Resident Work Hours Reviewed by IOM

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WASHINGTON — Five years after the establishment of across-specialty rules to limit resident work hours, the issue of trainee schedules in teaching hospitals is again under the microscope as a continuing threat to patient safety—and this time an Institute of Medicine committee has been forewarned that specific "workable" solutions are needed.

The schedules in teaching hospitals "belie virtually all the tenets of providing good health care. How can we profess to provide the best possible quality of care when we know we have staff members who are operating at levels of sleep deprivation so severe that they are similar to someone driving under the influence of alcohol?" Dr. Carolyn Clancy, director of the federal Agency for Health Care Research and Quality, asked at a meeting sponsored by the Institute of Medicine.

The IOM's Committee on Optimizing Graduate Medical Trainee Hours and Work Schedules, which held the first of four workshops in December, was formed at the request of Rep. John D. Dingell (D-Mich.) and colleagues on the House Committee on Energy and Commerce as part of an investigation into preventable medical errors. The IOM will publish a report including strategies and actions for implementing safe work schedules in February 2009.

The issue of residents' work hours received relatively little attention in the IOM's landmark 1999 report on medical errors, experts said at the workshop, despite several decades of research on the effects of sleep deprivation on human performance and research more specifically showing an impaired ability of interns to read ECGs after long shifts.

Since then—and especially within the past several years—various studies have demonstrated the effects of sleep deprivation in medical residents and have shown that reductions in work hours can reduce errors, physicians told the committee.

A prospective, national survey of more than 2,700 interns, for instance, showed that residents were seven times more likely to report a harmful fatigue-related error when they worked five or more 24-hour shifts in a month than when they worked no 24-hour shifts. They were four times more likely to report a fatal error.

And in a randomized controlled trial, residents had twice as many EEG-documented attention failures at night when working the traditional schedule of 24- to 30-hour shifts than when working a 16-hour maximum. Both studies were led by researchers at Harvard University, Boston.

Dr. Christopher P. Landrigan, who directs the Sleep and Patient Safety Program at Brigham and Women's Hospital, Boston, said the Harvard research has also shown that residents working 24- to 30-hour shifts make five times as many serious diagnostic errors as do those scheduled to work 16 hours or less. They're also twice as likely to crash their cars, and they suffer 61% more needlestick injuries, he told the IOM committee.

Limits instituted by the American Council on Graduate Medical Education in 2003 mark shifts of 24-30 hours as acceptable. The council's "common duty hour standards" call for a 24-hour limit on continuous duty, with an additional 6 hours allowed for continuity and the transfer of care, as well as an 80-hour weekly limit averaged over 4 weeks. Programs can request an increase of up to 8 hours a week and can apply for further exemptions.

Residents must also have a minimum rest period of 10 hours between duty periods, 1 in 7 days free from patient care responsibilities, and in-house call no more often than every third night, averaged over a 4-week period, the standards say.

The council said it has issued citations to individual programs for duty hour violations and has done resident surveys that demonstrate a compliance rate of 94%.

Others argue, however, that enforcement is inadequate and that an independent body is needed to ensure compliance with the rules. Culture and tradition are so entrenched, they say, that too little has changed and that residents routinely underreport hours for fear of retaliation.

"I'm a resident who said one thing on a survey and did another thing in real life," Dr. Sunny Ramchandani, past chair of the AMA Residents and Fellows Section, told the IOM committee. "I'd have a 30-hour shift, work at least 34 hours, and report 16."

Part of the problem is that residents' workloads tend to remain the same even when shifts are shortened.

"Changing duty hours means changing everything," from work flow and coverage strategies to transfer-of-care techniques and the "very fundamentals of how patients are treated" and what residents are responsible for, said Dr. Ethan Fried, director of graduate medical education at St. Luke's–Roosevelt Hospital Center in New York.

Hospitals in New York state have been dealing with work hour limits and supervision requirements since 1988, several years after the death of Libby Zion in a teaching hospital spurred the state to take action.

Changes made at Dr. Fried's hospital mean that a patient may now be admitted by one team of residents, treated by another, and discharged by yet another. "And it's up to educators to help residents integrate these experiences," he said. "I [still] don't know whether I can."

In Europe, the IOM committee was reminded, physicians and other health care workers are prohibited from working more than 13 hours straight or more than 48-56 hours per week.

Different methods of graduate medical education financing and other health system differences make comparisons difficult, however. Here in the United States, Dr. Fried said, "with duty hour restrictions coming at the same time as patient volumes have increased, as acuity (of illness) in teaching hospitals has increased, and even as our treatments have become higher-stakes treatments, we have the perfect storm." ■

POLICY & PRACTICE

Whither Comprehensive Care?

The American Board of Internal Medicine's draft proposal on a new maintenance of certification module on comprehensive care could potentially be just another hoop to jump through, without any validated value to the internist—according to comments the American College of Physicians' Board of Regents submitted to the ABIM. The comments were not all negative, Regents chairman Joel Levine told INTERNAL MEDICINE NEWS. The Regents found much to like—for instance, the draft endorses traditional internists who coordinate and deliver care to most adults, said Dr. Levine, professor of medicine at the University of Colorado at Denver. Another point of agreement: The proposal emphasizes the importance of the medical home. But there were some concerns that such a module might not bring more recruits into internal medicine, and that it doesn't discuss how such a certification would work in a variety of different practice settings, said Dr. Levine, adding that much work still needs to be done. "I don't think this is a done deal," he said. The ABIM board will next meet in February to discuss comments.

More Action Needed on MRSA

U.S. health care facilities are not doing enough to protect patients from methicillin-resistant *Staphylococcus aureus* (MRSA) infections, according to an online poll conducted by the Association for Professionals in Infection Control. A majority of infection control professionals (59%) responded that their health care facilities have stepped up efforts to curb MRSA in the past 6 months. But half said their facilities were "not doing as much as [they] could or should" to stop the transmission of MRSA. "MRSA could be beaten if the leadership at hospitals moved more aggressively to adopt strategies proven to protect patients from these virulent infections," said Lisa McGiffert, director of Consumers Union's Stop Hospital Infections campaign. "We need to require hospitals to report their infection rates so the public can see if they are achieving results." Consumers Union has worked to help pass laws in 20 states requiring hospitals to report their patient infection rates, and it supports a federal infection reporting law. The Centers for Disease Control and Prevention estimates that nearly 95,000 patients developed MRSA infections in 2005—most of which were acquired in health care facilities—and almost 19,000 people died.

Generics Could Save States Money

Increasing access to generic medicines would help states lower health care costs, which are putting pressure on state government budgets, according to the Generic Pharmaceutical Association (GPhA). The National Governors Association and the National Association of State Budget Officers said in December that "steadily rising health care costs" are contributing to deteriorating state fiscal conditions, and that states face many challenges in providing health care in Medicaid and other state programs. The GPhA noted in its own report that a 1% increase in the use of generics could save $4 billion annually off the total U.S. health care bill. The group advocates creating a workable pathway to approving generic biopharmaceutical medicines and preventing state governments from barring generic substitution for various therapeutic classes of medicines.

Part D Plans Not Tracking Costs

Medicare drug plans have not met all requirements for tracking out-of-pocket spending by beneficiaries in the Medicare Part D prescription drug program, according to a report from the Health and Human Services Department Office of Inspector General. Tracking out-of-pocket costs is necessary to determine when each beneficiary has reached the required spending threshold at which Medicare's catastrophic drug coverage starts. "Implementing the program has been a large undertaking for [the Centers for Medicare and Medicaid Services], its contractors, and the private Part D plans," HHS Inspector General Daniel Levinson said in a statement. Medicare "should place more emphasis on conducting Part D oversight." The report found that 29% of Part D plans did not submit required information to the CMS on enrollees' additional drug coverage data. And 34% of Part D plans—covering nearly half of Part D enrollees—did not submit prescription drug event data to CMS in the required time frames. In addition, the limited oversight the CMS has conducted so far on Part D plans' tracking of out-of-pocket costs relied on plans' self-reported data. And even then, about half of the plans were not in compliance with one or more of four CMS requirements in this area. The full report is available at www.oig.hhs.gov.

FDA Sets User Fees for DTC Ads

The Food and Drug Administration is charging pharmaceutical companies about $40,000 to review each of their direct-to-consumer television advertisements, according to a notice issued by the agency in December. Last September, Congress authorized the FDA to create a user-fee program for the advisory review of DTC prescription-drug television advertisements. The program is voluntary; drug sponsors can choose whether to seek FDA advisory review of their ads before broadcast. However, if they seek review by the agency, they must pay the fee. The $41,390 fee established for fiscal year 2008 is based on the number of ads slated for review and is expected to generate $6.25 million in total revenues during the first year of the program.

—Jane Anderson