US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection Program Summary Report: Evaluation of Medication Management in Veterans Health Administration Facilities

National Review | **23-01177-215** | **September 22, 2023**

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Figure 1. *Veterans Affairs Building, Washington, DC.*

Source: https://www.gsa.gov/real-estate/gsa-properties/visiting-public-buildings/veterans-affairs-building/image-galleries/veterans-affairs-architecture-gallery (accessed June 20, 2023).

Abbreviations

CHIP	Comprehensive Healthcare Inspection Program
OIG	Office of Inspector General
VHA	Veterans Health Administration

Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in randomly selected Veterans Health Administration (VHA) facilities. Comprehensive healthcare inspections are one element of the OIG's overall efforts to ensure the nation's veterans receive high-quality VA healthcare services. The OIG inspects each facility approximately every three years and selects and evaluates specific areas of focus each year.

The OIG initiated unannounced inspections at 45 VHA medical facilities from November 15, 2021, through February 15, 2023. The OIG assessed whether VHA providers safely prescribed teratogenic medications to patients with the potential to become pregnant.[1] The inspections involved interviews with key staff and evaluations of clinical and administrative processes. The findings in this report may help VHA leaders identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Results Summary

The OIG identified a vulnerability with providers counseling patients about the risks and benefits of teratogenic medications. The OIG issued one recommendation for improvement to the Under Secretary for Health, in conjunction with Veterans Integrated Service Network directors and facility senior leaders.[2]

The number of recommendations should not be used as a gauge for the overall quality of care provided within VHA. The intent is for leaders to use recommendations as a road map to help improve operations and clinical care moving forward. Recommendations are based on retrospective findings of deficiencies in adherence to VHA national policy and require action plans that can effectively address systems issues that may have contributed to the deficiencies or interfered with the delivery of quality health care.

[1] "A teratogen is any agent that may cause an abnormality, including miscarriage following fetal exposure during pregnancy. Classes of teratogens include radiation, maternal infections, chemicals, and drugs." VHA Directive 1330.03, *Maternity Health Care and Coordination*, November 3, 2020.

[2] VA administers healthcare services through a nationwide network of 18 regional systems referred to as Veterans Integrated Service Networks.

VA Comments

The Under Secretary for Health agreed with the comprehensive healthcare inspection finding and recommendation and provided an acceptable improvement plan (see appendix B pages 7-8). The OIG will follow up on the planned actions for the open recommendation until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to conduct routine oversight of VA medical facilities that provide healthcare services to veterans. Comprehensive healthcare inspections are one element of the OIG's overall efforts to ensure the nation's veterans receive high-quality VA healthcare services.

Women were estimated to represent 11 percent of the veteran population as of September 30, 2022, and around half were of childbearing age.[1] Patients with the potential to become pregnant may receive teratogenic medications that pose risks of fetal abnormality or miscarriage if used during pregnancy. The medications can also negatively affect infants if passed through breast milk during lactation.[2] To promote optimal health outcomes, Veterans Health Administration (VHA) prioritized safe medication prescribing for patients of childbearing age regardless of their intent to become pregnant.[3]

VHA requires facilities to have "a mechanism to monitor the prescription of high-risk or teratogenic medications."[4] VHA also requires providers to counsel patients on the risks and benefits of taking teratogenic medications and document this counseling in the electronic health record.[5]

The OIG evaluated medication oversight processes and providers' compliance with safe prescribing practices. Specifically, the OIG assessed each facility's process for monitoring teratogenic medications and reviewed electronic health records for evidence of discussions between providers and patients about medication risks and benefits.

[1] "Veteran Population," Table 1L: VetPop2020 Living Veterans by Age Group, Gender, 2020–2050, National Center for Veterans Analysis and Statistics, accessed February 27, 2023, https://www.va.gov/vetdata/Veteran_Population.asp. VHA considers childbearing age to be less than or equal to 52 years old. VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended July 24, 2018, and June 29, 2020. (This directive was in place until January 8, 2021. VHA made several more updates following this publication, most recently with 1330.01(7) on May 14, 2023. The versions contain the same or similar language related to childbearing age and safe medication prescribing.)

[2] "Reproductive Health Overview," VHA Women's Health SharePoint site.

[3] VHA Directive 1330.01(3).

[4] "A teratogen is any agent that may cause an abnormality, including miscarriage following fetal exposure during pregnancy. Classes of teratogens include radiation, maternal infections, chemicals, and drugs." VHA Directive 1330.03, *Maternity Health Care and Coordination*, November 3, 2020. The OIG reviewed electronic health records for patients who were prescribed a teratogenic medication.

[5] VHA Directive 1330.01(3).

Methodology

The OIG initiated unannounced inspections at 45 VHA medical facilities from November 15, 2021, through February 15, 2023 (see appendix A). The OIG reviewed facilities representing a mix of size and geographic location.

The OIG interviewed key staff and reviewed the electronic health records of 1,352 randomly selected patients with the potential to become pregnant, who received care at the inspected facilities from July 1, 2020, through June 30, 2021, and were prescribed a teratogenic medication.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.[6] The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

This report's recommendation for improvement addresses a problem that can influence the quality of patient care significantly enough to warrant OIG follow-up until VHA leaders complete corrective actions. The Under Secretary for Health's response to the report recommendation appears in appendix B. The OIG accepted the action plan that program leaders developed based on the reasons for noncompliance.

The OIG conducted the inspection in accordance with OIG procedures and *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

[6] Inspector General (IG) Act of 1978, as amended, 5 U.S.C. §§ 401–424.

Inspection Results

VHA requires providers to counsel patients about the risks and benefits of teratogenic medications prior to prescribing them and document this counseling in the electronic health record.[7] The OIG estimated that providers did not document they counseled 52 (95% CI: 49 to 56) percent of patients on the risks and benefits of the prescribed teratogenic medication, which is statistically significantly above the OIG's 10 percent deficiency benchmark.[8] This could have resulted in patients lacking the information needed to make a fully informed decision on whether to take the medication. Some providers explained they counseled patients on the risks and benefits but did not document the counseling in the electronic health record.

[7] VHA Directive 1330.01(3).

[8] A confidence interval (CI) is a range of estimates, computed based on a statistical sample, for an unknown true value. The 95% confidence level indicates that among confidence intervals computed from all possible samples with the same sample size and the study design, the true value would have been covered by the confidence intervals 95 percent of the time.

Recommendation 1

1. The Under Secretary for Health, in conjunction with Veterans Integrated Service Network directors and facility senior leaders, ensure providers counsel patients who have the potential to become pregnant on the risks and benefits of teratogenic medications prior to prescribing them and document this counseling in the electronic health record.

Appendix A: Parent Facilities Inspected

Table A.1. Parent Facilities Inspected (November 15, 2021, through February 15, 2023)*

Name	City
New Mexico VA Health Care System	Albuquerque, NM
James E. Van Zandt VA Medical Center†	Altoona, PA
Amarillo VA Health Care System	Amarillo, TX
West Texas VA Health Care System	Big Spring, TX
Gulf Coast Veterans Health Care System	Biloxi, MS
Butler VA Health Care System	Butler, PA
Coatesville VA Medical Center†	Coatesville, PA
VA North Texas Health Care System	Dallas, TX
El Paso VA Health Care System	El Paso, TX
Erie VA Medical Center	Erie, PA
Veterans Health Care System of the Ozarks	Fayetteville, AR
VA Central California Health Care System	Fresno, CA
VA Texas Valley Coastal Bend Health Care System	Harlingen, TX
VA Pacific Islands Health Care System	Honolulu, HI
Michael E. DeBakey VA Medical Center	Houston, TX
G.V. (Sonny) Montgomery VA Medical Center†	Jackson, MS
Lebanon VA Medical Center	Lebanon, PA
Lexington VA Health Care System	Lexington, KY
Central Arkansas Veterans Healthcare System	Little Rock, AR
VA Loma Linda Healthcare System	Loma Linda, CA
VA Long Beach Healthcare System	Long Beach, CA
VA Greater Los Angeles Healthcare System	Los Angeles, CA
Louisville VA Medical Center	Louisville, KY
VA Northern California Health Care System	Mather, CA
Memphis VA Medical Center	Memphis, TN
Mountain Home VA Healthcare System	Mountain Home, TN
Tennessee Valley Healthcare System	Nashville, TN
Southeast Louisiana Veterans Health Care System†	New Orleans, LA
VA Southern Nevada Healthcare System	North Las Vegas, NV
VA Palo Alto Health Care System	Palo Alto, CA

Name	City
Manila VA Clinic	Pasay City, PH
Corporal Michael J. Crescenz VA Medical Center	Philadelphia, PA
Phoenix VA Health Care System	Phoenix, AZ
Alexandria VA Health Care System	Pineville, LA
VA Pittsburgh Healthcare System†	Pittsburgh, PA
Northern Arizona VA Health Care System	Prescott, AZ
VA Sierra Nevada Health Care System	Reno, NV
South Texas Veterans Health Care System	San Antonio, TX
VA San Diego Healthcare System	San Diego, CA
San Francisco VA Health Care System	San Francisco, CA
Overton Brooks VA Medical Center	Shreveport, LA
Central Texas Veterans Health Care System	Temple, TX
Southern Arizona VA Health Care System	Tucson, AZ
Wilkes-Barre VA Medical Center	Wilkes-Barre, PA
Wilmington VA Medical Center†	Wilmington, DE

Source: VA OIG.

**The OIG initiated inspections within this time.*

†The OIG conducted a virtual inspection.

Appendix B: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: August 9, 2023

From: Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Comprehensive Healthcare Inspection Program Summary Report: Evaluation of Medication Management in Veterans Health Administration Facilities (VIEWS 10615500)

To: Office of Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report Comprehensive Healthcare Inspection Summary Report: Evaluation of Medication Management in Veterans Health Administration Facilities 2023-01177-HI-1357. The Veterans Health Administration concurs with the recommendation and provides an action plan in the attachment.
2. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)

Shereef Elnahal, M.D., MBA

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

CHIP Summary Report Evaluation of Medication Management in Veterans Health Administration Facilities (2023-01177-HI-1357)

Recommendation 1. The Under Secretary for Health, in conjunction with Veterans Integrated Service Network directors and facility senior leaders, ensure providers counsel patients who have the potential to become pregnant on the risks and benefits of teratogenic medications prior to prescribing them and document this counseling in the electronic health record.

VHA Comments: Concur

VHA's Office of Women's Health in collaboration with the Office for Clinical Services, the Office for Patient Care Services, and the Office for Operations will take action to develop consistent access to tools needed to counsel women of childbearing age during prescribing of teratogenic medication[s] and communicate to the field the importance of standardized documentation in the electronic health record.

a) Ensure enterprise-wide use of the Teratogenic Drugs Order Checks in the electronic health record pharmacy package. Ensure enterprise-wide installation of the Pregnancy Intentions Clinical Reminder and Templated Note in the electronic health record.
b) Send Memo to Veterans Integrated Service Network and facility Directors requiring the use of the Pregnancy Intentions Clinical Reminder or Templated Note when prescribing potentially teratogenic medications to women of childbearing age.
c) Develop a national measure to track rates of counseling about risks and benefits of potentially teratogenic medications.

Status: In progress Target date for completion: March 2024

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