In July 2011, the Accreditation Council for Graduate Medical Education (ACGME) reduced the consecutive number of hours that postgraduate year-1 residents can work in a single shift, from 30 to 16.1 This rule was intended to improve patient safety by reducing residents’ fatigue. Many worry that the new duty hour policy increases patient care handovers, which may cause patient harm. The net effect of the 16-hour duty limits on patient outcomes is uncertain.

Methods. In April 2011, the Vanderbilt Internal Medicine Residency Program redesigned its rotations to reduce the maximum continuous on-duty period to 16 hours (eAppendix; http://www.jamainternalmed.com). We retrospectively examined the efficiency and quality of care for non–intensive care unit (ICU) medical inpatients during the 30-hour (July-December 2010) and 16-hour (July-December 2011) duty limits at Vanderbilt Uni-
Table. Patient Care Outcomes on Resident Services With 30- and 16-Hour Duty Limits

<table>
<thead>
<tr>
<th>Outcome</th>
<th>30-Hour (n = 2025)</th>
<th>16-Hour (n = 1966)</th>
<th>Difference Between, Mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of stay, median 25th-75th (IQR)</td>
<td>3.04 (1.95 to 5.64)</td>
<td>3.11 (1.91 to 5.67)</td>
<td>−0.075 (−0.417 to 0.267)</td>
</tr>
<tr>
<td>Observed to expected length of stay</td>
<td>0.82</td>
<td>0.82</td>
<td>0.007 (−0.003 to 0.017)</td>
</tr>
<tr>
<td>Time of discharge, median 25th-75th (IQR)</td>
<td>14.47 (12.58 to 16.38)</td>
<td>15.15 (13.28 to 17.08)</td>
<td>0.076 (0.014 to 0.35)</td>
</tr>
<tr>
<td>All-cause 30-d readmission, %†</td>
<td>18.57</td>
<td>17.80</td>
<td>−0.77 (−3.20 to 1.60)</td>
</tr>
<tr>
<td>All-cause 30-d readmission for patients</td>
<td>7.69</td>
<td>0.00</td>
<td>−7.69 (−18.70 to 3.30)</td>
</tr>
<tr>
<td>AHRQ patient safety indicators/1000 patients</td>
<td>3.46</td>
<td>1.02</td>
<td>−2.44 (−5.86 to 0.98)</td>
</tr>
<tr>
<td>UHC complications/1000 patients</td>
<td>26.67</td>
<td>15.77</td>
<td>−10.90 (−20.30 to −1.48)</td>
</tr>
<tr>
<td>UHC observed: expected mortality</td>
<td>0.41</td>
<td>0.55</td>
<td>0.14 (−0.01 to 0.38)</td>
</tr>
<tr>
<td>Rapid response team events/1000 patients</td>
<td>16.30</td>
<td>18.31</td>
<td>2.02 (−6.59 to 10.61)</td>
</tr>
<tr>
<td>Code events/1000 patients</td>
<td>0.99</td>
<td>1.02</td>
<td>0.03 (−1.97 to 2.02)</td>
</tr>
<tr>
<td>ICU transfers/1000 patients</td>
<td>5.43</td>
<td>7.63</td>
<td>2.20 (−3.30 to 7.70)</td>
</tr>
</tbody>
</table>

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; ICU, intensive care unit; IQR, interquartile range; UHC, University HealthSystem Consortium.

†Planned and unplanned.

Results. Rotation changes increased the number of weekly handovers from 56 to 126. The 30-hour cohort (n = 2025 patients) and 16-hour cohort (n = 1966 patients) did not differ significantly in hospital LOS, although the mean time of discharge was 25 minutes later in the 16-hour cohort (Table). No statistically significant differences were seen in AHRQ PSIs, O:E mortality, 30-day readmissions, rapid response team events, codes, or ICU transfers. The UHC complications declined in the 16-hour resident cohort, with a similar trend observed among nonresident hospitalist services.

Comment. Restructuring resident rotations to accommodate the ACGME 16-hour duty limits substantially increased patient care handovers, but did not significantly affect efficiency and quality of care among medical inpatients.

Increased handovers were an unintended consequence of the 2003 duty hour changes. We anticipated increases in handovers with further work-hours restriction, because patients would be admitted by night residents and transferred to new health care providers in the morning. Indeed, we found a striking 2-fold increase in handovers. Although we expected a corresponding rise in inefficiencies, we demonstrated no significant change in hospital LOS. We did observe a delay in discharge time of almost 30 minutes, which may be relevant in an era of pressures to improve patient throughput.

Poorly executed patient handovers are associated with medical errors, and we therefore evaluated the effect of the 16-hour restrictions on patient safety outcomes. We found no significant change in rates of AHRQ PSIs, consistent with previous findings. Additional patient safety outcomes, including rapid response and code events, ICU transfers, and inpatient mortality, did not differ significantly between the study periods, although the relatively small sample size may have resulted in insufficient power to detect uncommon events. There was a statistically significant decrease in UHC complications after implementation of the 16-hour rule. However, a similar trend occurred among patients treated on the nonresident hospitalist services, which suggests a secular effect. It is important to note that the increase in patient handovers with the 2011 policy change coincided with the introduction of a new structured electronic handover application and formal handover education for residents. In addition, transfers of care to new health care providers may bring fresh insights and, therefore, may offer opportunities to appreciate and correct prior lapses in care. Both factors may have attenuated safety hazards introduced by discontinuity.

An outcome of increasing focus is hospital readmission. Residents are intimately involved in the discharge process, and discontinuity may lead to fragmented and poorly planned transitions of care. Consistent with the literature on prior duty hour changes, we found no significant changes in 30-day all-cause readmissions to our institution after implementation of 16-hour duty limits. Overall, the 16-hour duty hour changes seemed to have minimal effects on measures of efficiency and quality of care. Several reasons might explain the net neutral outcomes. Although a main goal of restricting shift length was to reduce resident fatigue, thereby improving resident performance and consequently patient care, residents' total work and sleep may not change. Others have hypothesized that the pressure to complete the same amount of work in less time might impair residents' concentration, leading to errors that might offset the potential benefits of reduced fatigue. Discontinuity and communication errors might also yield negative outcomes that mask any positive effects of reduced duty hours. Finally, resident duty hours are one variable in a complex hospital system that contributes to patient outcomes.
The 16-hour duty limit is the latest in a progression of changes aimed at reducing resident stress and fatigue, and potentially improving the quality of patient care. Our study highlights a potential balance between harmful and beneficial effects that in sum result in minimal overall impact when considering a wide-range of efficiency and quality outcomes.

Neesha N. Choma, MD, MPH
Eduard E. Vasilievskis, MD
Kelly C. Sponsler, MD
Jacob Hathaway, MD, MPH
Sunil Kripalani, MD, MSc

Published Online: April 1, 2013. doi:10.1001/jamainternmed.2013.3014

Author Affiliations: Department of Medicine, Vanderbilt University (Drs Choma, Vasilievskis, Sponsler, Hathaway, and Kripalani), and Medical Services, VA Tennessee Valley Healthcare System (Dr Sponsler), Nashville, Tennessee.

Correspondence: Dr Kripalani, Vanderbilt Center for Health Services Research, 1215 21st Ave S, Ste 6000 Medical Center E, Nashville, TN 37232 (sunil.kripalani@vanderbilt.edu).

Author Contributions: Dr Choma 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: All authors. Acquisition of data: Choma. Analysis and interpretation of data: All authors. Drafting of the manuscript: Choma, Sponsler, and Kripalani. Critical revision of the manuscript for important intellectual content: Choma, Vasilievskis, Hathaway, and Kripalani. Statistical analysis: Choma and Hathaway. Administrative, technical, and material support: Choma and Vasilievskis. Study supervision: Choma, Vasilievskis, and Kripalani.

Conflict of Interest Disclosures: None reported.

Previous Presentation: This study was presented at the Society of General Internal Medicine Annual Meeting, May 12, 2012; Orlando, Florida.


Additional Contributions: Daniel Stover, MD, Cecelia Theobald, MD, Jennifer Green, MD, MPH, Joshua Denny, MD, MS, Neeraja Peterson, MD, MSc, John Sergent, MD, and Nancy Brown, MD, provided input about study design and review of the manuscript. Shea Polancich, RN, PhD, Martha Newton, and Hank Domenico from the Vanderbilt Center for Clinical Improvement assisted with data extraction and statistical analysis. Tracy Dozier, MD, Eitan Friedman, MD, Waleed Khalaf, MD, Jay Montgomery, MD, Matthew Semler, MD, and Ciara Shaver, MD, assisted with the development and implementation of the resident night float system at Vanderbilt University Medical Center.


Adult Mortality in a Randomized Trial of Mass Azithromycin for Trachoma

Annual mass azithromycin treatments are provided to entire communities to clear the ocular strains of Chlamydia trachomatis that cause blinding trachoma. Mass treatments reduce the community burden of ocular chlamydia and have proven efficacious in community-randomized trials. Since 1999, more than 150 million doses of azithromycin have been distributed for trachoma worldwide.

Mass azithromycin distributions are directed at clearing ocular chlamydia but may have other effects. For example, in the Trachoma Amelioration in Northern Amhara (TANA) trial, we found that mass azithromycin distributions reduced childhood mortality. In contrast, a recent observational study suggested that azithromycin use may cause sudden death in adults. This finding could have major implications for trachoma elimination efforts. In our previous report, an intention-to-treat analysis found no evidence of increased mortality among individuals older than 9 years. However, in light of the recent observational study, we thought it worthwhile to reassess our data to determine the mortality rates and causes of death in an older subgroup of individuals and to compare mortality in individuals who received azithromycin with that in those who did not.

Methods. TANA was a National Institutes of Health–funded, cluster-randomized trial conducted in Ethiopia from 2006 through 2009 (clinicaltrials.gov Identifier: NCT00322972). The design and implementation of the trial, including the prespecified mortality outcome, have been described previously. Herein we report results from the following 4 study arms, each composed of 12 randomly selected “subkebeles” (government-defined units): (A) annual or (B) biannual directly observed mass distribution of azithromycin to persons 1 year or older, (C) quarterly mass distribution of azithromycin to children aged 1 to 9 years, and (D) no treatment. Mortality was defined as presence at the baseline census and absence at the 12-month census due to death. For each death, household members were asked about the cause of death.

In an intention-to-treat analysis, we compared communities where individuals aged at least 10 years received azithromycin (arms A and B) with communities where this age group did not receive treatment (arms C.