Sugar-Sweetened Beverages in the Supplemental Nutrition Assistance Program

To the Editor: The Commentary by Drs Brownell and Ludwig[1] about limiting purchases of sugar-sweetened beverages with Supplemental Nutrition Assistance Program (SNAP) funds misses an important point. SNAP is an effective program for addressing food insecurity.[2] It is intended to supplement resources available to families for buying food and was not designed to police the healthfulness of food purchases. Screening SNAP purchases for healthfulness is not feasible without unacceptable increases in costs.[3] Moreover, in caloric or glycemic index terms, juice, sports drinks, and other flavored water drinks can be as obesogenic as soda, depending on the level of intake and consumers' activity levels. Where and how does one draw the line? Until healthful food is accessible and affordable in all communities, modifying SNAP in an effort to reduce recipients' consumption of unhealthful foods will cost more and leave less to help families put food on the table.

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Conflict of Interest Disclosures: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Cook reported that he works as a paid consultant for Feeding America, the National Food Bank network.

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In Reply: Although the original Food Stamp Act of 1964 had several aims, improved nutrition was specifically cited in its preamble: "To strengthen the agricultural economy; to help to achieve a fuller and more effective use of food abundances; to provide for improved levels of nutrition among low-income households . . . and for other purposes."[1] Moreover, the law was crafted with the intention of avoiding harm, as demonstrated by the exclusion of alcohol.

In the last half century, obesity among low-income families has increased several-fold. For this reason, it is appropriate to consider whether the balance between potential benefit and harm for certain product classes may have changed as a consequence. Consumption of sugar-sweetened beverages, which includes many sports drinks in addition to soda, erodes overall diet quality and has been linked to obesity, diabetes, and heart disease.[2] Therefore, this unique category of beverages comprises a logical place to begin reassessment of US Department of Agriculture policy. Restricting the use of SNAP benefits for the purchase of sugar-sweetened beverages may do more good than harm, or more harm than good, and may or may not justify any administrative costs involved, but the only way to know is to conduct a test. Without such a test, policy decisions that affect the lives of many millions of people, and possibly billions of dollars of health care expenditures, cannot be based on objective evidence.

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RESEARCH LETTER

Consideration of Multiple Chronic Diseases in Randomized Controlled Trials

To the Editor: Before approval of a new drug, the US Food and Drug Administration (FDA) requires phase 3 clinical trials demonstrating efficacy. Usually trials are conducted in homogeneous populations and rarely include individuals with multiple chronic conditions. In the United States, more than 50% of people with chronic conditions have 2 or more diseases.[1] Twenty-eight percent of the population lives with multiple chronic conditions, including 2 of 3 older individuals.[2] Multiple chronic conditions account for 66% of the country's overall health expenditures[2] and more than 95% of Medicare expenditures.[3]

This study tested the hypothesis that patients with multiple chronic conditions are underrepresented in randomized controlled trials (RCTs) published in high-impact journals and that there are no significant differences by type of journal or changes over time.

Methods. We examined all RCTs published from January through March in 1995, 2000, 2005, and 2010 in the 5 highest impact factor general medical journals (*BMJ, Canadian Medical Association Journal, Journal of the American Medical Association, Lancet,* and *New England Journal of Medicine*; TABLE 1) and specialized journals that focus on the most prevalent chronic conditions (*American Journal of Respiratory and Critical Care Medicine, Annals of General Psychiatry, Circulation, Diabetes,* and *Journal of Clinical Oncology*; TABLE 2).

Trials on the effects of interventions for chronic conditions (any incurable or long-lasting illness) in adults were eligible. Pediatric studies, posttrial follow-up studies, or secondary subgroup analyses were excluded. Data for each trial were extracted and coded by 2 independent raters. When necessary, discrepancies were resolved by consensus and arbitration by a third individual. χ^2 Tests were used to compare the proportion of trials in general and specialized jour-

Table 1. Handling of Patients With Multiple Coexisting Diseases by General Medical Journals[a]

	BMJ (n = 18)	*CMAJ* (n = 1)	*JAMA* (n = 15)	*Lancet* (n = 44)	*NEJM* (n = 41)	Subtotal (n = 119)	Total (N = 284)[b]
Multiple diseases considered							
Implicitly	6 (33)	1 (100)	9 (60)	15 (34)	24 (59)	55 (46)	108 (38)[c]
Explicitly	5 (28)	0	0	1 (2.3)	7 (17)	13 (11)	57 (20)
Both	3 (17)	0	4 (27)	8 (18)	3 (7.3)	18 (15)	35 (12)
No	3 (17)	0	1 (6.7)	19 (43)	5 (12)	28 (24)	79 (28)
Unclear	1 (5.6)	0	1 (6.7)	1 (2.3)	2 (4.9)	5 (4.2)	5 (1.8)
Affected eligibility	(n = 14)	(n = 1)	(n = 13)	(n = 24)	(n = 34)	(n = 86)	(n = 200)
Yes	13 (93)	1 (100)	12 (92.3)	24 (100)	34 (100)	84 (98)	190 (95)
No	1 (7.1)	0	0	0	0	1 (1.2)	3 (1.5)
Unclear	0	0	0	0	0	0	0
Implicit	0	0	1 (7.7)	0	0	1 (1.2)	7 (3.5)
Affected selection	(n = 13)	(n = 1)	(n = 13)	(n = 24)	(n = 34)	(n = 85)	(n = 197)
Inclusion	0	0	1 (7.7)	1 (4.2)	3 (8.8)	5 (5.9)	6 (3)
Exclusion	12 (92)	1 (100)	11 (85)	22 (92)	29 (85)	75 (88)	179 (91)
Both	1 (7.7)	0	1 (7.7)	1 (4.2)	2 (5.9)	5 (5.9)	11 (5.6)
Unclear	0	0	0	0	0	0	1 (0.5)
Excluded people aged >65 y							
Yes	9 (50)	0	3 (20)	8 (18)	17 (42)	37 (31)	88 (31)
No	9 (50)	1 (100)	12 (80)	36 (82)	24 (59)	82 (69)	196 (69)

Abbreviations: *CMAJ*, *Canadian Medical Association Journal*; *JAMA*, *Journal of the American Medical Association*; *NEJM*, *New England Journal of Medicine*.
[a] Values are expressed as number (percentage).
[b] Includes specialized journals from Table 2.
[c] General medical journals vs specialized journals yielded a *P* value of less than .001.

Table 2. Handling of Patients With Multiple Coexisting Diseases by Specialized Journals[a]

	AJRCCM (n = 17)	*AGP* (n = 16)	*Circulation* (n = 36)	*Diabetes* (n = 6)	*JCO* (n = 90)	Subtotal (n = 165)	Total (N = 284)[b]
Multiple diseases considered							
Implicitly	4 (24)	5 (31)	18 (50)	3 (50)	23 (26)	53 (32)	108 (38)[c]
Explicitly	2 (12)	4 (25)	0	0	38 (42)	44 (27)	57 (20)
Both	2 (12)	3 (19)	4 (11)	1 (17)	7 (8)	17 (10)	35 (12)
No	9 (53)	4 (25)	14 (39)	2 (33)	22 (24)	51 (31)	79 (28)
Unclear	0	0	0	0	0	0	5 (1.8)
Affected eligibility	(n = 8)	(n = 12)	(n = 22)	(n = 4)	(n = 68)	(n = 114)	(n = 200)
Yes	8 (100)	9 (75)	22 (100)	4 (100)	63 (93)	106 (93)	190 (95)
No	0	1 (8.3)	0	0	1 (1.5)	2 (1.8)	3 (1.5)
Unclear	0	0	0	0	0	0	0
Implicit	0	2 (17)	0	0	4 (5.9)	6 (5.3)	7 (3.5)
Affected selection	(n = 8)	(n = 11)	(n = 22)	(n = 4)	(n = 67)	(n = 112)	(n = 197)
Inclusion	0	0	0	0	1 (1.5)	1 (0.9)	6 (3)
Exclusion	7 (88)	10 (91)	22 (100)	3 (75)	62 (93)	104 (93)	179 (91)
Both	1 (13)	1 (9.1)	0	1 (25)	3 (4.5)	6 (5.4)	11 (5.6)
Unclear	0	0	0	0	1 (1.5)	1 (0.9)	1 (0.5)
Excluded people aged >65 y							
Yes	8 (47)	9 (56)	9 (25)	5 (83)	20 (22)	51 (31)	88 (31)
No	9 (53)	7 (44)	27 (75)	1 (17)	70 (78)	114 (69)	196 (69)

Abbreviations: *AGP*, *Annals of General Psychiatry*; *AJRCCM*, *American Journal of Respiratory and Critical Care Medicine*; *JCO*, *Journal of Clinical Oncology*.
[a] Values are expressed as number (percentage).
[b] Includes general medical journals from Table 1.
[c] General medical journals vs specialized journals yielded a *P* value of less than .001.

nals that considered multiple chronic diseases implicitly (used names of specific conditions) or explicitly (mentioned terms such as comorbidities or coexisting diseases), or that used them as a selection criterion. Two-sided tests of significance were performed for all statistical analyses using SPSS version 18.0 (SPSS Inc); *P* values lower than .05 were considered statistically significant.

Results. Of the 284 trial reports included in the analysis, 165 RCTs (58%) were published in specialized journals. Two hundred trial reports (70%) mentioned multiple coexisting diseases; general medical journals described them more often than specialized journals (72% vs 69%; *P*=.02).

Of the 200 trial reports that mentioned multiple coexisting diseases, its presence affected the eligibility of participants in 190 RCTs (95%). Patients with polypathology were excluded in 179 of the trial reports, which represent 63% of the 284 RCTs identified, 90% of the 200 RCTs that mentioned coexisting diseases, and 94% of the 190 RCTs that considered polypathology as part of the selection process. Six RCTs (2.1%) included patients with multiple chronic diseases explicitly. There was no difference across the publication years (65% in 1995, 67% in 2000, 74% in 2005, and 75% in 2010; *P*=.49).

Comment. Few RCTs published in the last 15 years included patients with multiple chronic conditions. Although the external validity of this finding is limited by the small sample of journals and the short period covered by the study, it invites reflection about the risk of unintended harm from inappropriate generalization of trial results conducted in populations with a single disease.[4] Given the possible drug-to-drug, drug-to-disease, and disease-to-disease interactions that remain unexamined, most of the evidence gathered to date by RCTs is of limited value to guide decisions about medication use by patients with multiple chronic diseases.[5]

It may be beneficial for the FDA to consider large observational studies as sources of supplementary data on the value of interventions for multiple coexisting diseases; have manufacturers include subgroups of patients with the most frequent combinations of diseases in their drug development processes; increase the number of n-of-1 trials to assess the safety of new drugs added to polymedicated patients with conditions that could be temporarily alleviated; and have postmarketing surveillance studies include risk stratification and standardized outcomes that could allow meta-analyses across populations.

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Author Contributions: Dr Jones had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Jadad, To, Jones.
Acquisition of data: To, Emara, Jones.
Analysis and interpretation of data: Jadad, To, Emara, Jones.
Drafting of the manuscript: Jadad.
Critical revision of the manuscript for important intellectual content: Jadad, To, Emara, Jones.
Statistical analysis: To, Emara, Jones.
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Study supervision: Jadad, To, Jones.
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CORRECTION

Misspelled Investigator Name: In the Original Contribution entitled "Extracranial-Intracranial Bypass Surgery for Stroke Prevention in Hemodynamic Cerebral Ischemia: the Carotid Occlusion Surgery Study Randomized Trial," published in the November 9, 2011, issue of *JAMA* (2011;306[18]:1983-1992), a name was misspelled in the list of Carotid Occlusion Surgery Study (COSS) investigators. The name should have appeared as Bruce Ovbiagele.