Hospitalwide adverse drug events before and after limiting weekly work hours of medical residents to 80

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Purpose. Adverse drug events (ADEs) at a hospital before and after the weekly work hours of medical residents were limited to 80 were studied.

Methods. The study population included all adults admitted to a 750-bed academic tertiary care hospital where resident physicians provide direct care under the supervision of faculty attending physicians. The six-month period after implementation of the 80-hour work limit (July 1 to December 31, 2003) was compared with the same six-month period one year before implementation (July 1 to December 31, 2002).

Results. There were no significant differences between study periods in any measured variables, including number of confirmed ADEs (194 before, 172 after), number of ADEs per 1000 patient days (1.3 before, 1.1 after), and number of preventable ADEs (21 before, 22 after).

Conclusion. Hospitalwide ADEs remained constant despite limiting of resident physician weekly work hours to 80.

Index terms: Drugs, adverse reactions; Errors, medication; Hospitals; Hours; Physicians; Prescribing


Ever since the Institute of Medicine (IOM) reported that an estimated 44,000–98,000 patients die yearly as a result of medical errors, improving patient safety and reducing preventable medical errors have become leading priorities of teaching hospitals and medical schools.1,2 Adverse drug events (ADEs), or injuries resulting from a medical intervention related to a drug, are among the largest sources of preventable errors among hospitalized patients.3-8 Preventable (or avoidable) ADEs are defined as errors in medication prescribing, transcribing, dispensing, administering, or monitoring.9 It is well recognized that many systems-based variables contribute to these errors and that several changes in the delivery of medical care are necessary to reduce their frequency.8 Fatigue among resident physicians from excessive work hours has been cited as one significant contributor to medical errors and ADEs.2,10,11 Before July 1, 2003, some resident physicians reportedly worked in excess of 100 hours per week or had scheduled on-call periods lasting more than 36 hours.2,12,14 Such weekly work requirements far exceed those in other safety-sensitive industries, such as aviation and nuclear power.15,16 Only recently have residents openly acknowledged sleep deprivation as a factor contributing to their mistakes.2,14 Reducing fatigue among medical residents has been suggested as one strategy for reducing preventable errors, particularly ADEs.2,12,14 Most drug therapy decisions in academic teaching hospitals are initiated by resident physicians.7 In response to recent reports that excessive resident work hours may be detrimental to hospitalized patients, the Accreditation Council of Graduate Medical Education (ACGME) implemented a mandatory maximum work week of 80 hours, effective July 1, 2003.18 Although various work-hour restrictions had been enacted at the local and state levels in the past, this was the first work-hour limitation across all specialties on a na-
Adverse drug events limited their residents to an average of 80 hours weekly before July the residency programs and usually of weekly work hours varied among the internal medicine program accounts for the largest number of residents. The six-month period immediately after implementation of the 80-hour work limit (July 1 to December 31, 2003) was compared with the same six-month period one year after implementation (July 1 to December 31, 2002). The first study period saw 512 residents actively working at the hospital, and the second study had 533 residents (an increase of 4%). Although the average number of weekly work hours varied among the residency programs and usually exceeded 80 hours weekly before July 2003, all NMH residency programs limited their residents to an average of ≤80 hours weekly after that date.

As part of an ongoing quality assurance program at NMH, the pharmacy and therapeutics committee has used a computerized database of potential and confirmed ADEs for 15 years. Our analysis focused on all ADEs entered into our ADE database that met the inclusion criteria, and the primary study endpoint was the frequency of ADEs. Our definition of an ADE was consistent with that used by Bates et al.: “an injury resulting from medical intervention related to a drug.” An appropriate investigation of medication safety warrants use of the term “ADE,” since an ADE includes all injuries related to drugs. We did not limit our examination to drug events that fell within the more limited category of adverse drug reactions (ADRs), because an ADR is defined by the World Health Organization as an injury related to a drug used at appropriate dosages and naturally excludes injuries related to drugs used at inappropriate dosages or for inappropriate reasons. A potential ADE in the inpatient setting at our institution alerts the pharmacy staff to review the drug therapy episode, categorize the severity of the episode, categorize the cause, determine causality (the probability that the adverse event is related to the drug), determine preventability, and enter all relevant information into a computerized ADE database. Review of a potential ADE at NMH is triggered by abnormal laboratory values for drugs for which serum levels are routinely monitored (e.g., digoxin, phenytoin); voluntary incident reports generated by nurses, physicians, and pharmacists; and potential ADEs identified by routine review of inpatient charts. The Naranjo score is used to determine causality. ADEs from the ADE database for two matched six-month periods (July 1 to December 31, 2002, and July 1 to December 31, 2003) were reviewed by three pharmacists and a staff physician. Information from the database was transferred to a computerized spreadsheet (Excel XP, Microsoft, Redmond, WA) that included the monthly ADE rate, the severity of each ADE (lethal, severe, moderate, or minor), the type of reaction (intolerance, drug interaction, pharmacologic, or idiosyncratic), and whether the ADE was preventable. Preventable or avoidable events were considered as described by Winterstein et al.: inappropriate therapy (contraindicat-
ed therapy—wrong dose or drug for condition), required monitoring not properly done, history of drug allergy or intolerance, failure to monitor for a known drug interaction, predictably elevated serum drug concentration, noncompliance (as outpatient), or medication error.

Comparisons of ADE rates and associated ADE characteristics between the two study periods were performed by using two-sided Student’s t tests (version 2.3.7, StatsDirect, Cheshire, England).

The study was approved by the institutional review board, and all identifying patient characteristics were blinded in accordance with the Health Insurance Portability and Accountability Act of 1996.

**Results**

The results are summarized in Table 1. There were no significant differences between study periods in any measured variables.

**Discussion**

The reduction in the maximum average number of hours per week resident physicians could work to 80 did not meaningfully affect the occurrence of ADEs at this hospital. It seemed reasonable that a reduction in work hours would lead to fewer ADEs, but our results suggest that reducing fatigue among residents is not the only solution to the problem. Although the IOM estimate of 44,000–98,000 yearly deaths from medical errors has generated much controversy, the need to reduce preventable errors has not been debated. Nearly half of preventable ADEs result from errors in prescribing by physicians, since errors at this initial stage of drug therapy may have a cascading effect. If a resident’s judgment can be impaired while driving home after an extended work shift, a resident’s judgment in initiating drug therapy can also be affected after a prolonged work shift. Reduced fatigue should naturally lead to fewer prescribing errors and thus fewer preventable ADEs, but this was not observed in our study. In addition to examining preventable ADEs, we considered it
Adverse drug events

or the overall quality of care. A study that examined the effect of work-hour reductions among residents in a single medical specialty (obstetrics and gynecology) also found no significant impact on errors or the overall quality of care. A recent prospective study conducted in an intensive care unit suggested that even 80 hours weekly is associated with excessive errors. There was a significant difference in error rates between residents working an average of 80 hours weekly and residents working an average of 60 hours.

Although several studies have demonstrated that prolonged sleep deprivation and fatigue adversely affect a resident physician’s cognitive performance, those studies often examined performance on psychometric tests and were not hospitalwide or addressed the occurrence of errors over an extended period. Our study specifically addressed clinically relevant drug therapy-related events over two extended periods. Furthermore, previous studies examining resident fatigue typically looked at acute sleep deprivation, but chronic deprivation may be just as detrimental.

At the time of this study, our institution did not have a computerized prescriber-order-entry (CPOE) system. CPOE may further reduce preventable ADEs by limiting the transcription of illegible orders and nonsensical orders by unit secretaries. CPOE systems have the added benefit of alerting the prescriber to allergies and potential drug–drug interactions. Indeed, several studies confirm that CPOE systems meaningfully reduce preventable ADEs. The implementation of a CPOE system together with reduced work hours may have a significant effect on errors; simply implementing one change may not be enough. Errors appear to occur because of several systems flaws and are rarely the result of individual actions; this makes sense because of the number of safeguards in academic medical centers. The effect of pharmacist safeguards was recently demonstrated in our institution. When an order is written by a resident physician, it is usually transcribed by a unit secretary, reviewed by a pharmacist, and reviewed by the administering nurse. Each step in the process has the potential to halt an order that may be harmful, but simply correcting one step (reducing residents’ fatigue when they write orders) is not always enough to produce a hospitalwide change in the occurrence of ADEs.

Our study has some limitations. First, it did not specifically address site-specific (intensive care versus hospital-floor) or specialty-specific changes in ADEs. An increase in errors in certain inpatient areas or among certain specialties may have been balanced by a reduction in other areas, but we aimed to assess the hospitalwide impact of reduced work hours, since the impact of ACGME’s work-hour-reduction order was also meant to be hospitalwide. Second, our study could not address whether frequent handoffs or sign-outs of patients from one resident physician to another increased the likelihood of errors. With night float teams, hospitalists, and other creative solutions to the work-hour restriction, handoffs do occur more commonly now. Some have suggested that more frequent handoffs to physicians unfamiliar with the patient may increase the error rate. Our ADE surveillance database is not designed to assess this possible effect. A slight but insignificant increase in preventable ADEs after the work-hour reductions (from 10.8% to 12.7%) indicates that future studies should take patient handoffs into consideration.

A third limitation is that we counted only errors of commission; errors of omission (e.g., undertreatment or failure to initiate drug thera-

### Table 1.

**Hospitalwide Adverse Drug Events (ADEs) before and after Work-Hour Reduction**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before&lt;sup&gt;a&lt;/sup&gt;</th>
<th>After&lt;sup&gt;b&lt;/sup&gt;</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. potential ADEs reviewed</td>
<td>409</td>
<td>411</td>
<td>0.96</td>
</tr>
<tr>
<td>No. (%) confirmed ADEs</td>
<td>194 (47.4)</td>
<td>172 (41.8)</td>
<td>0.41</td>
</tr>
<tr>
<td>No. ADEs per 1000 patient days</td>
<td>1.285</td>
<td>1.070</td>
<td>0.18</td>
</tr>
<tr>
<td>No. (%) ADEs with indicated severity</td>
<td></td>
<td></td>
<td>0.59</td>
</tr>
<tr>
<td>Minor</td>
<td>72 (37.1)</td>
<td>80 (46.5)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>112 (57.7)</td>
<td>72 (41.9)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>8 (4.1)</td>
<td>18 (10.5)</td>
<td></td>
</tr>
<tr>
<td>Lethal</td>
<td>2 (1.0)</td>
<td>2 (1.2)</td>
<td></td>
</tr>
<tr>
<td>No. (%) preventable ADEs</td>
<td>21 (10.8)</td>
<td>22 (12.7)</td>
<td>0.59</td>
</tr>
<tr>
<td>No. (%) ADEs of indicated type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intolerance</td>
<td>43 (22.2)</td>
<td>30 (17.4)</td>
<td>0.28</td>
</tr>
<tr>
<td>Drug interaction</td>
<td>3 (1.5)</td>
<td>11 (6.4)</td>
<td>0.08</td>
</tr>
<tr>
<td>Pharmacologic</td>
<td>78 (40.2)</td>
<td>75 (43.6)</td>
<td>0.83</td>
</tr>
<tr>
<td>Idiosyncratic</td>
<td>70 (36.1)</td>
<td>56 (32.6)</td>
<td>0.34</td>
</tr>
</tbody>
</table>

<sup>a</sup>July 1 to December 31, 2002.<br><sup>b</sup>July 1 to December 31, 2003.
Adverse drug events

References
