Results. We estimate that from 1999 through 2006 approximately 1.5 million Americans 20 years or older had DSI, with nearly all affected individuals being older adults (Table). For individuals younger than 70 years, the prevalence of DSI was less than 1%, but among individuals 80 years or older, 11.3% had DSI, and only 19% remained free of having any sensory impairment. Prevalence rates for DSI were not substantively different between men and women at any age decade. At each age decade, the prevalence of HI was greater in men than in women; however, the prevalence of VI was not different between men and women at any age.

Comment. To our knowledge, this study presents the first national prevalence estimates of DSI in the United States based on objective data. Our results demonstrate that 1 in 9, or 11.3%, of all adults 80 years or older has prevalent DSI. This estimate is substantially higher than previous national estimates of DSI based on self-reported impairment among older adults1 (6.6%). Other estimates of DSI prevalence using objective assessments were based on a cohort of veterans2 or an Australian population3 and may not be generalizable to US adults.

Despite the relatively high prevalence in older adults, there is an inadequate understanding of the impact of DSI on cognition and physical functioning. Concurrent vision impairment could potentially accelerate the rate of cognitive decline and dementia previously reported in individuals with hearing impairment alone.5 There is also a lack of research examining how to effectively treat or rehabilitate older adults with DSI. Interdisciplinary, collaborative research efforts between ophthalmologists, otolaryngologists, and geriatricians are urgently needed to investigate the impacts of DSI, as well as to examine possible treatment and rehabilitative strategies in older adults.

Bonnielin K. Swenor, MPH
Pradeep Y. Ramulu, MD, PhD
Jeffery R. Willis, MD, PhD
David Friedman, MD, PhD, MPH
Frank R. Lin, MD, PhD

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Author Affiliations: Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health (Ms Swenor and Drs Friedman and Lin), and Dana Center for Preventive Ophthalmology, Wilmer Eye Institute (Ms Swenor and Drs Ramulu, Willis, and Friedman), and Department of Otolaryngology—Head and Neck Surgery (Dr Lin), Johns Hopkins School of Medicine, The Johns Hopkins University, Baltimore, Maryland.

Correspondence: Ms Swenor, Wilmer Eye Institute, School of Medicine, The Johns Hopkins Hospital, Woods 172, 600 N Wolfe St, Baltimore, MD 21287 (bswenor@jhmi.edu).

Author Contributions: Ms Swenor 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: Swenor, Ramulu, Friedman, and Lin. Acquisition of data: Ramulu, Willis, and Friedman. Analysis and interpretation of data: Swenor, Willis, Friedman, and Lin. Drafting of the manuscript: Swenor. Critical revision of the manuscript for important intellectual content: Swenor, Ramulu, Willis, Friedman, and Lin. Statistical analysis: Swenor, Willis, Friedman, and Lin. Study supervision: Ramulu, Friedman, and Lin.

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Characteristics of Cluster Randomized Trials: Are They Living Up to the Randomized Trial?

Cluster randomized control trials (RCTs) are a form of prospective study where groups of individuals are allocated to an intervention. They offer the unique advantage of rigorously evaluating practices that cannot feasibly be randomized to the individual—such as public health or quality programs.1 While cluster RCTs can test questions traditional RCTs cannot, the design requires more participants to achieve equivalent statistical power.1 Over the last decade, the number of cluster RCTs has grown dramatically,2 but some researchers remain uncertain of how to interpret this study design.

See Editor’s Note on page 315
A recent editorial highlights the debate regarding where to place cluster RCTs in the research hierarchy.³ Two paired articles in a high-impact journal reached different conclusions regarding routine screening and gown and glove precautions for patients with multidrug-resistant bacterial colonization. One article,⁴ a quasieperimental before-and-after study, found that the practice worked, while another,⁵ a multicenter cluster RCT, found no benefit. If an observational study reaches a different result than an RCT, most would conclude the RCT got it right (ie, hormone therapy and cardiovascular risk, beta carotene therapy and cancer prevention). Yet, in the case of contact precautions, the editorial was ambivalent.³ Ambivalence would be reasonable if cluster RCTs are more likely to reach negative conclusions than RCTs. We sought to examine this hypothesis. Herein, we provide a comparison of cluster RCTs and traditional RCTs for the 50 highest-cited articles (to compare high-impact work) and the most recent 50 articles (to compare a random sampling).

Methods. We used ISI Web of Science to identify cluster and traditional RCTs based on citation count and date of appearance. Topic and title searches performed for cluster RCTs included the following: cluster randomized trial, cluster randomized controlled trial, cluster randomized study, cluster randomized controlled study, and British spellings of these terms. A similar search strategy was performed for traditional RCTs. We retrieved 200 total articles, split evenly as cluster RCTs and traditional RCTs. Within each of these types, the 50 most highly cited articles and 50 most recent articles were reviewed.

We extracted the following information for each publication: journal name, year of publication, number of times cited, total number of clusters (if applicable), total number of participants, whether the results were positive, whether mortality was examined, and if mortality was positively affected by the intervention. The Wilcoxon-Mann-Whitney test and χ² test (or Fisher exact test when appropriate) were used to compare continuous and categorical variables, respectively. P ≤ .05 was considered statistically significant. Analysis was performed using Stata v.12 statistical software (StataCorp).

Results. Descriptive characteristics of the 4 types of articles (N = 200) are displayed in the Table. While highly cited RCTs appeared from 1991 to 2008, the earliest highly cited cluster RCT occurred in 1999. The citation count was significantly higher for highly cited RCTs than cluster RCTs (median, 1980 vs 108; P < .001). New England Journal of Medicine and British Medical Journal published the most highly cited RCTs and cluster RCTs, respectively. Highly cited cluster RCTs enrolled the same number of participants as RCTs (median, 1837 vs 1272; P = .53), whereas recent cluster RCTs enrolled more participants than recent traditional RCTs (median, 936 vs 84; P < .001). Cluster RCTs and traditional RCTs reached positive conclusions with equal frequency among highly cited studies (72% vs 80%; P = .58) and recent studies (76% vs 72%; P = .88). Highly cited cluster RCTs did not examine mortality as an end point as often as traditional RCTs (26% vs 80%; P < .001), whereas recent studies examined mortality in equal numbers (12% vs 8%; P = .74). When mortality was assessed, the results of highly cited cluster RCTs and traditional RCTs found improved mortality at equal frequency (85% vs 75%; P = .50).

Comment. Cluster RCTs address a gap in contemporary study design, and, to make sense of these trials, it is important to know whether they are comparable to time-tested RCTs. Our study demonstrates that cluster RCTs and traditional RCTs achieve the same frequency of positive study findings (both for highly cited work and a random sampling). We provide no evidence to support the belief that cluster RCTs are more likely to reach negative conclusions. Moreover, in the cases where cluster RCT findings are negative, examining the confidence in-

### Table. Characteristics of Highly Cited and Recent RCTs and Cluster RCTs

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Publications (N = 200)</th>
<th>Highly Cited Cluster RCTs (n = 50)</th>
<th>Highly Cited RCTs (n = 50)</th>
<th>Recent Cluster RCTs (n = 50)</th>
<th>Recent RCTs (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citation count⁴</td>
<td>42 (0-990)</td>
<td>108 (88-133)</td>
<td>190 (1766-3101)</td>
<td>0 (0-1)</td>
<td>0 (0-0)</td>
</tr>
<tr>
<td>Publishing journals, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clusters, No.⁴</td>
<td>33 (17-89)</td>
<td>31 (13-60)</td>
<td>NA</td>
<td>41 (18-129)</td>
<td>NA</td>
</tr>
<tr>
<td>Participants, No.³</td>
<td>693 (192-3780)</td>
<td>1837 (545-8430)</td>
<td>1272 (620-4162)</td>
<td>936 (399-3810)</td>
<td>84 (47-120)</td>
</tr>
<tr>
<td>Positive study findings, No. (%)</td>
<td>150 (75)</td>
<td>36 (72)</td>
<td>40 (80)</td>
<td>38 (76)</td>
<td>36 (72)</td>
</tr>
<tr>
<td>Studies assessing mortality, No. (%)</td>
<td>63 (32)</td>
<td>13 (26)</td>
<td>40 (80)</td>
<td>6 (12)</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Mortality studies showing impact on survival, No. (%)</td>
<td>48 (75)</td>
<td>11 (85)</td>
<td>31 (76)</td>
<td>5 (83)</td>
<td>1 (25)</td>
</tr>
</tbody>
</table>

Abbreviations: NA, not applicable; RCT, randomized controlled trial.

⁴Presented as median (25th-75th percentile) because data were not normally distributed.
terval may clarify the plausible effects of the therapy. If cluster RCTs reach different conclusions than quasixperimental 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

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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.

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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. In 2009, unemployment rates of African Americans (14.8%) and Hispanics (12.1%) were significantly higher than the rate for whites (8.7%). Median wealth fell 66% among Hispanic households, 53% among African American households, and 16% among white households. 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.

Loss of insurance coverage deteriorates access to care and is associated with reduced use of health services, particularly during recessions. Preventive service use is also sensitive to recessions. 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 Survey® (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