2015; He et al., 2014; Webster et al., 2014). A pre-mid impact evaluation was undertaken to assess the effectiveness of the legislative approach adopted in South Africa. The primary aim of this study was to determine whether population level sodium intake and blood pressure (BP) reduced in South Africa using the legislative approach adopted in South Africa. The study respondents were sampled from among the first W2 households visited within each probability sampled EA (day 1 in the EA) in order to ensure representativeness of the health effects of South Africa (WHO-SAGE) in Wave 2 (Pre: 2015) and again in Wave 3 (Post: 2017/18), according to age (young, 18 – 49y; older 50 + y).

2. Methods

2.1. Study population

WHO-SAGE is a multinational longitudinal study examining the health and well-being of adult populations and the ageing process in China, Ghana, India, Mexico, Russia and South Africa (Kowal et al., 2012) (See http://www.who.int/healthinfo/sage/cohorts/en/). Evaluation of the health effects of South Africa’s sodium policy on adults is conducted using a nested study design in Waves 2 and 3.

In Wave 1 (W1; 2007–2010), 4,223 respondents were recruited in South Africa (9% 18–49 years; 40% 50–59 years; 51% 60 + years) using probability sampled enumeration areas (EAs) according to a multistage cluster sampling strategy, with stratification by province, residence and race. (Kowal et al., 2012) The Wave 2 (W2; 2015) sampling strategy was designed to account for expected attrition as a result of participants having moved house or died since W1. Replacements for sample attrition used a systematic sampling approach to randomly select new households using EA aerial photograph maps. The sampling method used in SAGE Wave 3 (W3; 2018–2019) adopted the same follow-up and random systematic sampling method as in W2. The replacement method was the same as for W2, the intention being to include 8 households per EA, at least 1 of which should comprise 1 or more adults aged < 50 years.

2.2. Selection and data collection in the nested cohort

The SAGE South Africa main survey sample in W2 included 2,971 individuals whose systolic (SBP) and diastolic BP (DBP) were measured. Of these, a random subsample of n = 1,200 was targeted for urine collection, as described in the study protocol (Charlton et al., 2016). Adults aged 18 + years were eligible for inclusion in the sub-study, with the final distribution in the main and nested studies reflecting the weighting towards recruiting more adults aged 50 + years. The nested study respondents were sampled from among the first W2 households visited within each probability sampled EA (day 1 in the EA) in order to prioritise the freight of all collected urine samples to a central laboratory (Global Clinical and Viral Laboratory, Durban) within 3 days of collection while maintaining a cold chain regardless of where urine collection took place. Twenty survey teams, comprising one nurse and three interviewers per team, simultaneously collected data and urine from respondents across all provinces in the country over a 5-month period (August to December 2015). W3 fieldwork was conducted by 8 teams in the northern provinces from August to December 2018 and by 4 teams in the south of the country from October 2018 to March 2019.

All survey teams were trained with support from WHO Geneva, with survey teams using standardised household, individual and proxy questionnaires, anthropometry, blood sampling, BP and physical function tests as described previously in SAGE W1. Interviewers were fluent in the respondents’ home languages with consent forms available in the most widely spoken languages for each area. Wrist-worn Omron BP devices (R6) were used to record three sequential measures on the left arm (1 min between each measure), with positional sensors ensuring that the measurement was taken at the level of the heart while the respondent was seated with legs uncrossed. These wrist BP devices are validated to the European Society of Hypertension International Protocol. Valid BP was defined if: SBP and DBP were plausible; and if SBP > DBP with a pulse pressure ≥ 13 mmHg. Minimum acceptable pulse pressure was based on frequency distributions reported by other population studies (Chung et al., 2010) (Nakano et al., 2005). Implausible systolic and diastolic pressures were set using experience and expert consultation and participants with implausible values (defined as SBP < 80 mmHg or SBP > 270 mmHg; or DBP < 40 mmHg or DBP > 180 mmHg) were dropped from the data analysis. This follows the same approach as the NCDRF group and others (Cheng et al., 2016) (Collaboration NCDRF, 1975; Hermann et al., 2016) (Arku et al., 2018), with no consistent definition of plausible values within or across populations or age ranges.

The mean of the second and third readings were used to generate the final BP value. Pulse Pressure (PP) was defined as average SBP minus average DBP, while Mean Arterial Pressure (MAP) as (systolic + 2×diastolic)/3. Hypertension was determined by measured blood pressure (SBP ≥ 140 and/or DBP ≥ 90 mmHg) or previous diagnosis and on antihypertensive medication in the last two weeks.

2.3. Urine collection and analysis in the nested study (Waves 2 and 3)

Inclusion criteria for urine collection were: no urinary incontinence or other condition that could impede 24-hour urine collection; and if female, not menstruating, pregnant or breastfeeding on the day of collection. In W3, attempts were made to reach all respondents who had provided urine samples in W2, with procedures as described earlier for replacement and refreshment of the sample. Collection of 24-hour urine samples was conducted according to the WHO/Pan American Health Organization (PAHO) guidelines (WHO/PAHO, 2010). After excluding the first pass urine on day 1, all urine passed over the next 24 h was collected up to, and including, the first urine of the following morning (day 2), in a 5 L plastic container that included 1 g thymol as preservative. Thymol is easier and safer to transport than commonly used liquid acids, and does not cause changes in urinary creatinine, sodium and potassium concentrations for up to 5 days after collection (Nidar et al., 1987). Incomplete 24-hour urine collections were assumed to be: total volume < 300 mL; or creatinine excretion < 4 mmol/day (women) or < 6 mmol/day (men) (Stolarz-Skrzypek et al., 2011). Para-amino benzoic acid (PABA) was not used to validate 24-hour urine collection completeness due to its declining recovery rate with age in respondents older than 30 years (Jakobsen et al., 2003) and the additional burden of remembering to take the PABA pill 3 days before the urine collection, as discussed in the WHO/PAHO guidelines (WHO/PAHO, 2010).

Sodium and potassium were determined using the indirect ion-selective electrode method and creatinine analysed using the standardised urinary Jaffe kinetic method (Beckman Coulter Synchron DXC600/800 System). The WHO population target for salt intake is 5 g salt (NaCl) per day, equivalent to urinary sodium excretion of 85 mmol/24 h. Urinary potassium is recommended to be > 90 mmol/24 h, with a sodium-to-potassium ratio ≤ 1 shown to be protective for all-cause, cardiovascular and ischaemic heart disease mortality (WHO, 2012a, 2012b). Discretionary salt intake was assessed using a validated salt behaviour questionnaire (Menyanu et al., 2017) included in the main
2.4. Data capture and statistical analysis

All questionnaire data were captured using an electronic Computer Assisted Personal Interviews (CAPI) data capture system and uploaded to a secure central server. Cleaning and analysis of survey data was coordinated by WHO. Quantitative data are presented as medians and interquartile range (1st and 3rd quartiles), while categorical data as absolute numbers and percentages. Differences between W2 and W3 quantitative data were assessed by Mann-Whitney test when comparing independent subjects, while by Wilcoxon signed-rank test when comparing paired (follow-up) subjects. Differences in categorical data were inspected by Pearson Chi-Square test or Fisher Exact test when appropriate. Correlation coefficients were calculated between change in urinary sodium excretion and BP measures. Multivariable regression analyses were performed in order to assess predictors of change in sodium and potassium and the BP profiles in the follow-up sample, taking into account age, sex, BMI, ethnicity and location (urban/rural). Analogue multivariable regression analyses were performed on the independent samples, but given the higher sample size, the inclusion of additional socio-demographic (marital status and education level), health risk factors (alcohol use, smoking status, waist-hip ratio) and urine measurements (sodium, potassium, creatinine and iodine) was possible and these were included in the multivariable regression analysis. Changes in urinary sodium and potassium were also analysed in this way. All statistical analyses were performed using STATA SE, version 15.1 (Stata Statistical Software: Release 15. College Station, TX: StataCorp LP).

SAGE was approved by the WHO Ethics Review Committee (reference number RPC149) with local approval for the South African salt sub study from the North-West University Human Research Ethics Committee and University of the Witwatersrand Human Research Ethics Committee. All respondents provided written informed consent prior to taking part in the study. The study complied with the ethical principles for medical research involving human participants as per the Declaration of Helsinki (General Assembly of the World Medical Association, 2014).

3. Results

In W2, questionnaire data (CAPI) was collected from 3,183 respondents, while urine samples were provided by n = 1,299 subjects (n = 912 were considered as valid urine samples). CAPI and urine identifiers were matched in n = 746 subjects (n = 570 of these were considered to be valid urine collections). In W3, CAPI data was collected from 2,525 respondents, while n = 1,189 provided urine samples (n = 749 were considered as valid urine samples). CAPI and urine identifiers were matched in n = 876 subjects (n = 593 of these were considered to be valid urine collections). The 24 h urine collection was a nested sub-study within the larger WHO-SAGE endeavour. While the study questions and measurements (including salt intake behaviour questions and BP measurements) were asked of all respondents – the sample size calculations for urine sample collections were done independently as nested subsample. The main reasons for an inability to match survey and laboratory urine results were due to failures in the CAPI programming. The digital data collection platform for interviews were meant to be available to the laboratory team, with paper-based back-ups for the urine sample collections. However, the failures in the CAPI system were found only after pursuing the CAPI programmer and after the data collection was completed. Matching via paper records was checked in triplicate by the laboratory and two members of the research team to try locate any unmatched records. Because of CAPI errors, data from W2 matched with that collected in W3, producing two type of samples: independent samples (subjects present in W2 but not in W3, and vice versa) and follow-up sample (individuals present in both waves). Fig. 1 shows participant selection for the study.

The demographic profile, BP and urine measurements for Waves 2 and 3 are shown for individuals with valid urine in the independent samples for the total sample (Table 1) and for age groups 18 – 49y
regardless of CAPI data: W2 vs W3 independent samples.

Demographic profile and urine results for individuals with valid urine samples.

| Age (years) | Median (Q1, Q3) | N (% Missing) | p-value |
|-------------|----------------|---------------|---------|
| 49 | 54.0 (41.0, 65.0) | 741 (1.2%) | <0.001 |

| Age group | Median (Q1, Q3) | N (% Missing) | p-value |
|-----------|----------------|---------------|---------|
| 18–49 | 274 (37.0%) | 196 (36.1%) | <0.001 |

| Sex | Male | Female | p-value |
|-----|------|-------|---------|
| 177 (23.6%) | 158 (28.8%) | 0.033 |

| Ethnicity | African/black | Coloured | Indian/Asian | p-value |
|-----------|---------------|----------|--------------|---------|
| 277 (68.1%) | 273 (69.8%) | 40 (10.3%) | <0.001 |

| Location | Urban | Rural | p-value |
|----------|-------|-------|---------|
| 298 (73.2%) | 109 (26.8%) | 0.002 |

| Marital status | Never married | Married/cohabiting | Widowed | p-value |
|----------------|---------------|-------------------|--------|---------|
| 181 (44.5%) | 113 (27.8%) | 95 (23.3%) | 0.001 |

| Ever school | Yes | No | p-value |
|-------------|-----|----|---------|
| 337 (82.8%) | 70 (17.2%) | 0.424 |

| Education level | Low | High | p-value |
|-----------------|-----|------|---------|
| 253 (75.1%) | 84 (24.9%) | <0.001 |

| Alcohol | Yes | No, never | p-value |
|---------|-----|-----------|---------|
| 69 (17.1%) | 335 (82.9%) | 0.004 |

| Smoking | Yes | No | p-value |
|---------|-----|----|---------|
| 365 (90.3%) | 37 (9.7%) | 0.003 |

| Waist to Height ratio | <0.5 | Yes | p-value |
|-----------------------|------|-----|---------|
| 215 (73.6%) | 77 (26.4%) | 0.251 |

| Body Mass Index (kg/m2) | Median (Q1, Q3) | N (% Missing) | p-value |
|-------------------------|----------------|---------------|---------|
| 29.3 (24.6, 35.3) | 302 (59.7%) | 40.4 |

| Systolic BP (mm Hg) | Median (Q1, Q3) | N (% Missing) | p-value |
|---------------------|----------------|---------------|---------|
| 128.0 (118.0) | 364 (33.6%) | 0.012 |

| Diastolic BP (mm Hg) | Median (Q1, Q3) | N (% Missing) | p-value |
|----------------------|----------------|---------------|---------|
| 79.0 (71.5, 86.5) | 371 (32.3%) | <0.001 |

| Hypertension from measurement | No | p-value |
|-----------------------------|----|---------|
| 253 (65.5%) | 0.001 |

| Hypertension Self-reported | No | p-value |
|---------------------------|----|---------|
| 289 (77.9%) | 0.001 |

| Hypertension BP/SR/med | No | p-value |
|------------------------|----|---------|
| 195 (53.1%) | 0.001 |

| Sodium, mmol/24hr | Median (Q1, Q3) | N (% Missing) | p-value |
|-------------------|----------------|---------------|---------|
| 106.6 (71.2, 166.1) | 350 (63.9%) | 0.266 |

| Calculated salt excretion, g/day | Median (Q1, Q3) | N (% Missing) | p-value |
|----------------------------------|----------------|---------------|---------|
| 6.3 (4.2, 9.5) | 749 (0.1%) | 0.897 |

| Potassium (K), mmol/24hr | Median (Q1, Q3) | N (% Missing) | p-value |
|-------------------------|----------------|---------------|---------|
| 30.8 (19.5, 52.7) | 30.6 (20.1, 43.2) | 0.138 |

| Sodium-to-potassium ratio | Median (Q1, Q3) | N (% Missing) | p-value |
|---------------------------|----------------|---------------|---------|
| 3.5 (2.4, 4.6) | 548 (0.0%) | 0.953 |

| Creatinine, mmol/24 h | Median (Q1, Q3) | N (% Missing) | p-value |
|-----------------------|----------------|---------------|---------|
| 9.4 (6.7, 14.6) | 548 (0.0%) | <0.001 |

Data are presented as median (Q1:1st quartile, Q3:3rd quartile) and number of valid cases (N) for quantitative data and as absolute number (%) for categorical data. P-value obtained by: Mann-Whitney test when comparing medians, while Pearson Chi-Square test or Fisher Exact test when comparing categorical data.

*Valid urine defined as: volume ≥ 300 mL and urinary molar sodium:potassium ratio (Na:K) of 3.5 or 90 mmol/l/24 h (women) or ≥ 6 mmol/day (men). The CAPI data could not always be matched with the urine data thus there is missing data for some variables. BP: Blood Pressure, SR: Self-Reported, med: on medication for hypertension in the last two weeks.

Of the same 805 subjects from W2 that also were followed up in W3, only 48 had valid urine measurements, based on volume and creatinine data. P-value obtained by: Mann-Whitney test when comparing medians, while Pearson Chi-Square test or Fisher Exact test when comparing categorical data.

*Valid urine defined as: volume ≥ 300 mL and urinary molar sodium:potassium ratio (Na:K) of 3.5 or 90 mmol/l/24 h (women) or ≥ 6 mmol/day (men). The CAPI data could not always be matched with the urine data thus there is missing data for some variables. BP: Blood Pressure, SR: Self-Reported, med: on medication for hypertension in the last two weeks.

In both waves (Table 1), median urinary potassium excretion remained very low (30.8 (19.5, 52.7) vs 30.6 (20.1, 43.2) mmol/day in W2 and W3, respectively; P = 0.138). In W3, 97% of respondents had urinary concentrations less than the recommended potassium intake of 90 mmol/day and urinary molar sodium:potassium ratio (Na:K) of 3.5 (2.4, 4.6) vs 3.4 (2.4, 4.7) for W2 and W3, respectively (P = 0.963). Only 1.6% were achieving a Na:K ratio of 1 or below in W3 (P = 0.660).

In older adults (50 + y), median salt intake was 5.8 (4.0, 8.5) g/day in W2, and 6.0 (4.0, 8.6) g/day in W3 (P = 0.721) (Table 3). The proportion meeting the salt target of < 5 g/day remained similar (39.7 vs 38.2%, respectively; P = 0.650).

Salt intake in the independent samples differed between W2 and W3 for men and women, once adjusted for covariates, according to age groups (except for men aged 50 + y; P = 0.083), BMI categories (except for men with BMI ≥ 30; P = 0.064), and hypertensive status, as shown in Fig. 2.

In both waves (Table 1), median urinary potassium excretion remained very low (30.8 (19.5, 52.7) vs 30.6 (20.1, 43.2) mmol/day in W2 and W3, respectively; P = 0.138). In W3, 97% of respondents had urinary concentrations less than the recommended potassium intake of 90 mmol/day and urinary molar sodium:potassium ratio (Na:K) of 3.5 (2.4, 4.6) vs 3.4 (2.4, 4.7) for W2 and W3, respectively (P = 0.963). Only 1.6% were achieving a Na:K ratio of 1 or below in W3, which is considered to be protective for all-cause, cardiovascular and ischaemic heart disease mortality. (WHO, 2012a, 2012b).

Of the same 805 subjects from W2 that also were followed up in W3, only 48 had valid urine measurements, based on volume and creatinine reference cut-offs (See Table 4) and had accompanying CAPI data. In this under-powered sub-sample, median salt intake was 6.7 (4.3) g/day in W2 and 6.1 (5.4) g/day in W3 (P = 0.6444). The percentage meeting the < 5 g/day salt target increased from 27.1% to 33.3%, but again lacked statistical significance (P = 0.735). Potassium excretion continued...
remained similarly low over time (32.8 (26.2) vs 29.7 (15.2) mmol/day; P = 0.6371).

### 3.1. Change in BP and hypertension over time, and association with salt intake

In W2, for independent samples with CAPI, hypertension assessed by measured BP (≥140/90 mmHg) or previous diagnosis and on medication indicated an overall prevalence of 53% (Supplementary Table 1), rising to 70% for those aged 60-69y and 70-79y. In W3, overall hypertension prevalence was 62% (Supplementary Table 1), rising to 70% for those aged 60-69y and over 80% in 70-79y and 80-89y. A statistically significant increase of 3.5 mmHg in DBP between W2 and W3 was found in the independent samples by multivariable regression analysis when controlling for socio-demographic factors (alcohol use, smoking status, waist-hip ratio) and hypertension status at W3, SBP and DBP (β = 2.2 mmHg; P < 0.0001) (Table 5). This increase remained statistically significant when hypertension status in W3 was added into the model (β = 2.2 mmHg; P < 0.0001), and also when controlling for urinary Na, K, creatinine and iodine (β = 3.3 mmHg; P = 0.017). No statistically significant difference was found for SBP. In the W2 and W3 independent samples, SBP and DBP are shown according to age, sex, BMI and hypertension status in Supplementary Figures 1a and b, respectively.

A significant decrease in urinary sodium levels was observed in W3, compared to W2 in independent samples with valid urine (n = 522) in multivariable analysis adjusted for socio-demographic variables (age, gender, ethnicity, location, marital status, education level), health risk factors (alcohol use, smoking status, waist-hip ratio) and hypertension status at W3, SBP and DBP (β = −1.16 (SE 0.53) g salt/24hr; P = 0.028) (See Table 5). Urinary potassium levels also decreased in W3 when adjusting for these variables (β = −0.75 (SE 2.4) mmol/24hr; P = 0.028).

In subjects that were followed up in the larger CAPI survey sample and had BP measurements at both W2 and W3 (n = 771), there was a significant increase in median DBP (80.5 (16) vs 84 (18) mmHg, respectively (P = <0.001)) (Supplementary Table 3) and a subsequent increase in hypertension prevalence (53.7 ± 65.8%, P = 0.002).

When investigating predictors for change in SBP and DBP between

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**Table 2 (continued)**

| only W2 (N = 274) | only W3 (N = 92) | p-value |
|-------------------|-----------------|---------|
| N (%) Missing     | 274 (0.0%)      | 92 (0.0%) |
| Achieving K target (≥90 mmol/day) | 232 (84.7%) | 88 (95.7%) |
| <90 mmol/24 h     | 42 (15.3%)      | 4 (4.3%) |
| ≥90 mmol/24 h     | 3.7 (2.6, 4.8)  | 3.8 (2.9, 4.9) |
| Sodium-to-potassium ratio | 274 (0.0%) | 92 (0.0%) |
| Median (Q1, Q3)   | 7 (2.6%)        | 3 (3.3%) |
| Achieving Na:K ratio (<1) | 266 (97.4%) | 89 (96.7%) |
| ≥1                 | 11.9 (7.7, 18.8)| 10.6 (7.5, 14.0) |
| Creatinine, mmol/24 h | 274 (0.0%) | 92 (0.0%) |
| Median (Q1, Q3)   | 90.1 (48.0, 173.0) | 98.7 (57.0, 198.8) |
| iodine, µg/l      | N (%) Missing  | 274 (0.0%) |
| 0.002 | 92 (0.0%) |
| Iodine, µg/l      | 166 (39.4%)     | 82 (10.9%) |

Data are presented as median (Q1:1st quartile, Q3:3rd quartile) and number of valid cases (N) for quantitative data and as absolute number (%) for categorical data. P-value obtained by: Mann-Whitney test when comparing medians, while Pearson Chi-Square test or Fisher Exact test when comparing categorical data. 

*Valid urine defined as: volume ≥ 300 mL and creatinine excretion ≥ 4 mmol/day (women) or ≥ 6 mmol/day (men). The CAPI data could not always be matched with the urine data thus there is missing data for some variables: BP: Blood Pressure, SR: Self-Reported, med: on medication for hypertension in the last two weeks.
Demographic profile and urine results for individuals 50 years or older with valid urine* regardless of CAPI data: W2 vs W3 independent samples.

| Table 3 (continued) | only W2 (N = 467) | only W3 (N = 455) | p-value |
|----------------------|-------------------|-------------------|---------|
| Achieving K target (>90 mmol/day) | 448 (95.9%) | 442 (97.1%) | 0.315 |
| Sodium-to-potassium ratio Median (Q1, Q3) | 3.3 (2.3, 4.5) | 3.3 (2.3, 4.6) | 0.676 |
| Achieving Na:K ratio (≥1.0) | 466 (0.0%) | 455 (0.0%) | 0.115 |
| Achieving K target (>90 mmol/day) | 448 (95.9%) | 442 (97.1%) | 0.315 |
| Sodium-to-potassium ratio Median (Q1, Q3) | 3.3 (2.3, 4.5) | 3.3 (2.3, 4.6) | 0.676 |
| Achieving Na:K ratio (≥1.0) | 466 (0.0%) | 455 (0.0%) | 0.115 |
| Achieving K target (>90 mmol/day) | 448 (95.9%) | 442 (97.1%) | 0.315 |
| Sodium-to-potassium ratio Median (Q1, Q3) | 3.3 (2.3, 4.5) | 3.3 (2.3, 4.6) | 0.676 |
| Achieving Na:K ratio (≥1.0) | 466 (0.0%) | 455 (0.0%) | 0.115 |
| Data are presented as median (Q1:1st quartile, Q3:3rd quartile) and number of valid cases (N) for quantitative data and as absolute number (%) for categorical data. P-value obtained by: Mann-Whitney test when comparing medians, while Pearson Chi-Square test or Fisher Exact test when comparing categorical data. Asterisk: urine volume ≥ 300 mL and creatinine excretion ≥ 4 mmol/day (women) or ≥ 6 mmol/day (men). The CAPI data could not always be matched with the urine data thus there is missing data for some variables. BP: Blood Pressure, SR: Self-Reported, med: on medication for hypertension in the last two weeks |

W2 and W3 in the paired sample for urine (n = 48), in univariate analyses, there were positive and significant correlations between the two waves for change in urinary Na and (1) change in urinary K (r = 0.2160 (SBP) and 0.2465 (DBP), so other predictors are likely. When change in salt intake between W2 and W3 was added as a predictor to the models, BMI, hypertension and change in salt intake were statistically significant for both SBP and DBP, while adding hypertension status at W3 to the models, it resulted as marginally significant for change in DBP (P = 0.083). However the R² of the models were 0.2160 (SBP) and 0.2465 (DBP), so other predictors are likely. When change in salt intake between W2 and W3 was added as a predictor to the models, BMI, hypertension and change in salt intake were statistically significant for both change in SBP (β = -1.9, P = 0.051; β = -24.9, P = 0.048 and β = 0.12, P = 0.020, respectively) and change in DBP (β = -1.12, P = 0.060; β = -17.2, P = 0.031 and β = 0.06, P = 0.047, respectively). Adding change in salt intake to the models, the R² increased to 0.3472 and 0.3409 for SBP and DBP, respectively.

3.2. Reported salt use behaviours

In participants that were followed up in both waves (n = 771), there was a significant reduction in W3 in the proportion that reported frequently adding salt to food at the table (25.1% to 15.4%, P = 0.007 (See Table 6) but no change for other salt use behaviours.

4. Discussion

This is the first evaluation of the effectiveness of South Africa’s mandatory salt reduction legislation for salt levels permitted in a range of commonly consumed processed foods. Comparison between W2 and W3 for the nested samples included in the WHO-SAGE South Africa cohort study was conducted for salt intake, potassium excretion, and urinary Na/K ratio. For this purpose, two independent samples were compared and when background characteristics were accounted for in multivariable analyses, a reduction in salt intake by 1.16 g per day was evident. Potassium excretion remained low across both waves and reduced significantly by 9 mmol/day. In both W2 (reported elsewhere
and W3 (data not shown), the ratio of Na:K was more strongly associated, than urinary Na excretion alone, with the slope of SBP and DBP plotted against age. Other authors have reported that urinary sodium-to-potassium ratio may predict CVD mortality better than sodium excretion alone (Cook et al., 2009). In a smaller paired sub-sample that had both valid urine data and survey data in the same participants in both W2 and W3, change in salt intake over time was a significant predictor of increase in SBP thus confirming the importance of reducing salt intake.

Despite our finding that the magnitude of population salt reduction following introduction of South Africa’s mandatory salt reduction program exceeded the previously modelled estimate of 0.85 g/day (Bertram et al., 2012), the high reported level of salt being added during cooking and the fact that a third of the sample still had salt intakes greater than the target of 5 g per day indicates that a more multi-pronged approach that includes nutrition education, and possibly improved availability of low sodium salt replacements, is required. It is possible that the food industry had already adopted changes in formulation of processed products prior to the June 2016 implementation date for Phase 1 of the salt targets (Republic of South Africa, 2013). The salt reduction legislation had a two phased approach with the first level of targets set for June 2016 and the second, more stringent targets that were implemented in June 2019. The timing of W2 data collection may have occurred following changes having already been made to the food supply. This is supported by an analysis of food label information collected using the FoodSwitch app in South Africa around the time of W2 (Peters et al., 2017). It is also supported by previously higher estimates of salt intake reported from repeated 24hr urinary Na collections in a survey of South Africans in 2005. In that study, salt intakes were much higher than those reported by W2, namely values equating to a daily salt intake of 7.8, 8.5 and 9.5 g in black, mixed-ancestry and white individuals, respectively (Charlton et al., 2005). Population weighted estimates of salt intake based on that data was 8.1 g/day (Bertram et al., 2012). Similarly, in 2016, Swanepoel and colleagues reported a median salt intake of 7.2 g/d for a multi-ethnic sample of South Africans (Swanepoel et al., 2016). Considering these other sources of information on salt intake, our data suggests that there had already been shifts in salt intake by the time of W2 data collection. In Ghana, a comparative sub-Saharan African country that does not have a salt reduction policy, salt intake is estimated to be much higher than in South Africa from data collected in WHO-SAGE W3 in that country and with similar methodology. In Ghana, median salt intake in 2018–19 was 8.3 g/day, and higher in younger participants (18–49 y) compared to older ones (50 + y) (9.7 (IQR 7.9) vs 8.1 (7.1) g/day, respectively; p < 0.01) (Menyanu et al., 2020). While the median salt intake is higher than in South Africa, the pattern of elevated intakes in younger adults appears consistent across the two countries.

It remains to be seen how the second, stricter phase of the salt reduction targets (2019) impact population level salt intake and blood pressure. Previous modelling for salt reduction predictions (Bertram et al., 2012) were based on sodium reductions achieved in a limited number of foods in an experimental study (Charlton et al., 2008), and
Table 4
Demographic profile and urine results for individuals with valid urine*: W2 vs W3 follow-up sample.

|                          | W2 (N = 48) | W3 (N = 48) | p-value |
|--------------------------|-------------|-------------|---------|
| Age (years)              | 57.0 (51.0, 64.5) | 61.0 (53.0, 69.5) | <0.0001 |
| Median (Q1, Q3) N (% Missing) | 48 (0.0%) | 48 (0.0%) | N/A |
| Sex                      | 10 (20.8%) | 38 (79.2%) | N/A |
| female                   | 40 (83.3%) | 1 (2.1%) | N/A |
| Ethnicity                | 7 (14.6%) | 0 (0.0%) | N/A |
| African/Black            | 26 (54.2%) | 22 (45.8%) | N/A |
| White                    | 19 (39.6%) | 12 (25.0%) | <0.0001 |
| Never married            | 13 (27.1%) | 18 (37.5%) | N/A |
| Married/cobaiting        | 3 (6.3%) | 5 (10.4%) | N/A |
| Separate/divorced        | 13 (27.1%) | 13 (27.1%) | N/A |
| Widowed                  | 29 (62.2%) | 24 (50.0%) | N/A |
| Ever school              | 32 (66.7%) | 40 (83.3%) | 0.012 |
| No                       | 16 (33.3%) | 8 (16.7%) | N/A |
| Alcohol                  | 3 (6.3%) | 12 (25.0%) | 0.587 |
| Yes                      | 45 (93.8%) | 36 (75.0%) | N/A |
| Never, no Smoking        | 42 (87.5%) | 41 (85.4%) | 0.206 |
| Yes                      | 6 (12.5%) | 7 (14.6%) | N/A |
| Waist to Height ratio < 0.5 | 29 (62.2%) | 37 (84.1%) | 0.310 |
| No                       | 6 (17.1%) | 7 (15.9%) | N/A |
| Body Mass Index (kg/m2)  | 29.7 (24.4, 33.0) | 30.9 (26.0, 37.6) | 0.1392 |
| Median (Q1, Q3) N (% Missing) | 36 (25.0%) | 45 (6.3%) | N/A |
| Systolic BP (mm Hg)      | 135.3 (123.0, 151.5) | 132.5 (126.0, 147.0) | 0.2232 |
| Median (Q1, Q3) N (% Missing) | 44 (8.3%) | 45 (6.3%) | N/A |
| Diastolic BP (mm Hg)     | 85.0 (75.8, 96.8) | 83.5 (77.5, 97.0) | 0.6455 |
| Median (Q1, Q3) N (% Missing) | 44 (8.3%) | 45 (6.3%) | N/A |
| Hypertension from measurement | 20 (45.5%) | 23 (51.1%) | 0.89 |
| No                       | 24 (54.5%) | 22 (48.9%) | N/A |
| Hypertension Self-reported | 37 (82.2%) | 24 (50.0%) | 0.022 |
| Yes                      | 8 (17.8%) | 24 (50.0%) | N/A |
| Hypertension BP/SR/med   | 15 (34.1%) | 14 (29.8%) | 0.162 |
| No                       | 29 (65.9%) | 33 (70.2%) | N/A |
| Sodium, mmol/24hr        | 112.5 (78.3, 150.6) | 103.0 (71.0, 161.5) | 0.6444 |
| Median (Q1, Q3) N (% Missing) | 48 (0.0%) | 48 (0.0%) | N/A |
| Calculated salt excretion, g/day | 6.7 (4.6, 8.9) | 6.1 (4.2, 9.6) | 0.6444 |
| Median (Q1, Q3) N (% Missing) | 48 (0.0%) | 48 (0.0%) | N/A |
| Achieving salt target (≥5 g/day) | 13 (27.1%) | 16 (33.3%) | 0.735 |
| <5 g/day                 | 35 (72.9%) | 32 (66.7%) | N/A |
| ≥5 g/day                 | 39 (81.3%) | 40 (83.3%) | 0.322 |
| High salt intake (≥10 g/day) | 9 (18.8%) | 8 (16.7%) | N/A |
| <10 g/day                | 30 (62.2%) | 32 (66.7%) | N/A |
| ≥10 g/day                | 29 (62.2%) | 24 (50.0%) | N/A |

Table 4 (continued)

|                          | W2 (N = 48) | W3 (N = 48) | p-value |
|--------------------------|-------------|-------------|---------|
| Potassium (K), mmol/24hr | 8.75 (6.3), 10.3 | 8.99 (7.4, 11.1) | <0.0001 |
| Median (Q1, Q3) N (% Missing) | 48 (0.0%) | 48 (0.0%) | N/A |
| Achieving K target (≥90 mmol/day) | 44 (91.7%) | 48 (100.0%) | N/A |
| <90 mmol/24 h            | 4 (8.3%) | 0 (0.0%) | N/A |
| ≥90 mmol/24 h            | 3.5 (2.6, 4.6) | 3.5 (2.5, 4.4) | 0.356 |
| Sodium-to-potassium ratio | 26 (54.2%) | 22 (45.8%) | N/A |
| Achieving NaK ratio (≤1.0) | 4 (8.3%) | 2 (4.2%) | N/A |
| <≤1                      | 44 (91.7%) | 46 (95.8%) | N/A |

Data are presented as median (Q1:1st quartile, Q3:3rd quartile) and number of valid cases (N) for quantitative data and as absolute number (%) for categorical data. P-value obtained by: Wilcoxon signed-rank test when comparing medians, while Pearson Chi-Square test or Fisher Exact test (†) when comparing categorical data. *Valid urine defined as: volume ≥ 300 mL and creatinine excretion ≥ 4 mmol/day (women) or ≥ 6 mmol/day (men). BP: Blood Pressure, SR: Self-Reported, med: on medication for hypertension in the last two weeks. **Available on n = 26 subjects in W2; ***Calculated on the total n = 48 subjects for W3.

South Africa is now one of a number of countries with mandatory sodium targets for food reformulation. A review of national salt reduction initiatives around the world in 2019 identified a 28% increase in the number of all initiatives since 2014, to number 96 countries (Santos et al., 2021). Of the 57 countries with salt targets for food reformulation, 19 have mandatory maximum salt limits for foods. Half of these countries set mandatory targets for bread alone (Bahrain, Belgium, Hungary, Netherlands, Palestine, Paraguay, Portugal, Qatar, Spain, and included stricter levels in bread, namely 350 mg Na/100 g, compared to those adopted in the interim and final legislation targets (400 and 380 mg/100 g, respectively). (South African Department of Health, 1972)

Table 5
Multivariate regression analyses for differences in blood pressure and urinary Na and K excretion between W2 and W3 in the independent sample.

| Outcome                          | β of change from W2 to W3 | Std. Err. | p-value | n sample |
|----------------------------------|---------------------------|-----------|---------|----------|
| SBP                              | 0.94                      | 0.92      | 0.309   | 2,332    |
| SBP**                            | −1.09                     | 0.80      | 0.172   | 2,249    |
| SBP***                           | 0.94                      | 1.95      | 0.628   | 443      |
| DPB                              | 3.54                      | 0.65      | 0.0001  | 2,331    |
| DBP**                            | 2.23                      | 0.57      | 0.0001  | 2,249    |
| DBP***                           | 3.36                      | 1.40      | 0.017   | 443      |
| Calculated urinary salt (NaCl) excretion, g/day | −1.16                      | 0.53      | 0.028   | 522      |
| Urinary potassium (K), mmol/24hr  | −8.75                     | 2.76      | 0.002   | 522      |

All models are adjusted for: age, gender, ethnicity, location, marital status, education level, alcohol use, smoking status, waist-hip ratio. * including hypertension status as adjusting factor. **including hypertension status, sodium, potassium, creatinine and iodine as adjusting factors. † including hypertension status, SBP and DBP as adjusting factors. SBP: systolic blood pressure, DBP: diastolic blood pressure.
studies. This design, on the other hand, may limit generalization to the entire population. Women are more likely to volunteer to participate in surveys than men, as was evident in the current study and has been observed in another 24 h urine collection study in South Africa. (General Assembly of the World Medical Association, 2014) Robust methodology and strict quality control was applied in data collection processes across both study waves. Collection of a single 24 h urine collection may be insufficient to assess usual salt intake in individuals (Lerchl et al., 2015) but in larger population studies, multiple days of collection results in more refusals and incomplete samples (Mente et al., 2015), and potential underestimates of salt intake (Wielgosz et al., 2016). We conducted a sensitivity analysis in a random subsample of 48 participants in W3 in order to assess whether correction for intra-individual variability in Na excretion was required (Charlton et al., 2020). Three repeated 24 h urinary Na collections resulted in shrinkage of the population distribution at the upper extremes but did not influence the median value, thereby suggesting that a single 24 h urinary Na collection is appropriate for our use. A study limitation is the inability to follow up many of the same participants in the salt sub-study between W2 (2015) and W3 (2018–19) because of logistical complexities in the South African context. This resulted in some sociodemographic differences between participants in W2 and those in W3 samples which could have introduced bias in ability to compare salt intake directly between the two groups. However, multivariable analyses adjusting for these differences showed that sodium intakes have reduced.

South Africa is known to have a highly mobile population with increased levels of circular migration and individuals moving between households based on fluid family and social relationships, and economic pressures or opportunities (Kosegoud et al., 2005; Jinnah, 2020). Such challenges require longitudinal cohorts in the region to have adaptive and flexible methods and designs for follow-up.

5. Conclusion

These first results of salt intake from South Africa following implementation of its mandatory sodium legislation in 2016 use valid 24 h urinary Na concentrations in a countrywide sample. Our data suggest that salt intake reduced by 1.16 g salt per day between 2015 and 2018/early 2019, with older adults having significantly lower salt intakes than younger South Africans. It is likely that salt intake may have already been reduced by the time of baseline measurements, which occurred during the year leading up to implementation of the first phase of the legislation. It remains to be demonstrated how the stricter maximum sodium levels in foods, enforced from June 2019, will further impact population salt reduction and blood pressure change. Systematic monitoring and surveillance of the food system is an integral and essential component to further evaluate the effectiveness of South Africa’s salt reduction strategies.

Author contributions

K.E.C., L.J.W., A.E.S., and P.K. designed the research; L.J.W. and L.W. implemented the research; B.C. and N.M. performed the statistical analyses; N.N. oversaw data quality for the main SAGE survey data collection. K.E.C. wrote the first draft of the manuscript, while all authors contributed to data interpretation and the final write-up. All authors have read and agreed to the published version of the manuscript.

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Table 6
Reported salt use behaviours W2 and W3 respondents, all CAPI data.

|                           | W2 (n = 2,378) | W3 (n = 771) | p-value |
|---------------------------|---------------|--------------|---------|
| Frequently add salt to food at table | 684 (22.2)    | 416 (17.6)   |         |
| Frequently add salt to food during cooking | 1,831 (59.5)  | 1,540 (65.0) |         |
| Believe they consume too much salt | 234 (7.66)    | 234 (10.2)   |         |
| Believe a high salt diet is bad for health | 2,042 (70.5)  | 1,749 (82.8) |         |
| Regularly control of salt intake | 1,346 (58.8)  | 1,035 (64.6) | <0.0001 |
| Independent samples        | W2 (n = 2,378) | W3 (n = 771) |         |
| Frequently add salt to food at table | 483 (21.1)    | 294 (18.4)   | 0.036   |
| Frequently add salt to food during cooking | 1,346 (58.8)  | 1,035 (64.6) | <0.0001 |
| Believe they consume too much salt | 161 (7.1)     | 166 (10.8)   | <0.0001 |
| Believe a high salt diet is bad for health | 1,497 (69.8)  | 1,169 (82.4) | <0.0001 |
| Regularly control of salt intake | 628 (28.6)    | 596 (42.7)   | <0.0001 |
| Follow-up sample           | W2 (n = 771)  | W3 (n = 771) |         |
| Frequently add salt to food at table | 189 (25.1)    | 107 (15.4)   | 0.007   |
| Frequently add salt to food during cooking | 468 (62.1)    | 452 (64.9)   | 0.650   |
| Believe they consume too much salt | 71 (9.4)      | 59 (8.6)     | 0.541   |
| Believe a high salt diet is bad for health | 526 (72.6)    | 530 (84.1)   | 0.147   |
| Regularly control of salt intake | 256 (35.6)    | 241 (38.7)   | 0.220   |

Data are presented as absolute number (%) and p-value obtained by Pearson Chi-Square.
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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2021.101469.

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