

terval may clarify the plausible effects of the therapy. If cluster RCTs reach different conclusions than quasiexperimental work, we find no reason why traditional experimental design hierarchies would not apply.

Notably, our study found that mortality is less often an end point in highly cited cluster RCTs than in highly cited RCTs. This remains a deficit of this burgeoning methodology. When cluster RCTs do address mortality, however, they reach positive findings as often as traditional RCTs.

In conclusion, if cluster RCTs reach negative conclusions, our study provides no reason to doubt those results. Meanwhile, cluster RCTs should more often assess mortality, a hard and important end point, to match their RCT counterparts.

Senthil Selvaraj, MA
Vinay Prasad, MD

Published Online: January 21, 2013. doi:10.1001/jamainternmed.2013.1638

Author Affiliations: Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Mr Selvaraj); and Medical Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland (Dr Prasad).
Correspondence: Dr Prasad, Medical Oncology Branch, National Cancer Institute, National Institutes of Health, 10 Center Dr, Building 10, Room 12N226, Bethesda, MD 20892 (vinayak.prasad@nih.gov).

Author Contributions: *Study concept and design:* Prasad. *Acquisition of data:* Selvaraj. *Analysis and interpretation of data:* Selvaraj and Prasad. *Drafting of the manuscript:* Selvaraj and Prasad. *Critical revision of the manuscript for important intellectual content:* Selvaraj and Prasad. *Statistical analysis:* Selvaraj. *Study supervision:* Prasad.

Conflict of Interest Disclosures: None reported.

Disclaimer: The views and opinions of Dr Prasad do not necessarily reflect those of the National Cancer Institute or National Institutes of Health.

1. Campbell MK, Elbourne DR, Altman DG; CONSORT group. CONSORT statement: extension to cluster randomised trials. *BMJ*. 2004;328(7441):702-708.
2. Bland JM. Cluster randomised trials in the medical literature: two bibliometric surveys. *BMC Med Res Methodol*. 2004;4:21.
3. Platt R. Time for a culture change? *N Engl J Med*. 2011;364(15):1464-1465.
4. Jain R, Kralovic SM, Evans ME, et al. Veterans Affairs initiative to prevent methicillin-resistant *Staphylococcus aureus* infections. *N Engl J Med*. 2011;364(15):1419-1430.
5. Huskins WC, Huckabee CM, O'Grady NP, et al; STAR*ICU Trial Investigators. Intervention to reduce transmission of resistant bacteria in intensive care. *N Engl J Med*. 2011;364(15):1407-1418.

EDITOR'S NOTE

In Support of More Clustered Randomized Trials

When faced with logistical issues that preclude doing patient-level randomized trials, researchers should be looking to use at least cluster randomization as the next best method, rather than before-and-after observational studies. Selvaraj and Prasad attempt to provide empirical evidence of the superior validity of cluster randomized controlled trials (RCTs) by

showing that such trials have comparable effect sizes to patient-level RCTs in published studies in select high-impact journals. One might quibble over whether this proves its comparable validity without direct comparison of methods on the same research question. However, we believe this work raises the importance of the underused method of cluster randomization in clinical research. Although cluster randomization would never be preferred to patient-level randomization, when this is not feasible researchers should be looking to cluster randomization as the next best design, rather than before-and-after observational studies.

Patrick G. O'Malley, MD, MPH

RESEARCH LETTERS

The Great Recession and Racial and Ethnic Disparities in Health Services Use

The "Great Recession" of 2007 to 2009 affected Americans of all backgrounds, across education, age, race/ethnicity, and household type, but took a far greater toll on African Americans and Hispanics than on whites.^{1,2} In 2009, unemployment rates of African Americans (14.8%) and Hispanics (12.1%) were significantly higher than the rate for whites (8.7%).³ Median wealth fell 66% among Hispanic households, 53% among African American households, and 16% among white households.² Rates of employment-based health insurance declined more steeply for minorities than for whites, as 25% of African Americans and Hispanics lost their job during the recession compared with 15% of whites, and minorities were more likely to become uninsured.⁴

Loss of insurance coverage deteriorates access to care and is associated with reduced use of health services,⁵ particularly during recessions.^{6,7} Preventive service use is also sensitive to recessions.^{6,7} Taken together, these forces suggest that health services use patterns of minorities may have been significantly altered during the recession. The objective of the present study was to examine differences in health services use regarding office-based physician visits, inpatient stays, emergency department visits, and prescription drug fills for racial and ethnic minorities before and during the Great Recession.

Methods. To investigate the association between the economic recession and health care use, we used data nationally representative of the civilian noninstitutionalized US population from the Medical Expenditure Panel Survey⁸ (MEPS) for 2005 to 2006 and 2008 to 2009 for adults aged 18 to 64 years. The total sample (N = 54 007) included non-Hispanic whites (whites) (n = 30 760), non-Hispanic African Americans (n = 9822) (African Americans), and Hispanics (n = 13 425). Our outcome variables included use counts of office-based physician visits, inpatient stays, emergency department visits, and prescription drug fills over the calendar year. We estimated negative binomial models for the count data. We report the incident rate ratios (IRRs), which indicate the estimated rate ratio of an explanatory variable relative to its

reference category, if all the other variables are held constant in the model.⁹

The key explanatory variables included a dichotomous indicator equal to 1 for 2008 to 2009 and equal to 0 for 2005 to 2006. We also controlled for the interaction terms of this recession indicator with race and ethnicity. We controlled for respondents' demographics, socioeconomic status, health insurance coverage, self-reported health, and chronic conditions. Characteristics of the sample are available in the eTable (<http://www.jamainternalmed.com>).

Results. There were significant differences in health services use by race/ethnicity before and during the recession. Unadjusted statistics show that the mean number of office-based physician visits over the 2-year prerecession period were lower for African Americans (5.75) and Hispanics (4.51) than for whites (7.34) (**Table**). During the recession, whites and Hispanics reported fewer physician visits compared with the period before the recession. Prescription drug use was highest for whites in the prerecession period (14.08), with a statistically significant drop during the recession to a mean of 13.44 prescription drug fills. Hispanics had the lowest mean prescription drug fill counts before the recession (8.40) and no significant drop during the recession (8.09). The drop in prescription drug fills for African Americans (from 12.93 to 12.74) was not significant. For African Americans, the mean number of inpatient stays was higher before the recession (0.16) and lower during the recession (0.14), but inpatient stays were not significantly reduced for whites or Hispanics. Emergency department use did not differ significantly across the 2 periods. African Americans reported the most visits, whereas use was similar for whites and Hispanics.

The IRRs from the negative binomial regressions show that there were fewer prescription drug fills (IRR, 0.91; $P < .01$) and inpatient stays (IRR, 0.90; $P < .05$) across all races and ethnicities during the recession relative to the prerecession period. There were no statistically significant overall reductions in physician visits or emergency department use related to the recession. The coefficients for the interaction terms of the year indicator (2008-2009) and "Hispanic" or "African American" show the differential associations of the recession compared with the prerecession period for minorities relative to whites. The Hispanic \times year indicator shows that Hispanics had a greater (IRR, 0.91; $P < .05$) reduction of physician visits than did whites during the recession.

Comment. Our results show the recession of 2007 to 2009 is associated with downward trends in health care utilization relative to the period before the recession across race/ethnicity and services. Physician visits, prescription drug fills, and inpatient visits were statistically significantly lower in the recession period for whites, African Americans, and Hispanics. Negative binomial results show that the recession is associated with lower counts of prescription drug fills and inpatient stays across race/ethnicity.

Although minorities bore the brunt of the recession in terms of losses in employment, income, and insur-

Table. Differences in Health Services Use Before and During the Recession by Race and Ethnicity^a

Health Service Use	Mean Count ^b		Negative Binomial Results, ^c IRR
	2005-2006 [Reference]	2008-2009	
Physician visits, No.			
Whites ^d	7.34	6.95 ^f	1 [Reference]
Hispanics	4.51	4.14 ^f	0.86 ^g
African Americans ^e	5.75	5.29	0.82 ^g
Year indicator: 2008-2009	0.93
Hispanic \times year indicator	0.91 ^f
African American \times year indicator	0.91
Prescription drug fills			
Whites	14.08	13.44 ^f	1 [Reference]
Hispanics	8.40	8.09	0.81 ^g
African Americans	12.93	12.74	0.78 ^g
Year indicator: 2008-2009	0.91 ^g
Hispanic \times year indicator	0.95
African American \times year indicator	0.98
Inpatient stays			
Whites	0.11	0.10	1 [Reference]
Hispanics	0.11	0.10	1.00
African Americans	0.16	0.14 ^f	1.23 ^g
Year indicator: 2008-2009	0.90 ^f
Hispanic \times year indicator	0.96
African American \times year indicator	0.91
ED visits			
Whites	0.22	0.22	1 [Reference]
Hispanics	0.22	0.22	1.14
African Americans	0.34	0.33	1.29 ^g
Year indicator: 2008-2009	0.98
Hispanic \times year indicator	0.96
African American \times year indicator	0.95

Abbreviations: ED, emergency department; IRR, incident rate ratio; ellipses, not applicable.

^aAnalysis of the 2005 to 2006 and 2008 to 2009 Medical Expenditure Panel Survey (MEPS) data (N = 54 007).

^bThe counts were summarized using MEPS data. Unpaired *t* tests were used to compare use before and during the recession for different racial and ethnic groups.

^cThe negative binomial models control for age, age², sex, marital status, citizenship, education, employment, family income, US born, region, interview language, self-reported physical and mental health status, chronic conditions, health insurance, and usual source of care.

^dWhites are non-Hispanic whites.

^eAfrican Americans are non-Hispanic African Americans.

^f $P < .05$.

^g $P < .01$.

ance, our findings suggest that trends in use patterns were similar across race and ethnicity. The only evidence of ethnic disparities is the statistically significant finding that Hispanics reduced office-based physician visits more than whites during the recession.

Karoline Mortensen, PhD
Jie Chen, PhD

Published Online: January 7, 2013. doi:10.1001/jamainternmed.2013.1414

Author Affiliations: Department of Health Services Administration, University of Maryland, College Park.

Correspondence: Dr Mortensen, Department of Health

Services Administration, University of Maryland, 3310 School of Public Health Bldg, College Park, MD 20742 (Karoline@umd.edu).

Author Contributions: *Study concept and design:* Mortensen and Chen. *Acquisition of data:* Chen. *Analysis and interpretation of data:* Mortensen and Chen. *Drafting of the manuscript:* Mortensen. *Critical revision of the manuscript for important intellectual content:* Mortensen and Chen. *Statistical analysis:* Chen. *Administrative, technical, and material support:* Mortensen. *Study supervision:* Mortensen.

Conflict of Interest Disclosures: None reported.

Online-Only Material: The eTable is available at <http://www.jamainternalmed.com>.

1. Hacker JS, Huber GA, Nichols A, Rehm P, Craig S. Economic insecurity and the great recession. *Economic Security Index*; 2011. <http://economicssecurityindex.org/assets/ESI%20Full%20Report%202011.pdf>. Accessed August 27, 2012.
2. Kochhar R, Fry R, Taylor P. Twenty-to-one: health gaps rise to record highs between whites, blacks and Hispanics. Pew Research Center; 2011. http://www.pewsocialtrends.org/files/2011/07/SDT-Wealth-Report_7-26-11_FINAL.pdf. Accessed August 28, 2012.
3. US Bureau of Labor Statistics. The recession of 2007-2009. BLS Spotlight on Statistics; 2012. http://www.bls.gov/spotlight/2012/recession/pdf/recession_bls_spotlight.pdf. Accessed August 28, 2012.
4. Doty MM, Collins SR, Robertson R, Garber T. Realizing health reform's potential: when unemployed means uninsured: the toll of job loss on health coverage, and how the Affordable Care Act will help. *The Commonwealth Fund*; 2011. http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2011/Aug/1540_Doty_when_unemployed_means_uninsured_COBRA_reform%20brief.pdf. Accessed August 28, 2012.
5. Kasper JD, Giovannini TA, Hoffman C. Gaining and losing health insurance: strengthening the evidence for effects on access to care and health outcomes. *Med Care Res Rev*. 2000;57(3):298-325.
6. Ruhm CJ. Are recessions good for your health? *Q J Econ*. 2000;115(2):617-650.
7. Dorn SD, Wei D, Farley JF, et al. Impact of the 2008-2009 economic recession on screening colonoscopy utilization among the insured. *Clin Gastroenterol Hepatol*. 2012;10(3):278-284.
8. Cohen JW, Cohen SB, Banthin JS. The medical expenditure panel survey: a national information resource to support healthcare cost research and inform policy and practice. *Med Care*. 2009;47(7)(suppl 1):S44-S50.
9. Jones A. Health econometrics. In: Culyer AJ, Newhouse JP, eds. *Handbook of Health Economics*. Amsterdam, the Netherlands: Elsevier; 2000.

A Crossover Study of Noodle Soup Consumption in Melamine Bowls and Total Melamine Excretion in Urine

Melamine exposure remains common even after the 2008 melamine-tainted baby formula incident, which resulted in 6 deaths and approximately 50 000 hospitalizations.¹ A continuous low-dose melamine exposure has been linked to urolithiasis in both children and adults.^{2,3} Another source of melamine exposure is melamine tableware.⁴ In a pilot study, we asked 16 healthy volunteers (age range, 20-27 years) to consume 500 mL of hot noodle soup (initial temperature, 90°C) served in melamine bowls in the morning of October 2011. We collected from each participant 1 spot urine sample immediately before and at 2-hour intervals for 12 hours after consuming the noodle soup. This experiment simulated the natural situation; thus, not all participants provided urine samples at every 2-hour interval. However, all urine samples from all participants were collected after consumption for 12 hours. Postconsumption mean urinary melamine concentrations, corrected for urinary creatinine, initially increased sharply, peaked at 4 to 6 hours, and then declined sharply for 2

hours and then less steeply for the remainder of the monitoring period (eFigure 1; <http://www.jamainternalmed.com>). We therefore investigated if consumption of hot noodle soup served in melamine bowls would increase total urinary melamine excretion.

Methods. In a randomized 2 × 2 crossover study in December 6, 2011, we asked 1 group (3 men and 3 women [group A]) to fast for 8 hours before consuming 500 mL of hot noodle soup (initial temperature, 90°C) served in a melamine bowl as a 30-minute breakfast. The study design was the same as the aforementioned pilot study. We collected spot urine sample before and at 2-hour intervals for 12 hours after consumption. Another group (3 men and 3 women [group B]), following the same procedures, consumed the same soup from ceramic bowls (eFigure 2), in which melamine levels were nondetectable.⁴ All subjects were different from those of the pilot study and were advised not to use any melamine tableware 3 days before the experiment. Soft drinks were not restricted. After a 3-week washout period, the assigned treatments were reversed (December 27, 2011). This study had institutional review board approval, and each participant provided written informed consent.

Urinary melamine levels were measured by triple-quadrupole liquid chromatography tandem mass spectrometry. The method of detection limit (MDL) was 0.8 ng/mL (parts per billion) in urine, with any measurement below the MDL treated as 0.4 ng/mL.³ Total melamine excretion was calculated as melamine concentration of 1-spot urine sample × the amount of that spot urine and the amounts of all the urine samples collected for 12 hours after the participant consumed hot noodle soup were summed. A Wilcoxon signed rank test was used to examine the absolute differences of total melamine excretion between the 2 groups, whereas a Wilcoxon rank sum test was used to compare the differences of total melamine excretion in the 2 melamine or ceramic groups. *P* values were 2-sided, with a significance level of .05.

See Invited Commentary on page 319

Results. Twelve healthy people (6 men and 6 women; age range, 20-27 years) participated. All urine samples from all participants were collected after consumption for 12 hours in both groups. Temporal change in mean urinary melamine concentration corrected for urinary creatinine was similar to the previous pilot study (Figure, A; eFigure 1). The mean (range) and total number of postconsumption spot-urine specimens collected from melamine bowl users were 4.3 (1-13) and 52, respectively; all melamine concentrations were detectable. In contrast, the mean (range) and total number of postconsumption spot-urine specimens collected from ceramic bowl users were 4.3 (2-7) and 51, respectively, but melamine concentrations in 17 urine samples (33%) were below the MDL. Total melamine excretion (mean [SE]) in urine for 12 hours was 8.35 (1.91) µg and 1.31 (0.44) µg in melamine bowls and ceramic bowls, respectively (Figure, B). The difference was statistically significant (7.04 [1.62] µg; *P* < .001). In contrast, there was no significant difference in the 2 melamine