Many Psychiatry Residents Face Stress, Career Change

BY BRUCE JANCIN
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CHICAGO — The majority of American and Canadian psychiatric residents feel stressed out—and one-quarter of those residents are contemplating a career change, a new survey suggests.

Fully 56% of the 893 psychiatric residents who responded to the online survey rated their lives as either stressed or very stressed. Nineteen percent of respondents were dissatisfied with their physical health and 14% were dissatisfied with their mental health, Dr. Paul O'Leary reported at the American Psychiatric Association's Institute on Psychiatric Services.

Only 7% of the residents categorized themselves as relaxed. One-quarter of the respondents who characterized themselves as stressed or very stressed indicated they want to switch their residency program and 22% want to change specialty, according to Dr. O'Leary of the University of Alabama at Birmingham.

The survey was conducted to examine resident wellness in the wake of changes to the work environment that culminated in the 80-hour work week introduced in 2003. The survey elicited responses from 17% of all North American residents in the American Psychiatric Association database, a response rate low enough to raise selection bias as a potential concern, Dr. O'Leary conceded.

Stressed residents identified time pressure, workload, and the hectic pace of training as their biggest stressors. They were twice as likely as relaxed residents to identify family and relationship issues as major stressors outside the workplace.

Many of the coping mechanisms used by stressed residents differed from those employed by relaxed residents. Stressed trainees were markedly more likely to cope through sleep, eating, isolation, blaming others, and ignoring their problems. One-quarter of stressed residents used prescription drugs to cope, a rate twice that of the relaxed residents.

Dr. O'Leary zeroed in on the longer hours worked by stressed residents: 70% worked 9 hours or more per day, compared with 19% of relaxed residents. ■

Privacy Called Top Priority For Personal Health Records

BY MARY ELLEN SCHNEIDER
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Privacy should be the top priority when developing certification criteria for personal health records, a task force created by the Certification Commission for Healthcare Information Technology has recommended.

Adequate security and interoperability also must be included in certification efforts, according to the task force.

The Certification Commission for Healthcare Information Technology (CCHIT) will use these recommendations as it prepares to begin certifying personal health records (PHRs) this summer.

Since the PHR field is still "rapidly evolving," the task force said that certification requirements should not be so prescriptive that they interfere with the progress of the technology.

The task force recommended that the voluntary certification process should apply to any products or services that collect, receive, store, or use health information provided by consumers. Certification should also apply to products or services that transmit or disclose to a third party any personal health information. This would allow the CCHIT to offer certification to a range of products and applications, from those that offer a PHR application and connectivity as an accessory to an electronic health record (EHR) to stand-alone PHRs.

CCHIT hopes that, just as it did in the EHR field, certification will create a floor of functionality, security, and interoperability, said Dr. Paul Tang, cochair of the PHR Advisory Task Force and vice president and chief medical information officer for the Palo Alto (Calif.) Medical Foundation.

The task force called for requirements to maintain privacy in monitoring and enforcement, and for consumer protection that would allow patients to remove their data if certification is revoked. The group also recommended that standards-based criteria be developed that would require PHRs to send and receive data from as many potential data sources as possible.

If done right, certification would have significant benefits for both physicians and patients, Dr. Tang said. A PHR could provide physicians with better access to secure, authenticated data that could help them make decisions, while patients would have more control over their own care, he said.

In July, the task force made its recommendations and handed over responsibility for PHR certification to a CCHIT work group. That work group will develop the actual certification criteria that will be used to test PHR products starting next July, according to Dr. Jody Pettit, strategic leader for CCHIT's PHR work group.

Offering certification for PHR platforms and applications could help spur consumer acceptance and adoption of PHRs, Dr. Pettit said. "The consumer wouldn't feel so far out on a limb in terms of putting in their data." ■

POLICY & PRACTICE

Lilly Settles Zyprexa Charges

As anticipated, Eli Lilly & Co. has agreed to settle various federal complaints about off-label promotion of its antipsychotic Zyprexa (olanzapine). Lilly pleaded guilty to a misdemeanor violation of the Food, Drug, and Cosmetic Act for illegal promotion of Zyprexa for dementia from 1999 to 2001. The company will pay $615 million in that plea. Lilly did not admit to civil allegations against it, but will pay $800 million to settle those charges. Of that, $438 million will go to the federal government and $362 million will be set aside for ongoing state investigations. The company also entered into a corporate integrity agreement with the government that requires Lilly to submit to third-party review of its policies and procedures.

Most Favor Family Consent

University of Michigan health researchers say that a nationally representative survey of older adults shows that most believe it's okay for a family surrogate to give consent for a cognitively impaired person to be a research subject. The surveyors queried 1,515 people aged 51 years and older who were randomly selected from the government-funded National Health and Retirement Survey. Group members responded to questions about a family member's consenting to a patient's joining one of four research scenarios: a lumbar puncture study; a randomized, controlled trial of a new drug; a similar trial of a vaccine; or a gene-transfer study. In all, 82% said that consent by a surrogate was allowable for a drug trial, 72% for a lumbar puncture, 70% for a vaccine trial, and 67% for gene transfer. The federal government defers to states on when surrogate consent may be authorized, but the states' rules are far from clear, said the authors. Their survey results are in the Jan. 13 issue of Neurology.

Mixed Grades on Tobacco Control

In 23 states, smoking in workplaces and public spaces has been banned, but the pace of adoption of those life-saving prohibitions has slowed, according to the American Lung Association's annual State of Tobacco Control report. Only two states passed such laws in 2008, compared with five in 2007 and six states and Washington, D.C., in 2006. Similarly, only three states and Washington, D.C., increased tobacco taxes in 2008. New York tops the list at $2.75 in taxes per pack, whereas South Carolina exacts only 7 cents per pack. In 2008, Arizona, Nebraska, and Washington state increased Medicaid beneficiaries' access to smoking cessation benefits—important because the Medicaid population smokes at a rate 50% higher than the national average, according to the association. The group's state-by-state report card on various tobacco-control measures is available at its Web site.

Jump in Singulair Psych Reports

Surging reports of aggressive and suicidal behavior associated with the asthma drug Singulair (montelukast) contributed to another high number of serious adverse events reported to the Food and Drug Administration in the second quarter of 2008, according to the nonprofit Institute for Safe Medicine Practices. The group said that a sevenfold increase in Singulair reports (to 644) was driven by the FDA's announcement in March 2008 that it was taking a closer look at the drug's side effects. For all drugs, 22,980 reports of drug-related serious injuries included 2,968 deaths. Digoxin accounted for 650 deaths, and the institute's analysis linked most of those to the recalled Digitek brand. After digoxin, the smoking-cessation drug Chantix (varenicline) accounted for the greatest number of reports: 910 cases of serious injury or death.

FDA Posts Guidance on Handouts

The FDA has issued updated guidance for manufacturers that distribute journal articles or other scientific publications concerning off-label uses for their FDA-approved drugs, devices, or biologics. On its Web site, the agency suggests that distributed journal articles be only from organizations using editorial boards with "demonstrated expertise in the subject of the article," independence to review articles, and fully disclosed conflicts of interest. Authors and editors should also disclose conflicts. Acceptable articles can't be from special supplements that are funded even partially by a manufacturer. In its presentation to practitioners, an article shouldn't be highlighted, otherwise marked up, or attached to promotional materials.

FDA Approvals Increase

The FDA approved 21 new molecular entities and 4 new biologic drugs in 2008, compared with 17 NMEs and 2 biologics in 2007. Four of the 2008 approvals came in December. In 2006, the FDA approved 22 new drugs and biologics. Although the agency has increased the annual number of novel therapies approved in the recent years, it is still not meeting statutory deadlines for reviewing and approving products. The FDA said it did not meet the 2008 target of reviewing 90% of approval applications within the time limits set by law. Many of the delays were attributable to resource constraints, the agency said. The FDA has hired 800 new people to review drug and biologic applications, which should help reduce delays by the second half of 2009, according to analyst Ira Loss at the firm Washington Analysis Corp. However, delays may persist for new diabetes therapies and opioids, Mr. Loss said, noting that the potential for cardiac toxicity and abuse hangs over those products.

—Alicia Ault