Federal Health Matters

OIG Finds Irregularities in VA Research

Internal reviews of some VA research studies have uncovered problems with informed consent, documentation, and adverse event reporting. During a July 9 hearing before the House VA Committee, VA leaders described irregularities in an ongoing, 11-site study of smoking cessation treatment in veterans with posttraumatic stress disorder (PTSD). And, in an August 6 report, the VA's Office of the Inspector General (OIG) said that it was able to substantiate internal allegations of serious research integrity and human subjects protection violations at the Central Arkansas Veterans Healthcare System (CAVHS) in Little Rock.

The July hearing focused on VA researchers' efforts to notify study participants about a possible link between the smoking cessation drug varenicline—which some of the participants were taking—and adverse psychiatric effects, including suicidal thoughts. Although the FDA issued an "early communication" about this potential link in November 2007, VA researchers did not take action to notify study participants until the FDA issued a Public Health Advisory on February 1, 2008. Following this advisory, study leaders drafted an addendum to the informed consent form and an accompanying cover letter, which were to be reviewed by each study site's institutional review board (IRB) and, once approved, sent to all study participants. While researchers at some sites distributed the letters and forms promptly, others did not. As a result, some study participants did not receive notification about varenicline's possible adverse effects until June 2008.

John D. Daigh, Jr., the OIG's assistant inspector general for healthcare inspections, described specific problems at one of the study sites: the Washington, DC VA Medical Center (WDCVAMC). Study staff at this site did not verify participants' receipt of the notification letters and addendum forms, he said, nor did they document any follow-up for letters that were returned undeliverable. Daigh also noted that records of some WDCVAMC participants taking varenicline did not include signed addendum forms and some patient data were not obtained in accordance with the study protocol.

While VA Secretary James B. Peake suggested that it may have been appropriate for researchers to wait until February to notify study participants, he expressed concern over the delay between IRB approval and some participants' receipt of the materials. He added that the VA is working on creating a central IRB to ensure "better and tighter execution" of study procedures, common standards, and improved accountability and communication.

The OIG's August report on CAVHS research activities described the findings of a year-long investigation that reviewed 13 projects and examined the facility's research program as a whole. The OIG found that CAVHS researchers performed HIV tests without participants' consent, could not produce informed consent documentation for all research participants, did not appropriately obtain witness signatures for study participants with dementia, and failed to report 105 deaths that occurred during cancer studies (although these deaths probably were unrelated to the studies). The report criticized the IRB at the University of Arkansas Schools of Medicine, which oversaw CAVHS research until the CAVHS formed its own IRB in August 2007, for failing to "identify and address serious and continuing noncompliance." The OIG recommends that the VA determine whether human-subject research should continue at the CAVHS and, if so, devise a plan for addressing the problems identified.

VA Publicizes Suicide Hotline in DC Area

On July 21, the VA launched a three-month advertising campaign in Washington, DC to promote its national, 24-hour, toll-free suicide prevention hotline: 1-800-273-TALK. The campaign includes a television public service announcement by actor Gary Sinise and visual displays featuring the slogan, "It takes the courage and strength of a warrior to ask for help," in 220 subway cars, 80 buses, and 10 subway stations. If the campaign increases hotline calls from DC, the VA will extend it to other areas of the country.

The VA started the hotline in July 2007 in collaboration with the Substance Abuse and Mental Health Services Administration. When callers to the line press "1" to indicate that they are veterans, they are transferred to mental health counselors in Canandaigua, NY. The counselors are able to check veterans' medical records and connect them to local VA suicide prevention coordinators when provided with the veterans' names and locations.

VA officials say that over 22,000 veterans have called the hotline since its inception and that 1,221 callers were in extremely dangerous situations before hotline counselors convinced them not to take their own lives. As of late July, the VA had spent $2.9 million on the hotline. ●