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Testimony

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VA HEALTH CARE

Progress and Challenges in Conducting the National Vietnam Veterans Longitudinal Study

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GAO

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Mr. Chairman and Members of the Committee:

I am pleased to be here today as you discuss the National Vietnam Veterans Longitudinal Study (NVVLS). According to the Department of Veterans Affairs (VA), experts estimate that up to 30 percent of Vietnam veterans have experienced post-traumatic stress disorder (PTSD), an anxiety disorder that can occur after a person is exposed to a life-threatening event.¹ Veterans suffering from PTSD may experience problems sleeping, maintaining relationships, and returning to their previous civilian lives.² Additionally, studies have shown that many veterans suffering from PTSD are more likely to be diagnosed with cardiovascular disease and other diseases.

After the Vietnam War, Congress wanted information about the psychological effects of the war on Vietnam veterans to inform the need for PTSD services at VA. Consequently, in 1983, Congress mandated that VA provide for the conduct of a study on PTSD and related postwar psychological problems among Vietnam veterans.³ VA contracted with an external entity, the Research Triangle Institute, to conduct the National Vietnam Veterans Readjustment Study (NVVRS).⁴ According to VA, the NVVRS was a landmark study and is the only nationally representative study of PTSD in Vietnam veterans. PTSD is an ongoing concern for Vietnam veterans, and today, Vietnam-era veterans still constitute the

¹Unless otherwise noted, Vietnam veterans refers to those who served in Vietnam during the Vietnam era, from February 28, 1961, through May 7, 1975. See 38 U.S.C. § 101(29). Estimates for Vietnam veterans who have experienced PTSD vary. For example, according to the Centers for Disease Control and Prevention's 1989 *Vietnam Experience Study*, about 15 percent of Vietnam veterans have experienced PTSD. American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (Washington, D.C., 2000).

²Those diagnosed with PTSD may also suffer from other ailments, such as depression and substance abuse.

³Veterans' Health Care Amendments of 1983, Pub. L. No. 98-160, § 102, 97 Stat. 993, 994-95. This law defined Vietnam veterans as those who served in Vietnam or elsewhere in the Vietnam theater of operations from August 5, 1964, through May 7, 1975, the Vietnam era. See 38 U.S.C. § 101(29) (1982).

⁴Other collaborators, such as Louis Harris and Associates, Inc., and The Graduate Center of the City University of New York, were also involved in conducting the NVVRS.

largest group of veterans receiving VA care for PTSD.⁵ Congress and others have been concerned about the continued prevalence of PTSD and VA's capacity to meet the needs of Vietnam veterans. In section 212 of the Veterans Benefits and Health Care Improvement Act of 2000, Congress required that VA contract with an appropriate entity to conduct a follow-up study to the NVVRS.⁶ The law specifies certain requirements that the follow-up study must meet, including that the study must use the database and sample of the NVVRS and be designed to yield information on the long-term effects of PTSD and whether particular subgroups were at greater risk of chronic or more severe problems with PTSD. In 2001, VA awarded another contract to the Research Triangle Institute to plan and conduct a follow-up study, the NVVLS.⁷ However, in 2003, before data collection for the study began, VA terminated the contract and the study was not completed.⁸ In September 2009, the Secretary of Veterans Affairs announced that the agency planned to award a new contract to an external entity to conduct the NVVLS.

My testimony is based on our May 2010 report,⁹ which is being released today, and discusses two issues related to VA's current efforts to address the law: (1) the recent progress VA has made in conducting the NVVLS and (2) the challenges VA faces in its plans to conduct the NVVLS.

To obtain information about VA's progress in conducting the NVVLS and its challenges, we interviewed VA officials responsible for managing VA's

⁵When we use "Vietnam-era veteran" in this testimony, we are using the current governing definition: from February 28, 1961, through May 7, 1975, for veterans who served in Vietnam, and from August 5, 1964, through May 7, 1975, for veterans who served in any other location. See 38 U.S.C. § 101(29).

⁶Pub. L. No. 106-419, § 212, 114 Stat. 1822, 1843-44. Throughout this testimony, we refer to section 212 as the law.

⁷A longitudinal study approach involves the repeated examination of a set of study participants over time.

⁸In this testimony, we use "2001 NVVLS attempt" to refer to the efforts that began in 2001 to complete the NVVLS. After the contract was terminated, VA's Office of Inspector General investigated the 2001 NVVLS attempt. The resulting 2005 report found that VA did not properly plan or administer the study contract. It recommended that VA use appropriate contracting processes to complete the mandated follow-up study. See Department of Veterans Affairs, Office of Inspector General, *Audit of VA Acquisition Practices for the National Vietnam Veterans Longitudinal Study* (2005).

⁹GAO, *VA Health Care: Status of VA's Approach in Conducting the National Vietnam Veterans Longitudinal Study*, [GAO-10-578R](#) (Washington, D.C.: May 5, 2010).

PTSD research, including officials on the project team responsible for restarting the NVVLS.¹⁰ We also interviewed VA officials who are conducting VA's studies of PTSD in male twin Vietnam-era veterans and female Vietnam-era veterans. In addition, we obtained and reviewed relevant documents regarding VA's PTSD research studies, including a draft performance work statement¹¹ and progress report for the NVVLS, study protocols for the studies on male twin Vietnam-era veterans and female Vietnam-era veterans,¹² and other documents related to the study methodologies. In order to understand how the NVVLS will be conducted, we also obtained and reviewed information about the NVVRS and the 2001 NVVLS attempt.

To provide context for the information we obtained from VA, particularly about VA's reported challenges in conducting the NVVLS, we interviewed 10 researchers who are currently involved in or have previously been involved in managing or conducting PTSD research.¹³ The criteria we used to select the researchers we interviewed included expertise in PTSD, as indicated, for example, by service on national committees focused on veterans and PTSD, and knowledge of or involvement with the NVVRS, the 2001 NVVLS attempt, or the NVVLS. We chose these researchers to represent a range of perspectives on the studies we examined: for example, we interviewed both researchers who are currently employed by VA and researchers who are not employed by VA. To obtain additional perspectives on study design techniques and feasibility issues, we also interviewed three Department of Health and Human Services methodologists: two from its Agency for Healthcare Research and Quality and one from its Centers for Disease Control and Prevention.¹⁴

¹⁰The NVVLS project team is composed of 14 individuals, including 7 VA officials who are handling various aspects of the study, 3 VA representatives who are subject matter experts, 2 non-VA representatives who are subject matter experts, and 2 facilitators.

¹¹A performance work statement, also known as a statement of work, is a description of the work the government expects the contractor to perform.

¹²A study protocol is a document that describes the formal design of a research study.

¹³We contacted a total of 13 researchers, but 3 researchers declined to speak with us. Two of them felt unable to provide specific comments on our issues, and the third stated that he did not have time to speak with us.

¹⁴In addition, we interviewed representatives of two veteran service organizations, the Vietnam Veterans of America and Disabled American Veterans, in order to obtain their perspectives on the concerns and needs of veterans with PTSD. We also contacted representatives from the American Legion.

We conducted this performance audit from October 2009 through April 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, we found that since September 2009, VA has taken a number of steps toward conducting the NVVLS. VA convened a project team for the NVVLS consisting of VA officials and PTSD experts both within VA and outside of VA. According to VA officials, the NVVLS project team developed a performance work statement, which outlines VA's requirements for the contractor selected to conduct the NVVLS.¹⁵ VA expects to select a contractor for the NVVLS in the summer of 2010 and for the NVVLS to be completed in 2013. VA officials stated that they plan for the NVVLS to meet all of the requirements of the law where scientifically feasible. In addition, VA is conducting studies of PTSD in male twin Vietnam-era veterans¹⁶ and female Vietnam-era veterans,¹⁷ and VA officials maintain that these studies will also provide useful information in response to the law.

VA reported that it faces several challenges in restarting the NVVLS. However, in several instances, the researchers and methodologists we interviewed offered suggestions for how these challenges could be addressed. The challenges reported by VA included the following:

¹⁵We reviewed a draft version of this performance work statement.

¹⁶This study, officially titled "A Twin Study of the Course and Consequences of PTSD in Vietnam Era Veterans," began in 2006 and is projected to finish in 2013. The objectives of the study are (1) to estimate the longitudinal course and current prevalence of PTSD; (2) to identify the relationships between the longitudinal course of PTSD and veterans' current mental and physical health conditions, such as cardiovascular disease, diabetes, depression, and substance use disorders; and (3) to identify the relationships between PTSD and veterans' current functional status and disability. VA estimates that 5,306 men will participate in the study. This study defines the Vietnam era as 1965 through 1975.

¹⁷This study, officially titled "Long Term Health Outcomes of Women's Service During the Vietnam Era," began in 2008 and is projected to conclude in 2014. The study will examine the following issues in Vietnam-era female veterans: (1) the prevalence of lifetime and current psychiatric conditions, including PTSD; (2) physical health; and (3) the level of current disability. According to VA, approximately 7,000 women will participate in the study. This study defines the Vietnam era as July 4, 1965, through March 28, 1973.

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- *Locating and gaining consent from NVVLS participants.* VA officials stated that they did not know how many of the NVVRS participants can be located and would agree to participate in the NVVLS, which could impact the feasibility of the study. While 6 of the 10 researchers and the 3 methodologists we interviewed agreed that it could be challenging to locate the original participants, 9 of the researchers offered suggestions for overcoming this challenge, such as using the data sources and methods from previous successful efforts to reconnect with study participants and taking advantage of current technology.¹⁸ All 10 researchers and 3 methodologists stated that to encourage participation, it was important for NVVLS participants to receive assurances of confidentiality—that is, assurances regarding use of their identifying information, as was done with the NVVRS participants.¹⁹ According to VA’s draft performance work statement for the NVVLS, the NVVLS consent form will not contain these assurances of confidentiality but it will state that study participation will not affect participants’ VA benefits or VA health care. However, the draft performance work statement also states that the agency plans to take possession of study participants’ identifying data at the conclusion of the NVVLS. While nine of the researchers commented that this requirement could impact whether veterans would agree to participate in the NVVLS, VA stated that it conducts many internal research studies and has no material issues recruiting study participants due to mistrust of VA.
 - *Mitigating possible bias in a follow-up study.* VA officials said that there could be bias in the NVVLS because the NVVRS was not designed to accommodate a follow-up study. The three methodologists we interviewed stated that this challenge was closely related to the challenges of locating the original participants and obtaining their agreement to participate in the study—that is, bias will be present in the NVVLS if representative participation across the subgroups included in the NVVRS is not achieved.²⁰ The methodologists stated that if bias in the NVVLS is a concern, VA could survey additional individuals from the general Vietnam-era population to supplement the original NVVRS cohort or develop a new sample of participants from the general Vietnam-era population for the

¹⁸The one researcher who did not offer a suggestion stated that VA may not be able to overcome the challenge.

¹⁹The NVVRS provided participants with assurances of confidentiality via the NVVRS consent form, which stated that their identifying information would not be disclosed in any government proceedings.

²⁰The NVVRS was required by law to provide information on certain subgroups, specifically veterans with service-connected disabilities, female veterans, and minorities.

NVVLS. VA's draft NVVLS performance work statement states that the contractor can choose to examine all or some of the NVVRS participants, but does not address the question of whether the contractor could propose to survey other Vietnam-era veterans.

- *Assessing PTSD in the NVVLS.* VA officials were concerned about appropriately assessing PTSD in the NVVLS. Because there was no widely accepted PTSD screening method at the time the NVVRS was conducted, the study's estimates of PTSD prevalence were based on a multimeasure approach involving the use of 10 PTSD assessment instruments administered to a subset of NVVRS participants by doctoral-level mental health professionals. VA officials stated that this complex approach has not been used in other PTSD studies and would not be desirable to replicate. Nine of the 10 researchers we interviewed stated that the multimeasure method used to identify PTSD in the original study was not of concern.²¹ In order to provide comparable longitudinal data, 9 of the researchers and 2 of the methodologists we interviewed recommended that the NVVLS contractor use PTSD assessment instruments similar or identical to those used in the NVVRS in addition to more current approaches.²² According to the NVVLS draft performance work statement, the PTSD instruments used in the NVVRS should be used in the NVVLS, when appropriate, to enhance consistency and facilitate long-term analyses. The draft performance work statement also recommends that newer measures should be included when possible.

Overall, VA officials do not know whether, given the challenges they face, the NVVLS can be completed. VA's NVVLS draft performance work statement includes an initial phase during which VA expects the contractor to assess the feasibility of the study. All 10 researchers we interviewed said that restarting the study soon is important because as the study participants continue to age, an increasing number will be lost for follow-up because of illness or death.²³ Nine of the researchers told us that

²¹One researcher thought the method used to identify PTSD in the NVVRS was of concern because the PTSD assessment instruments used in the method lacked validity. However, this researcher acknowledged that these instruments may have been the best available at the time.

²²One researcher said that this approach would not necessarily be recommended because it may burden the participants and reduce participation rates.

²³The youngest Vietnam-era veterans still living today would be approximately in their early 50s. During the 2001 NVVLS attempt, the researchers estimated that 8.5 percent of the Vietnam-era veterans who originally participated had died.

they believe it is important for VA to complete the NVVLS because it will potentially provide important, nationally representative information on PTSD and related issues in Vietnam-era veterans.

In responding to a draft of the report from which this testimony is based, VA explained its position on the ownership of the NVVRS and NVVLS study data. VA stated that the NVVRS contract provided that the study data was the property of the agency and did not provide that the identifying information be kept from VA. The agency also stated that the NVVRS consent documents did not restrict VA from possessing the identifying information of participants. VA confirmed that the agency intends to receive all the NVVLS study data, including participants' identifying information, upon completion of the study, and stated that the NVVLS consent form will explain to participants that VA does not intend to use the data to determine eligibility for VA benefits.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other members of the committee may have.

Contacts and Acknowledgments

For further information about this testimony, please contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Individuals who made key contributions to this testimony include Mary Ann Curran, Assistant Director; Susannah Bloch; Stella Chiang; Martha R. W. Kelly; Lisa Motley; Rebecca Rust; and Suzanne Worth.

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